PharmaEssentia

PharmaEssentia Corporation

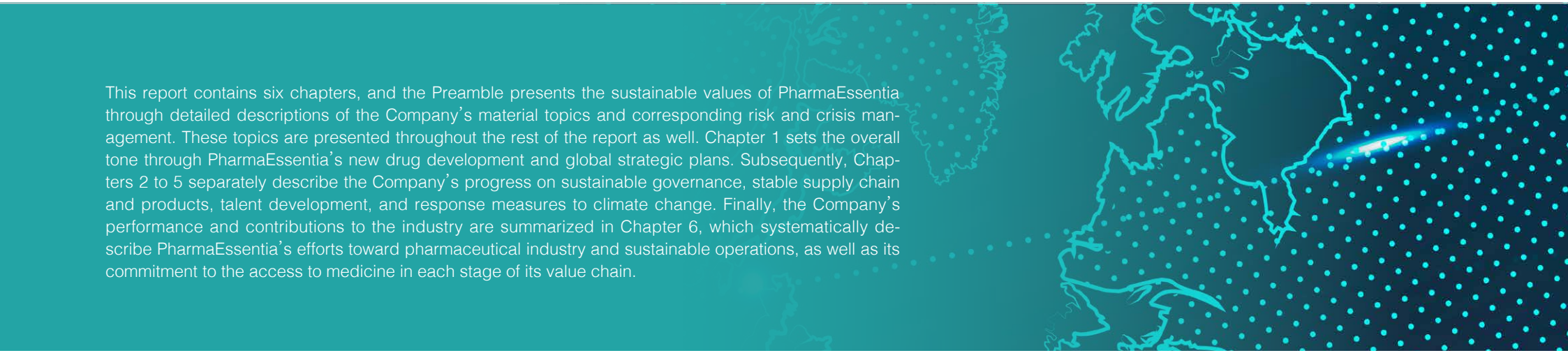
2021 Sustainability Report

CONTENTS

Presemble

1. About Our Sustainability Report

This report contains six chapters, and the Preamble presents the sustainable values of PharmaEssentia through detailed descriptions of the Company's material topics and corresponding risk and crisis management. These topics are presented throughout the rest of the report as well. Chapter 1 sets the overall tone through PharmaEssentia's new drug development and global strategic plans. Subsequently, Chapters 2 to 5 separately describe the Company's progress on sustainable governance, stable supply chain and products, talent development, and response measures to climate change. Finally, the Company's performance and contributions to the industry are summarized in Chapter 6, which systematically describe PharmaEssentia's efforts toward pharmaceutical industry and sustainable operations, as well as its commitment to the access to medicine in each stage of its value chain.



Reporting Period

GRI 102-50~52

This report published in June, 2022 is the third sustainability report issued by PharmaEssentia, and its reporting period is from January 1 to December 31, 2021. The content encompasses the Company's specific actions taken and performances in the aspects of Environment (E), Society (S), and Corporate Governance (G). In order to fully pre sent the performance of the Company's medium- and long-term projects in our sustainability report, and for the comparability and timeliness, part of the content covers the information up to February 25, 2022. Future sustainability reports will be published on a yearly basis.

Reporting Boundaries

GRI 102-45 GRI 102-46

- The financial information found in this report is based on the Corporation's publicly disclosed financial reports.
- The scope of data disclosed in this report is mainly based on the Taiwan headquarter of PharmaEssentia (Taipei Office and Taichung Plant), with partial information from its subsidiaries:
  - Panco Healthcare disclosed its human resource statistics in Chapter 4, with internal policies following those in PharmaEssentia; information on environmental impacts is disclosed in Chapter 5, with partial data that has not been compiled before 2021 is noted in tables and charts.
  - Summary of the U.S. Subsidiary information is dislosed in Chapter 2 Business Ethics and Compliance and Chapter 4 Talent Attraction Strategy.
- The sustainability report of PharmaEssentia will continue to expand the disclosure boundaries to cover more information in the future.

Reporting Changes

GRI 102-49

- PharmaEssentia re-identified material topics at the end of 2021; hence, the latest material topics are presented in this report. The changes to the material topics and their respective reasons are listed below, and please refer to Appendix 4 for the status of completion on material topics in 2021:
- Newly added material topics : **Human Rights**, **Patient Relation and Community Engagement**, **Climate Governance**.
- Consolidated/combined material topics: **The R&D and Discovery of New Drugs** has been renamed as R&D and Innovation of New Drugs, Stable and Safe Supply Chain has been renamed as **Supply Chain Management**, while Quality and Safety Management and Drug Safety have been combined to **Drug Quality and Safety Management**.
- Former material topics that are now either moderate or general topics: Occupational Health and Safety, Privacy and Safety, Corporate Governance, Risk Management, and Intellectual Property .

Reporting Principles

GRI | 102-54

- This report is prepared in accordance with the "GRI Standards: 2016" issued by the Global Reporting Initiative (GRI), and is disclosed based on the Core Option. The topics of "GRI 303: Water and Effluents" and "GRI 403: Occupational Health and Safety" adopt the updated GRI guidelines in 2018, and the topic of "GRI 306: Waste" adopts the updated GRI guidelines in 2020.
- This report is also prepared with reference to the following guidelines:
  - AA1000 Account Ability Principles: 2018
  - UN Global Compact (Please refer to Appendix 3)
  - UN Sustainable Development Goals, SDGs
  - ISO 26000: 2010 Guidance on Social Responsibility
  - Sustainability Accounting Standard Board, SASB
  - Access to Medicine Index 2020

Report Management Process

GRI | 102-32

Execution Center for Corporate Sustainability (ECCS) is responsible for planning and promoting cross-departmental and unit-related corporate sustainable development policies, goals, strategies and sustainable development implementation plans, and other related affairs. Five inter-departmental functional taskforces, including the "Corporate Governance, Product Quality and Patient Safety, Employee Welfare, Environmental Friendliness, and Access to Medicine" carry out relevant plans. The information and projects disclosed in this report are provided by the Company's various responsible departments, and are collected and compiled by the ECCS, then published after the information and the projects are audited by corresponding functional teams and approved by responsible supervisors.

External Assurance

GRI | 102-56

This report was commissioned by the British Standards Institution Taiwan (BSI Taiwan) in accordance with the AA1000 Assurance Standard v3, using Type I medium assurance level. Please refer to Appendix 5 for details of the statement.

Contacts

GRI | 102-53

We would like to know your suggestions and thoughts. If you have any needs, please contact us.

Contact of PharmaEssentia's Corporate Sustainability Unit

Execution Center for Corporate Sustainability

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2. PharmaEssentia's Missions and Sustainability Performances GRI 102-16

PharmaEssentia Corporation (hereinafter referred to as PharmaEssentia or the Company) is a biopharmaceuticals company focused on new drug development. It is based in Taiwan and aims to expand worldwide. Founded with the mission of "Better science, Better lives," PharmaEssentia commits to develop safer and more effective new drugs focusing in four major diseases: rare hematologic diseases, neoplastic diseases, viral infection diseases, and cutaneous diseases. We research and develop innovative new drugs under the core philosophy of sustainable development. To promote patient health and welfare, we are also committed to promoting access to medicine strategies for patients around the world, and expanding our products' patient coverage in the global market.

Philosophy

Better science, Better lives

Corporate Philosophy

Bold innovation, rapid adaptation, honesty & integrity, and sustainable operation

Goals

Building a new biopharmaceutical company that is innovative and performance-oriented, as well as trustworthy and prestigious among patients

Access to Medicine Strategies

Focusing on patients' "accessibility," "affordability," and "attainability" to pharmaceuticals to maximize human health and welfare

Vision

Becoming the top-tier innovative biopharmaceutical company

PharmaEssentia's Milestones

2003

PharmaEssentia was founded by a group of high-ranking scientists from leading biotechnology companies overseas.

2009

- Signed a cooperation agreement with AOP Orphan.
- Ropeginterferon alfa-2b (P1101) was approved by US FDA and entered phase I clinical trial.

2016

Became a TPEx-listed company.

2018

- The Taichung plant obtained an EU GMP license certification.
- Initiated mass production for commercialization.
- AOP Orphan released Ropeginterferon alfa-2b (P1101) phase III clinical trial results at the annual meeting of American Society of Hematology.

2021

- BESREMi® obtained medication license from Israel and South Korea's MFDS.
- BESREMi® obtained medication license from US FDA and qualified as an orphan drug in the United States, qualifying it for seven years of exclusive distribution rights in the American market.
- Phase II single-arm bridging study proposal of Ropeginterferon alfa-2b (P1101) for the treatment of Polycythemia Vera (PV) has been approved by National Medical Products Administration in China.
- Phase III clinical trial proposal for KX01 on treatment of Actinic keratosis (AK) in Japan from Japanese subsidiary has been approved by PMDA.
- PEC's drug verification and registration of indication of Tirbanibulin (KX01) on AK has been submitted to the TFDA.

A fully integrated protein innovative biopharmaceutical company

R&D of New Drugs | **Clinical Trials** | **Manufacturing and Production** | **Global Sales**

2005

Developed the flagship drug Ropeginterferon alfa-2b (P1101).

2012

Construction of the Taichung plant started.

2013

AOP Orphan initiated Ropeginterferon alfa-2b (P1101) phase III clinical trial.

2019

- AOP Orphan obtained BESREMi® EU regulatory marketing approval.
- US-based Athenex authorized Oral Paclitaxel Oradoxel for the treatment of prostate cancer, and Phase I clinical trial has been approved by TFDA.
- Phase II clinical trial proposal for Polycythemia Vera (PV) to be conducted in Japan by our Japanese subsidiary has been successfully submitted to PMDA.

2020

- BESREMi® obtained letter of approval from TFDA.
- The aseptic preparation and filling plant has been certified for GMP and GDP by TFDA
- A multi-center phase III clinical trial of Essential Thrombocythemia (ET) has been initiated in the United States, China, Japan, Korea, Taiwan, and Hong Kong.
- Ropeginterferon alfa-2b(P1101) for the treatment of chronic hepatitis B or chronic hepatitis B combined with hepatitis D has been approved by TFDA for Phase Ib clinical trial.

Honors and Awards in Recent Years

2021

Received **Gold Medal** for Sustainability Report in Medical and Insurance sector of the 14th Taiwan Corporate Sustainability Awards (TCSA)

Polycythemia Vera (PV) video of the U.S. subsidiary's marketing team received multiple marketing awards from The Communication Awards and The Digital Health Awards

2020

Won the **Gold Medal** of Go-Global category in 2020 Taipei Biotech Award

2019

Awarded with the "2019 Innovative Products of Excellent Manufactures in Central Taiwan Science Park Award" for Ropeginterferon alfa-2b (P1101) (product name: 百斯瑞明®)

Awarded with the "Gold Award in the Pharmaceutical Category" of the "2019 Pharmaceutical Research and Development Award from the Ministry of Health and Welfare and the Ministry of Economic Affairs" for Ropeginterferon alfa-2b (P1101) (百斯瑞明®) – new generation of long-acting interferon

CEO Ko-Chung Lin was awarded the "Humanitarian Award" from the Cancer Research & Treatment Fund. He is also the first Asian to receive this award

Awarded with the "Taiwan Merck Advance Biotech Grant – Emerging Biotech Second Prize"

Sustainability Performances

Environmental

- Introduced **ISO14064-1:2018 GHG Inventories** for the first time
- Introduced **TCFD framework educational training course** for the first time; total number of participants from the ESG functional groups was 40, reaching a 76.92% attendance rate
- Unit product's **CO_2 emissions intensity has been reduced by 40.5%**, **waste generation intensity has decreased by 21.3%**, and capacity has increased while environmental impacts have been reduced
- Actively sent employees to participate in external environmental protection seminars and regulatory briefings, **participated in 8 rounds** of external training in 2021
- Replaced **36** of T5 lights with LED lights at the office, each can **conserve 26 watts/hour**
- **0** environmental protection law violations; **0** toxic chemical substance leakage incident
- **All audits' results indicated legal compliance**: Audited 2 waste disposal vendors and conducted 4 audits over temporary waste storage areas

Social

- **Compassionate use** of Ropeginterferon alfa-2b benefitted 1 additional patient in Korea, who suffered from a rare disease, Erdheim-Chester disease (ECD) and has cumulatively benefited 39 myeloproliferative neoplasm (MPN) patients in Taiwan; cumulatively it has benefited **40 patients**
- BESREMi® has been launched at **37 countries globally**, and benefited a total of **1,500 patients** from clinical trials to marketing and sales
- BESREMi® has **7.5 years of safety and validity data**, which attest to its safety and effectiveness, allowing patients to begin treatments safely
- BESREMi® obtained the **U.S. FDA regulatory marketing approval and orphan drug qualification in the United States**, and is projected to benefit over **150,000** PV patients
- BESREMi® is the first drug approved for the front-line treatment of polycythemia vera (PV) in South Korea, and is expected to bring better treatment solutions to approximately 5,000 local patients
- Collaborated with Chiayi Chang Gung Memorial Hospital to establish Taiwan's first **MPN center**
- Organized rare hemophilia education programs, which are cumulatively participated by **70 people**
- Established **"MPNiCare"** Platform and launched **SOURCE program** in the United States
- Accumulated **hundreds of activities** with PV Organization and supported patient organizations in the U.S. to ensure the drug use safety of patients
- The **average retention rate of Taiwan headquarters exceeds 90%**, the retention rate of senior managers is **89%**, and the **gender ratio** of employees is well-balanced
- Total expense on employee benefits reached approximately **NT$2.52 million**, and **473 employees** filed for various benefits
- **0 occupational hazard incident**; PharmaEssentia's headquarters and Panco Healthcare co-hosted **over 58 rounds** of internal and external occupational safety training for employees, and total number of participants reached **252 employees**

Governance

- Participated and completed the submission of **S&P Global Corporate Sustainability Assessment** for the first time and ranked in **92 percentiles** among all global biotech companies
- PEC's corporate governance evaluation results ranked among top **6% to 20%**
- 12 Board meetings were held in 2021 with the average attendance rate reaching **94.7%**
- ESG risk evaluation from international independent Sustainlytics was reduced to moderate for the first time, and ranked **Top 15%** among all global biotech companies
- Completed **the second BESREMi® Periodic Safety Update (PSUR)** and continue to monitor the drug safety of all patients
- **83 R&D clinical personnel** around the world (accounting 24.3% on all employees) and **NT$1.27 billion** toward unmet medical needs
- Total number of valid patents reached 83 and total trademarks around the world reached **96**
- All vendors required to sign quality agreements have signed, and all required internal assessments and on-site audits have been completed for three consecutive years
- Carried out PEC Sustainability Report advocacy to **177 suppliers**
- Taichung Plant passed the **U.S. FDA's plant inspection** with no major deficiency
- **Built comprehensive U.S. supply chain**, in which injection medicine OEM and third-party logistics company will sell to professional pharmacies, and deliver the drugs to the patients
- Organized **5 ESG sustainability functional trainings** to increase the awareness and practice of senior managers and employees on the correlations between core functions and sustainable performances
- GMP training organized for **2,234 individuals**, and total hours of training reached **54,618 hours**

3. Messages from the Management Team GRI | 102-14

Chairwoman **Ching-Leou Teng**:

Continuous Improvement and A Wholehearted Commitment to Sustainability

2021 is a year of challenges and breakthroughs. Though the world was severely affected by the COVID pandemic, it was also swept by a wave for sustainability. PharmaEssentia was able to re-evaluate and gradually fortify our road map to sustainability amidst such trends. At the end of 2021, Ropeginterferon alfa-2b (P1101), the next-gen long-acting interferon used to treat Polycythemia Vera (PV), was authorized by the U.S. Food and Drug Administration (FDA) and the Korean Ministry of Food and Drug Safety (MFDS), and regulatory marketing approval was obtained from both the U.S. and South Korea under the product name BESREMi®. Moreover, exclusive distribution agreement for seven years in the United States' Market is obtained for its orphan drug status. Not only does this represent the greatest recognition and encouragement for PharmaEssentia's global team, but it also realizes our mission of "Better science, Better lives," in which we strive to alleviate the pain and bring a better life for all of mankind through scientific R&D of new drugs.

With such breakthrough comes even more social responsibility. This is the third year for PharmaEssentia's sustainable development, and over the past two years, we strove to build a sustainable development road map and to realize our goals. Our efforts were rewarded with a Gold Medal in Sustainability Report in the medical insurance sector from the 14th Taiwan Corporate Sustainability Awards in 2021. In terms of risk control, the ESG risk evaluation from international third-party agency Sustainlytics was also reduced from High Risk to Moderate Risk; furthermore, we were also invited to complete the S&P Global Corporate Sustainability Assessment (CSA) from Dow Jones Sustainability Index (DJSI) and ranked at 92 percentiles of all pharmaceutical companies in the world for the first time. It shows our efforts are positively received by international sustainability agencies. We relaunched material topic identification in this 3rd sustainability report to be published this year. We will explore PharmaEssentia's sustainable topics with a more comprehensive perspective and invite more stakeholders throughout the world to engage in our path toward sustainability. Data from foreign subsidiary in the United States is also included to practice the 3 major aspects of environmental, social, and governance (ESG) and to continuously enhance our long-term sustainable value.

Since founded in 2003, PharmaEssentia has always taken a patient-oriented approach, standing at the forefront of medical technology to seek innovative biological drugs and providing high-quality medicines with accurate, transparent and effective drug information to support the healthy lives of people around the world. To date, BESREMi® has successfully obtained regulatory marketing approval from 37 countries, including the European Union, Liechtenstein, Israel, Taiwan, South Korea, and the United States, and it is used by patients around the world. We are gradually addressing our commitment to "cater to unmet medical needs around the world, to explore and develop potential new medicines and technologies, and to provide affordable and accessible medicines to patients". Looking ahead, under our strategy of globalization and continuous development of innovative new drugs, we will continue to recruit talents in biopharmaceutical R&D and various professional fields to develop high-quality new drugs with the best technology and the highest quality control, while achieving optimized business strategies and fulfill our sustainable commitment to drug accessibility to satisfy the expectations and needs of all stakeholders.

Finally, we also cordially invite you to read this sustainability report and welcome your valued advice and suggestions. We will carry on to work tirelessly for continuous improvements and innovations on this path toward sustainability, and to become a reliable and accountable biopharmaceutical company to all stakeholders. Thank you!

CEO **Ko-Chung Lin:**

Develop Locally and Expand Globally while Upholding Our Mission

In spite of the various challenges and impacts, including the COVID-19 pandemic, climate change, and global geopolitical frictions in recent years, everyone throughout PharmaEssentia's global operations continued to work together to achieve regulatory marketing approval for the next-generation, long-acting interferon, Ropeginterferon alfa-2b (P1101), throughout the world. The drug has obtained the EU regulatory marketing approval for treatment of Polycythemia Vera (PV) under the product name BESREMi® as well as regulatory marketing approval from the Taiwan Food and Drug Administration (TFDA) since 2019, and was further granted regulatory marketing approval by Israel, South Korea, and the United States in 2021, benefiting PV patients throughout the world. To date, our Taichung Plant is certified with the Good Manufacturing Practice for Medicinal Products (GMP) from TFDA, GMP from the EU's European Medicines Agency (EMA), GMP from South Korea's MFDS, and further passed the U.S. FDA's GMP plant verifications in 2021. To achieve our sustainable vision for drug accessibility through our core competencies, we have prepared the expected drug demand for the upcoming year in the U.S. market and aim to increase patient usage after product launch via stable and safe supply chain and well-rounded "SOURCE patient care program".

In addition to the treatment of PV, we will continue to expand the clinical application of Ropeginterferon alfa-2b (P1101) to draw on the strengths of creating "one drug for multiple indications." The phase III clinical trial of Ropeginterferon alfa-2b (P1101) for Essential Thrombocythemia (ET) had initiated in Taiwan, Japan, South Korea, China, the United States, Canada, and Singapore. We are actively recruiting trial subjects and expect to file for drug licence for ET treatment after the phase III trial. To contribute toward epidemic preventions in Taiwan, when Taiwan was heavily impacted by the pandemic, we actively launched the "PharmaEssentia Can Help" project to actively provide BESREMi® to medical institutions that participated in the clinical trial to treat mild to moderate COVID-19 patients.

As the world enters a post-pandemic era, PharmaEssentia's years of precious experience since it was founded have prompted us to face various challenges with a more positive and proactive outlook. This is the gene for resilience and sustainable operations found in all PharmaEssentia employees. As a comprehensively integrated biopharmaceutical company founded in Taiwan and engages in new drug innovations and R&D, trial development, manufacturing and production, and drug marketing and sales worldwide, our goal is to become an international pioneer in the area of biopharmaceutical development. This is a challenging path and we aspire to lead Taiwan's biotech and pharmaceutical industry to grow and shine in the international market, and to become a beacon of hope for patients worldwide.

4. Stakeholder Engagement

GRI 102-40 GRI 102-42~44

In accordance with the AA1000 Stakeholder Engagement Standards (SES) and with the interviews and feedback from all departments, PharmaEssentia has identified 10 stakeholders relevant to our operations. We further distributed sustainability topics questionnaires in 2021 to comprehensively identify current topics of stakeholders' concern. After analyzing the risks and impacts of such topics on our operations, we have formulated corresponding management approaches to regularly engage in sustainability topics of stakeholders' concern to address their expectations and needs in our operations.

Significance of Stakeholder to PharmaEssentia

Stakeholders	Meaning to the Organization	Topics of Concern	Communication Channel and Frequency	2021 Response Measures
Patients	Patients are important stakeholders who are most directly related to PharmaEssentia. Our founding philosophy, "Better science, Better lives" aims to continuously work toward patient health through innovative new drugs that alleviate their pains. We aim to make it easier for patients to obtain the drugs they need and reduce the gap in drug accessibility.	• Drug Quality & Safety Management • Supply Chain Management • Business Ethics & Compliance • R&D and Innovation of New Drugs • Access to Medicine • Patient Relation and Community Engagement	• Sales meetings: bi-weekly • Visits or conference-calls: when necessary • Seminar: occasionally • Phone calls or E-mails: anytime • Company's website: anytime	• Formulated a pharmacovigilance team to be in charge of pharmacovigilance and management; regularly issue PSUR/PBRER in line with the requirements from competent authorities of various countries • Ropeginterferon alfa-2b (P1101) benefits more than 1,500 PV patients • Collaborated with Chiayi Chang Gung Memorial Hospital to establish Taiwan's first MPN center to reinforce Taiwan's medical research in terms of myeloproliferative neoplasm (MPN) and to be more aligned with international trends • Panco Healthcare formulated an interactive patient health education platform "MPN iCare" to provide health care information to patients and their families • Panco Healthcare organized MPN Nurse Seminar, which was participated by 30 medical staff from 14 hospitals • Filed application to the Ministry of Health and Welfare to include Ropeginterferon alfa-2b (P1101) in Taiwan's national health insurance scheme • Commenced patient health care SOURCE Program to patients in the United States
Employees	Employees are the most precious asset of an enterprise, especially for PharmaEssentia. From R&D of new drugs to drug marketing and sales, employees' cohesion and positive recognition pose material impacts on a company throughout its value chain. We hope that our present or future employees can grow together with PharmaEssentia in an enjoyable working environment.	• Business Ethics & Compliance • Drug Quality & Safety Management • Supply Chain Management • Talent Attraction and Retention • Human Rights • Hazardous Substance Management • Waste Management • Climate Governance	• Welfare Committee: quarterly • Labor-management meeting: quarterly • Employee performance assessment: Every six months • Onsite medical and health care service: monthly • Health promotion services: annually • Phone calls or face-to-face interviews: when necessary • Internal website: occasionally • Online reporting and complaint channels and mailbox: occasionally • Company's website: anytime • Sustainability Report in English and Chinese: annually	• Organized 4 routine Welfare Committee meetings and 4 labor-management meetings • The HR department coordinates and manages employee performance assessments; assessments are carried out twice a year: mid-year and at the end of the year • HR department organized two rounds of ethical business management and human rights management policy advocacy courses, which retrieved 132 course feedback surveys that were distributed • HR department organized 3 routine employee onsite medical and health care services every month and conducted "abnormal workload questionnaire" survey; retrieved 101 surveys at Taipei headquarters • "Abnormal workload questionnaire" was included in employee health examination at Taichung Plant; 104 surveys were retrieved • 70 copies of "2021 Employee Health Examination Satisfaction Survey" were retrieved • No complaints were received in internal/external complaint mailbox • Retrieved 332 copies of Sustainability Material Topic Questionnaire • Released Sustainability Report in English and Chinese

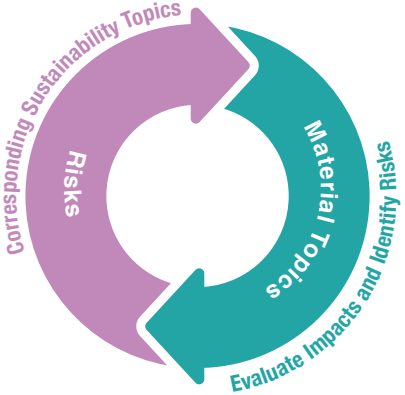
Stakeholders	Meaning to the Organization	Topics of Concern	Communication Channel and Frequency	2021 Response Measures
Contract Research Organizations (CROs) / Experiment Units	The topic selection in the early stage of new drug R&D relies heavily on the academic research units. Therefore, we support many universities to conduct research on drugs and to develop new applications. Each research result is a step towards disease treatment. In addition, most of the Company's animal experiments are outsourced.	• Drug Quality & Safety Management • R&D and Innovation of New Drugs • Business Ethics & Compliance • Access to Medicine • Hazardous Substance Management	• Correspondence: when necessary • Seminar: occasionally • Phone calls or E-mails: anytime • Conference-calls: when necessary • Development outsourcing contract: when necessary	• PEC's phase III multi-center clinical trial of using Ropeginterferon alfa-2b (P1101) to treat COVID-19 was approved by the Ministry of Health and Welfare to be executed in 5 hospitals throughout Taiwan • Expanded indication of Ropeginterferon alfa-2b (P1101) to Pre-fibrotic Primary Myelofibrosis (Pre-PMF) passed the review from Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB), and will begin the Investigator Initiated Trials (IIT) • All tests using animals for PEC's internal R&D projects are outsourced to qualified, specialty institutions in accordance with relevant compliance. Furthermore, locally outsourced institutions accounted for 75% and foreign institutions accounted for 25% in 2021
Medical Personnel	Medical personnel are stakeholders who work with patients on the frontline. Their understanding in patients and their expertise in medication can boost PharmaEssentia's chances of success in new drug R&D and benefit more users. They are also the closest partners of PharmaEssentia around the world.	• Drug Quality & Safety Management • R&D and Innovation of New Drugs • Business Ethics & Compliance • Access to Medicine • Patient Relation and Community Engagement	• Correspondence: when necessary • Seminar: occasionally • Phone calls or E-mails: anytime • Conference-calls: when necessary	• Collaborated with Chiayi Chang Gung Memorial Hospital to establish Taiwan's first MPN center • Panco Healthcare formulated an interactive patient health education platform "MPN iCare" to provide health care information to patients and their families • To contribute toward epidemic preventions in Taiwan, we launched the "PharmaEssentia Can Help" project to actively provide BESREMi® to medical institutions that participated in the clinical trial to treat mild to moderate COVID-19 cases • Sponsored the MPN Asia for 5 consecutive years, invited European/American experts and scholars to share clinical experiences to promote interactions and sharing of the latest treatment perspectives between Asian experts, scholars, and clinical physicians. MPN Asia 2021 was held online for the first time due to the pandemic • PharmaEssentia and Panco Healthcare assisted in organizing 2021 Taiwan MPN Workshop, which was attended by 167 individuals • Panco Healthcare organized the MPN Nurse Seminar, which was participated by 30 medical staff from 14 hospitals • Commenced patient health care SOURCE Program in line with medical personnel to serve patients in the United States • Results from phase II clinical trial of using Ropeginterferon alfa-2b (P1101) to treat chronic Hepatitis C Virus (HCV) genotype 2 was published in Journal of the Formosan Medical Association (JFMA) in March 2021 • Results of using Ropeginterferon alfa-2b (P1101) to treat chronic HCV genotype 1 was published in JGH Open in July 2021

Stakeholders	Meaning to the Organization	Topics of Concern	Communication Channel and Frequency	2021 Response Measures
Shareholders and Investors	A long period of capital investment is required before a new drug is marketed. Therefore, the trust and support from our shareholders and investors are particularly important. PharmaEssentia is committed to improving its information transparency, for shareholders and investors to grasp the information of PharmaEssentia in real time and accuracy.	• R&D and Innovation of New Drugs • Drug Quality & Safety Management • Business Ethics & Compliance • Access to Medicine • Talent Attraction and Retention • Hazardous Substance Management • Waste Management	• Shareholders' Meeting: annually • Special shareholders' meeting: occasionally • Board of Directors: quarterly • Special board meeting: occasionally • Investor conference: when necessary • Press conference: when necessary • Spokesperson: anytime • Company's website: anytime • Taiwan Stock Exchange Market Observation Post System: when necessary • Sustainability Report in English and Chinese: annually	• An Investors Relations section has been set up on the Company's website to disclose information including the Shareholders' Meeting, finance, and business operations etc. • Monthly revenue and press release are announced on the Taiwan Stock Exchange Market Observation Post System (MOPS) and the Company's website • Important progress on international arbitration and litigation disputes with externally licensed partner AOP is updated/announced on the Company's website when it becomes available • 7 investor conferences (including online conference) were held • PEC's corporate governance evaluation results ranked among top 6% to 20% • Released Sustainability Report in both English and Chinese
Suppliers and Business Partners	The raw materials, calibration services, contract manufacturing, and plant engineering required for the product life cycle rely on stable and reliable suppliers / contractors to fully implement the concept of Access to Medicine.	• Business Ethics & Compliance • Supply Chain Management • Drug Quality & Safety Management • Human Rights • Talent Attraction and Retention • Waste Management • Hazardous Substance Management	• Production-marketing meetings: bi-weekly • Visits: when necessary • On-site audit: annually • Phone calls or E-mails: anytime • Conference-calls: when necessary • Company's website: anytime • Sustainability Report in English and Chinese: annually	• October - Obtained PV regulatory marketing approval in South Korea • September - passed plant verifications from the U.S. FDA and obtained PV regulatory marketing approval from the United States in November; this is the first regulatory marketing approval granted by the FDA to treat all adult PV patients • Established multinational supply chain; based on operating procedures, we began supplying to third-party warehouse in the U.S. in December, prepared to deliver to distribution channels, then delivered the product to end-users (patients) • Top 3 sustainability management priorities for suppliers: Carried out the PEC CSR Report advocacy to 177 suppliers in 2021 • All vendors required to sign quality agreements have signed, and all required internal assessments and on-site audits have been completed for three consecutive years • Organized GMP related trainings for 2,234 individuals, and the total hours of training reached 54,618 hours
Local Community	Of all stakeholders that PharmaEssentia engages in, though the local community is not directly affected but they are the closest to us. PEC is intricately tied to the local community in terms of social engagement, and local community has therefore been classified as a separate stakeholder in order to thoroughly practice our social responsibility.	• Business Ethics & Compliance • Access to Medicine • Human Rights • Patient Relation and Community Engagement • Waste Management	• Correspondence: when necessary • Seminars and speeches: occasionally • Phone calls or E-mails: anytime • Conference-calls, charity events or work study programs: when necessary • Company's website: anytime • Taiwan Stock Exchange Market Observation Post System: when necessary • Sustainability Report in English and Chinese: annually	• PEC carried out 3 rounds of industry-academic cooperation/exchange with the local community in 2021, these included a seminar at the National Central University in May: MPNs and R&D of new drugs practices; PEC was invited to share CMC & Clinical in successfully launching a biopharmaceutical drug at NanKang Biotech Incubation Center by the Biopharmaceutical Committee of the Taiwan Pharmaceutical Manufacturer's Association in October; and gave a speech titled "A Fully Integrated Operating Global Biopharmaceutical Company in Taiwan" at BioAsia in November • PEC co-organized investors conference and recruitment fair with Academia Sinica and businesses from the Nangang Biotech Incubation Center in 2021 • Subsidiary Panco Healthcare formulated an interactive patient health education platform "MPN iCare" to provide health care information to patients and their families • Subsidiary Panco Healthcare organized MPN Nurse Seminar, which was participated by 30 medical staff from 14 hospitals • Released Sustainability Report in English and Chinese

Stakeholders	Meaning to the Organization	Topics of Concern	Communication Channel and Frequency	2021 Response Measures
Government and Competent Authorities	The government's support for the industry is the most important helping hand. With the support from National Development Fund, PharmaEssentia has achieved stable results in the early stage of development. Nonetheless, the government's regulations and standards for the pharmaceutical industry are relatively strict, such as environmental protection. PharmaEssentia must pay close attention to the adjustment of relevant laws and regulations to avoid impairment of the rights or interests of interested parties due to violation of laws.	• Business Ethics & Compliance • Drug Quality & Safety Management • Patient Relation and Community Engagement • Waste Management • Hazardous Substance Management • Climate governanace	• Correspondence: when necessary • Seminar: occasionally • Phone calls or E-mails: anytime • Conference-calls, charity events or work study programs: when necessary • Company's website: anytime • Taiwan Stock Exchange Market Observation Post System: when necessary • Sustainability Report in English and Chinese: annually	• Appointed dedicated legal personnel to manage correspondence with government institutions • Uploaded data to MOPS for information disclosure • PEC complies with laws and regulations related to the biopharmaceutical industry, and did not suffer from any penalties or violations due to environmental safety or drug quality or safety problems in 2021 • TFDA completed the first routine plant inspection in April after granting regulatory marketing approval to our BESREMi®, results indicated no severe deficiency • Ropeginterferon alfa-2b (P1101) for the treatment of ET has been carried out in phase III clinical trials in many places around the world, and we received approximately NT$32.92 million in project-based grant from the Ministry of Economic Affairs • In 2021, PEC was penalized as earmark transaction and violation of information reporting due to violation of material information disclosure, and total fines amounted to NT$1.5 million • Released Sustainability Report in English and Chinese
Media	In the era of multimedia and the Internet, in addition to the active communication channels of PharmaEssentia, it is necessary to communicate with many stakeholders and rely on the communication power of domestic and foreign press and media to accumulate the trust of stakeholders. Therefore, we maintain good relationship with the press and media.	• Business Ethics & Compliance • R&D and Innovation of New Drugs • Drug Quality & Safety Management • Access to Medicine • Patient Relation and Community Engagement	• Media gathering: annually • Press conference: when necessary • Press release: occasionally • Exclusive interview: when necessary • Spokesperson: anytime • Company's website: anytime • Taiwan Stock Exchange Market Observation Post System: when necessary • Sustainability Report in English and Chinese: annually	• Designated public relations personnel to interact and communicate with the press and media • An Investors Relations section has been set up on the Company's website to disclose information including the Shareholders' Meeting, finance, and business operations etc. • Monthly revenue and press release are announced on the Taiwan Stock Exchange MOPS and the Company's website • Released Sustainability Report in English and Chinese • 2021 Media/News Report
NPOs / NGOs	Non-profit organizations are important partners while we strive to realize drug accessibility. They assist PharmaEssentia in identifying patients need, but lacking access, to relevant drugs. Subsequently, patients can continue to obtain such drugs to sustain their lives either through donation or charity.	• Supply Chain Management • Access to Medicine • Patient Relation and Community Engagement • Waste Management	• Correspondence: when necessary • Seminar: occasionally • Phone calls or E-mails: anytime • Conference-calls: when necessary	• Sponsored One Song's 2022 New Year Concert, attended by 52 individuals • Sponsored two health promotional events, "2021 Joining Young Patients" and "Relaunching Health" for hemophilia patients, and assisted patients at Tung's Taichung MetroHarbor Hospital and Sin-Lau Hospital to learn the latest health care and medical information • In 2021, permitted cases of compassionate use of Ropeginterferon alfa-2b (P1101) reached 40 cases

5. Identifying Material Topics GRI 102-46

To pursue sustainable development, PharmaEssentia has re-identified our material topics in 2021 to integrate the concern of materials topics from our stakeholders into our strategic development. By referencing the four major AA1000 AccountAbility Principles: Inclusivity, Materiality, Responsiveness, and Impact, we have formulated PharmaEssentia's information and management framework for the three major ESG aspects of sustainability. We disclosed comprehensive management approaches and goals based on 11 material topics that our 10 stakeholders are concerned with and continue to monitor and evaluate current performances and future goals.



Identification Process of Sustainability Topics

Principle 1: Inclusivity

By referring to the AA1000 Stakeholder Engagement Standards, interviews, and feedback from all departments, we have identified targets of engagement among our 10 stakeholder groups. Through communication feedback and international sustainability trends and other channels, 22 sustainability topicss covering ESG aspects have been compiled.

Principle 2: Materiality

To address the stakeholders' expectations for our operations, we re-distributed material topic survey to research the sustainability topics of stakeholders' concern in order to include them in our strategic development. Moreover, we examined our sustainability development roadmap by evaluating the impact of the sustainability topics and related risks on our organization and stakeholders.

1 Confirmed Communication Targets

10 Stakeholders

Including patients, PharmaEssentia's employees throughout the world, medical personnel, CROs/experiment units, shareholders and investors, government and competent authorities, suppliers and business partners, media, local community, and NPO/NGO. Please refer to "Preamble 4 Stakeholder Engagement"

2 Collected Sustainability Topics

3 ESG Aspects
22 Topics

References include various international benchmark principles and standards (SDGs, GRI Standards, SASB, TCFD), sustainable investment agencies (DJSI, MSCI, Sustainalytics), sustainability trends in the biopharmaceutical industry, internal development indices, and collection of stakeholder concerns etc.

3 Researched Levels of Stakeholders' Concern

332 Surveys

Distributed Sustainability Material Topic Questionnaire:
- 13 distributed to senior managers
- 319 distributed to stakeholders: For certain stakeholders: department heads answered the questionnaire on behalf of the stakeholders from the stakeholders' perspectives (e.g., patients)

4 Analyzed Impacts on Operation

19 Risk Impacts

In accordance with "Corporate Risk Management Framework" to identify sustainability topics and risks on the Company's operation. Please refer to "Preamble 6 Risks Management"

5 Produce Materiality Matrix

11 Material Topics

Based on the quantitative questionnaire results, after discussions from the Sustainable Development Executive Center and in line with PEC's future strategic development goals, 11 material topics were identified in preparing PharmaEssentia's materiality matrix (please reference to page 20)

Principle 3: Responsiveness	Principle 4: Impacts
Based on the results of the materiality research and analysis and having confirmed the materiality of the 11 sustainability topics, we examined the impact of each topic on our operating value chain. The boundary includes Taiwan headquarters, Panco Healthcare, and our U.S. subsidiary. Disclosed internal information and corresponding management management approaches based on the GRI reporting standards.	Short-, medium-, and long-term strategic goals are formulated for each of the 11 material topics. The Sustainable Development Executive Center will regularly examine the goal achievement status as well as timely monitor and manage each of the sustainability topics.

Significance of Sustainability Topics to PharmaEssentia, Risks and Opportunities on the Value Chain

GRI 102-49 GRI 103-1

According to the analysis based on PharmaEssentia's operation value chain, 11 material topics and their impact on the organization were identified. Its related risks were also evlauated from 4 aspects: strategy, operation, finance and legal. We further identified the corresponding relevant risks (probability and severity), and established the corresponding risk management mechanism, risk management performance in 2021 and future improvement actions. Please refer to the material topic management table in each corresponding chapter.

6 Determining Disclosure Boundaries

6 - Tiered Value Chain

3 Major Business Operational Boundaries

- Value chain includes R&D and innovation of new drugs, preclinical study, clinical trial, manufacturing and production, regulatory marketing approval application, marketing and sales
- PEC's operational boundaries: Taiwan headquarters, Panco Healthcare, U.S. Subsidiary

7 Formulating Management Approach

11 Management Approaches

Information collection and disclosure on the 11 material topics are conducted in line with the reporting requirements and management approaches from GRI standards

8 Drafting Implementation Goals

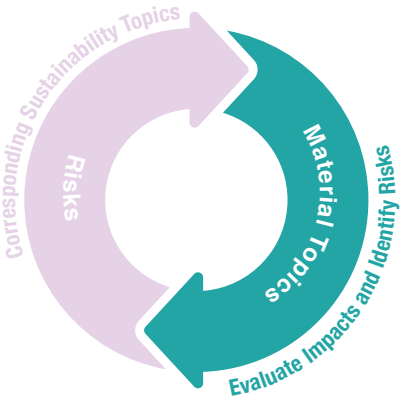
Short-, Mid-, Long-term Goals

Sustainable Development Executive Center's inter-departmental functional groups formulate short-, medium-, and long-term implementation goals for each significant topic

9 Evaluating Implementation Performance

Quarterly Meetings

Sustainable Development Executive Center will regularly report the implementation progress and results to the Board of Directors, as well as monitor and manage the implementation performance



Material Topics and Corresponding Risk Impacts

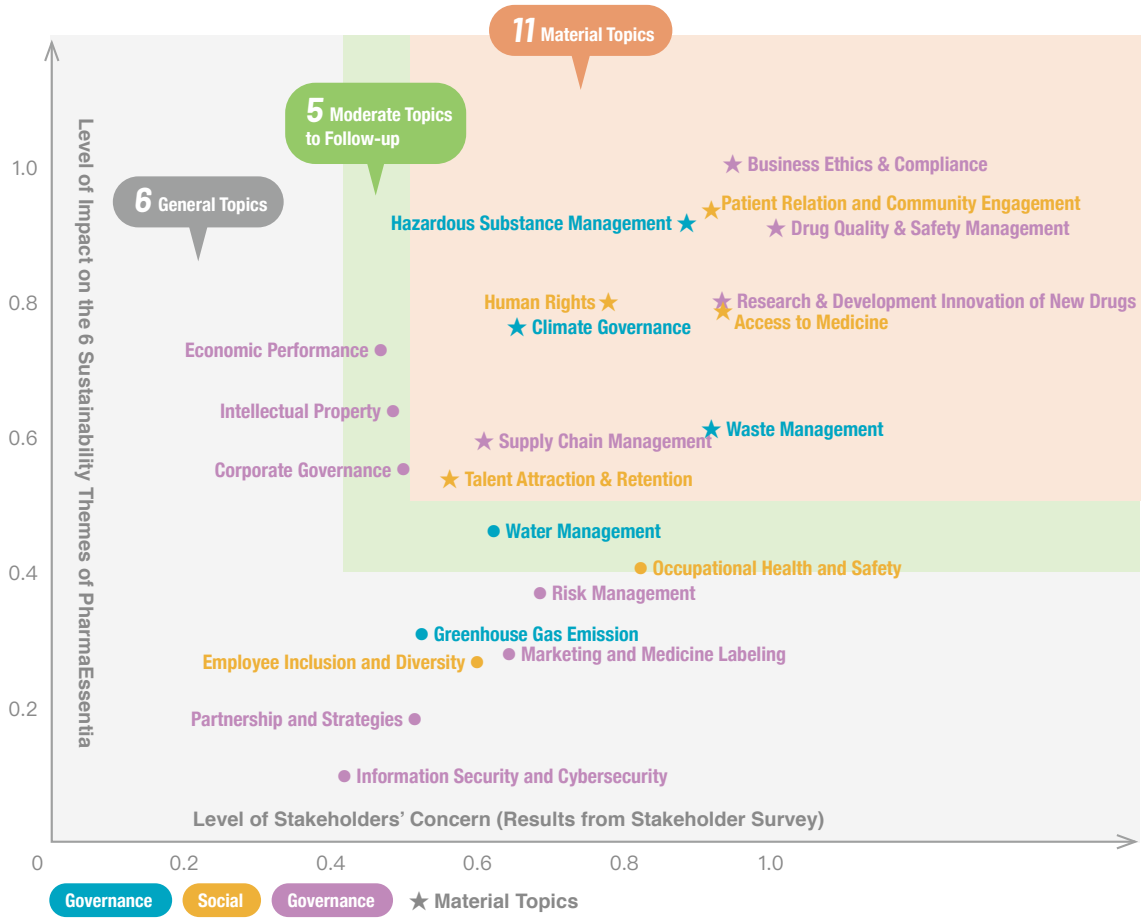
ESG	Environmental		
Material Topics	Hazardous Substance Management	Waste Management	Climate Governance
Significance to PharmaEssentia	PharmaEssentia properly manages special chemical substances and toxic chemical substances used in laboratories and plants to minimize their impacts on the environment.	To protect environment, we adopt proactive pollution prevention and treatment methods for general waste and hazardous waste generated by PharmaEssentia.	Climate change and mitigation is closely related to energy management. In addition to energy conservation and carbon reduction, the enhancement of energy efficiency is also a key to PharmaEssentia's green operations. We further initiated greenhouse gas (GHG) inventories to formulate substantial and feasible carbon reduction goals. At the same time improving operational competitiveness and lower energy costs, thereby reducing irreversible and negative impacts to the human health and the planet.
Impacts on Value Chain: Innovative Drug Discovery	✓	✓	✓
Preclinical Study			✓
Clinical Trial			✓
Manufaturing and Production	✓	✓	✓
Innovative Drug Registration			✓
Marketing and Sales			✓
Risk Issues	• Improper storage and management of chemicals	• Improper storage and management of waste	• Climate change risks
Corresponding GRI Principles	★ Industry-exclusive topic	GRI 306: Waste (2020)	GRI 302: Energy
Corresponding Chapters	5.3 Hazardous Substance Management	5.2 Waste Management	5.1 Climate Governance

ESG	Social			
Material Topics	Talent Attraction and Retention	Patient Relation and Community Engagement	Access to Medicine	Human Rights
Significance to PharmaEssentia	Talent is a necessary criterion for sustainable and competitive corporate management. We provide various talent attraction and retention measures including comprehensive career development planning, educational training, and compensation and benefit to our employees. This is the key to PharmaEssentia's sustainable operations.	We uphold a patient-oriented philosophy and make sure all patients using PharmaEssentia's products are aware of drugs' effects and results, and continuously monitor and care for patients' health during the entire treatment period. At the same time, we promote local healthcare and community engagement to extend PharmaEssentia's external influence to the medical system as well as the society at large and to make positive contributions.	In line with PharmaEssentia's philosophy of "Better science, Better lives," we established PharmaEssentia's "Access to Medicine Guidelines" and set promotional methods including reasonable drug pricing, reliable drug supply, and the implementation of compassionate use, etc., with the goal of providing a steady supply of PharmaEssentia's drugs to patients.	PharmaEssentia supports and respects human rights as well as practices human rights policy in our day-to-day operations. We comply with various international human rights policies and initiatives. Founded on our core competencies, we protect the patients' and employees' privacy and exercise due care over the control and responsibility of data protection.
Impacts on Value Chain: Innovative Drug Discovery	✓		✓	✓
Impacts on Value Chain: Preclinical Study	✓		✓	✓
Impacts on Value Chain: Clinical Trial	✓		✓	✓
Impacts on Value Chain: Manufaturing and Production	✓		✓	✓
Impacts on Value Chain: Innovative Drug Registration	✓	✓	✓	✓
Impacts on Value Chain: Marketing and Sales	✓	✓	✓	✓
Risk Issues	• Talent loss	• Product endangering patient life safety	• Unable to provide stable or timely supply of products • Inadequate quality assurance of clinical procedures • Violations of the Code of Business Conduct and Compliance	• Internet security and data protection under attack
Corresponding GRI Principles	GRI 404: Training and Education	★ Industry-exclusive topic	GRI 203: Indirect Economic Impacts	GRI 412: Human Rights Assessment
Corresponding Chapters	4.4 Talent Training and Career Development	6.4 Stable, Safe and High-Quality Drugs	6.1 Governance on Access to Medicine	2.3 Data Security and Privacy Protection 4.3 Human Rights Protection

ESG	Governance			
Material Topics	Business Ethics and Compliance	Drug Quality & Safety Management	R&D and Innovation of New Drugs	Supply Chain Management
Significance to PharmaEssentia	As we continue to launch multi-center clinical trials in multiple countries and progress towards obtaining multinational drug licenses, we must comply with local market regulations in each country and strictly enforce ethical behavior at all levels of the product value chain, with integrity as our highest guiding principle.	Comply with "PIC/S Good Manufacturing Practice" (hereinafter referred as "GMP") and other related regulations to ensure the safety and effectiveness of the drug life cycle. Implement pharmacovigilance in the clinical stage, establish an effective quality management system, and submit drug safety reports on a regular basis; formulate immediate adverse drug reaction notification mechanism for marketed drugs to ensure drug quality.	We continue to explore and develop possible new drugs and technologies. And enhance the innovative R&D capabilities of PharmaEssentia for unmet medical needs from patients around the world.	To ensure the products delivered to patients are safe, high in quality, and available in a timely manner to avoid delaying the optimal treatment of patients, we strive to establish a stable and safe product supply chain through series of process such as identifying market demand, production scheduling, quality control, drug transportation and storage, and drug traceability or tracking.
Impacts on Value Chain: Innovative Drug Discovery	✓		✓	
Impacts on Value Chain: Preclinical Study	✓		✓	
Impacts on Value Chain: Clinical Trial	✓	✓	✓	
Impacts on Value Chain: Manufaturing and Production	✓	✓		✓
Impacts on Value Chain: Innovative Drug Registration	✓	✓		✓
Impacts on Value Chain: Marketing and Sales	✓	✓		✓
Risk Issues	• Violations of the Code of Business Conduct and Compliance • Inadequate protection of intellectual property, control, and defense against infringement of rights	• Product endangering patient life safety • Product safety monitoring mechanism failure • Severe plant inspection deficiencies • Improper management of product transportation operations • Inadequate quality assurance of clinical procedures	• R&D and business development directions are not closely aligned	• Improper management of product transportation operations • Unable to provide stable or timely supply of products • Improper management of outsourced suppliers
Corresponding GRI Principles	★ Industry-exclusive topic	★ Industry-exclusive topic	★ Industry-exclusive topic	★ Industry-exclusive topic
Corresponding Chapters	2.2 Compliance and Business Ethics	3.3 Ensuring the Quality and Safety of Drugs 3.6 Effective Pharmacovigilance and Recall Mechanism	1.3 R&D of Innovative Biopharmaceuticals	3.1 Constructing a Comprehensive Supply Chain System

Materiality Matrix in the Year of Sustainability Performance GRI | 102-47

Material, moderate, and general sustainability topics are determined by cross-referencing the "level of impact on the sustainability topics" and "level of stakeholders' concern" on the material sustainability matrix. This report comprehensively discloses the management approaches and performance information of the 11 material topics and continues to monitor and manage the rest of the topics.



6. Risk Management

Risk Management Organization and Mechanism

GRI | 102-11 GRI | 102-15

PharmaEssentia properly manages all risks that correspond with material topics and has formulated risk management policies, procedures, and internal control systems based on relevant standards and rules. For financial risks such as market risk, credit risk, and liquidity risk, all relevant financial activities are carried out in line with PEC's internal control mechanisms. And all major financial activities shall be reviewed by the Board of Directors in line with relevant standards and the internal control system. The Auditing Office also reviews such activities and reports them to the Board. The Execution Center for Corporate Sustainability oversees coordinating non-financial risk identifications relate to ESG aspects. It oversees the likelihood and level of impact of risks for business operations, and provide feedback on existing management mechanisms to the management approaches to material topics. To effectively prevent risks and hazards, PharmaEssentia has further formulated management practices against emerging risks to identify the types of risks that are new or are expected to have potential/long-term effects on the Company's operations and business activities. Their impacts on PharmaEssentia's operations are analyzed; relevant management mechanisms are actively formulated; and the management effectiveness is regularly monitored.

Board of Directors	Highest directing unit for risk management of PEC; it supervises, reviews, and approves the effectiveness of the risks and important risk management mechanisms that may be faced by the operations of the head office and subsidiaries.
Audit Committee	Assist the Board of Directors in controlling the existing or potential risks of the Company to strengthen PEC's internal control mechanism.
Auditing Office	Prepare annual audit plans in accordance with the Company's risk management policies and systems, conduct independent audits, and submit audit reports to the Board of Directors and Audit Committee on a quarterly basis.
Corporate Governance Officer	Handle tasks related to the Board of Directors meetings and Shareholders' Meetings, provide information required by Directors to perform their duties, collect the latest legal developments related to the Company's operations in order to facilitate the Board of Directors in legal compliance. Facilitate Directors in taking their office and their continued education etc.
CEO	As the chief convener, the CEO coordinates the management teams from Taiwan headquarters and subsidiaries, in addition to measuring, implementing, and controlling the key risks in each department
Execution Center for Corporate Sustainability and 5 taskforces	Assist the Company in assessing the impacts of ESG-oriented, non-financial risks on sustainable operations, draft corresponding measures. Representatives from the Execution Center for Corporate Sustainability will submit business reports to the Board of Directors on a quarterly basis.
Functional Departments	Department Managers conduct risk identification, impact assessment, analysis, and evaluation, and identify countermeasures and improvement measures in accordance with the department's job description. Conduct education and promotion of risk awareness management to employees in daily operations.

Note: Please refer to "2.1 ParmaEssentia's Governance Framework" for PEC' risk management organization.

Identifying Non-financial Risks

In line with the 2018 Corporate Risk Management Framework from the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and the World Business Council for Sustainable Development (WBCSD), PharmaEssentia's non-financial risks of PharmaEssentia are identified through understanding the likelihood and impact of risks through organized and structured COSO framework, which management mechanisms and future action plans are planned accordingly. Our process of identifying non-financial risks is described below.

Understanding the importance of risk to PharmaEssentia

- Global and industrial ESG risk trends
- Case sharing

Listing potential risks in terms of likelihood of occurrence and impact

- Impact level: Strategic, operational, financial, and compliance aspects
- Likelihood: Whether the risk has occurred in the past and chances of it happening going forward

Risk issues in the order of importance

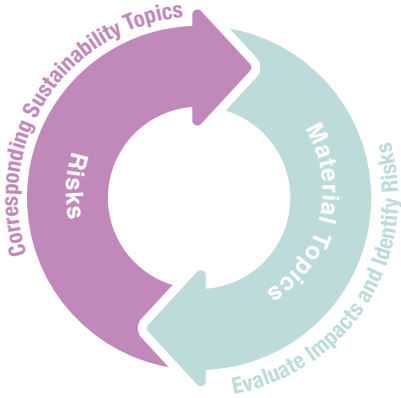
- Complete the risk matrix in two dimensions: likelihood of occurrence and impact

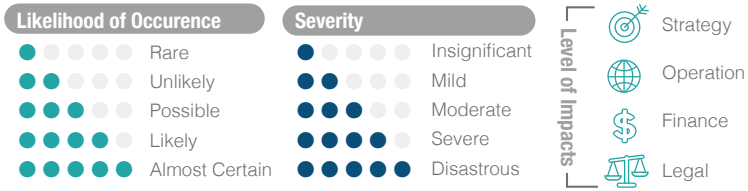
Planning of risk response strategy

- The main investment and action plan will be developed according to the ranking of risks in the future

Existing Management Mechanism and Future Optimization Actions for Non-financial Risk Issues

For the risks that have been identified, we are making actual improvements based on the existing management mechanisms and reviewing, optimizing the improvement plans going forward in order to further feedback to the management approaches to the material topics. Since PharmaEssentia has re-identified the material topics in 2021, certain existing material topics have been deemed as either moderate or general topics. Nevertheless, we will continue to follow up on the risks associated with such topics and to actively manage them accordingly. (Risks denoted with ◎ indicate emerging risks, while the ones denoted with ★ refer to material sustainability issues for 2021. Please refer to "Preamble 5 Identifying Material Topics")





	Social	
Risk Issues	Occupational disasters and accidents	Employee turnover
Material Topics	Occupational Health and safety	Talent Attraction and Retention ★
Possibilities/ Existing Management Mechanisms	• Formulate procedures for all departments to follow accordingly • Enforce in line with the Occupational Safety and Health Act • Environmental safety units will regularly patrol/inspect • Annual facilities and equipment maintenance	• Employee compensation mechanism. • Annual salary adjustments and promotional channels • Functional and professional training • Provide learning opportunities to employees by assigning them to new plans or projects
Likelihood of Occurence	●●○○○	●●●○○
Severity	●●●●○	●●●○○
Actual Improvement Actions in 2021	• Hazardous areas will be marked from the production sites by evaluating factors including raw material consumption and ventilation effectiveness etc. • Increased manpower to prioritize the planning and execution of plant inspection projects • Filed COVID-19 comprehensive vaccination insurance and comprehensive infectious disease insurance	• Review and formulate new subsidy/allowance system for the Welfare Committee • Reinforce the functions of the onsite medical personnel to monitor employees' mental/physical stress levels and health improvements. • File epidemic prevention insurance for employees to strengthen epidemic prevention measures. • Provide personal development and learning opportunities as well as incentive measures to key personnel. • Invite external professional consultants to provide on-the-job-training and to share their experiences. • Develop a legacy system and collaborate with external professional consultants.
Expected Improvement Actions for 2022 and Onward	• Replaced electronic equipment at the hazardous production areas with explosion-proof electronic machinery • Taichung Plant to adopt ISO45001 Occupational Safety and Health Management System in 2023 • Increased manpower to reinforce the implementation of relevant tasks	• Improve the working environment and welfare system of employees. • Develop and provide professional functional training courses to new employees. • Strengthen and enhance employees' language skills. • Formulate and implement personal development plans for key talent. • Formulate talent development mechanisms step by step.

	Environmental		Governance
Risk Issues	Improper storage and management of chemicals	Improper storage and management of waste	Product safety monitoring mechanism failure
Material Topics	Hazardous Substance Management ★	Waste Management ★	Drug Quality & Safety Management ★
Possibilities/ Existing Management Mechanisms	• Adhere to the restricted operating volume and reporting schedule from the competent authority. • Handle disposal of chemicals and waste in accordance with the internal chemical and Waste Management procedures. • Join the regional toxic chemical substance disaster prevention organization	• Adhere to the restricted operating volume and reporting schedule from the competent authority. • Handle disposals in accordance with internal waste management procedures.	• Regularly confirm the numbers and items of safety incidents reported by CROs. • Regularly confirm the contents and numbers of safety incidents/reports with subsidairies.
Likelihood of Occurence	● ○ ○ ○ ○	● ○ ○ ○ ○	● ○ ○ ○ ○
Severity	● ● ○ ○ ○	● ● ○ ○ ○	● ● ● ● ○
Actual Improvement Actions in 2021	• Continue to practice transportation standards of toxic chemical substances and to follow the routine reporting system to reduce the risk of toxic chemical hazards. • Taichung Plant commissions legitimate vendors to dispose of waste toxic chemical substances and the competent authority is also notified for review. • Taichung Plant was permitted to join Taichung City's toxic and concerned chemical substance regional joint prevention organization. • No deficiency was found during Taichung Plant's audit.	• Outsource waste disposal and clearance in line with regulations from the competent authority. • Inspected temporary waste storage area at Taichung Plant in line with applicable laws and regulations (4 times/year) and conducted annual audit on waste disposal vendor (twice/year); no abnormality was found. • Taichung Plant submitted application for change in "Commercial/industrial waste disposal plan" based on the characteristics of the waste, source of waste generation, and volume of the wate generated etc. • No deficiency was found during Taichung Plant's audit.	• Determine the competency of the drug safety CROs by evaluating the quality and completion time of the Periodic Safety Update Report (PSUR) and Periodic Benefit-Risk Evaluation Report. • Ask CROs to regularly confirm the numbers of safety incident reported every month.
Expected Improvement Actions for 2022 and Onward	• Taichung Plant to implement ISO45001 Occupational Safety and Health Management Systems、ISO14001: 2015 Environmental Management Systems in 2023 • Disclose the annual greenhouse gas emissions, water consumption, and total volume of waste generation over the years. • Monitor anticipated environmental protection laws and information on revision/amendment announcements to follow legal regulations and control. Revise plant implementations and management measures as soon as possible. • Strengthen employees' emergency response skills by requiring operators of toxic chemical substances to participate in external professional personnel training courses regarding response measures to toxic and concerned chemical substances.		• Determine the competency of the drug safety CROs outsourced by subsidiaries through evaluating the quality and completion time of their reports. • Continue to develop and amend standard operating procedures (SOP) related to drug safety. • Increase the manpower in Pharmacovigilance department at PharmaEssentia's headquarters to ensure pharmacovigilance and legal compliance of drug safety monitoring tasks.

	Governance		
Risk Issues	Severe plant inspection deficiencies	Product endangering patient life safety	Improper management of product transportation
Material Topics	Drug Quality & Safety Management ★	Drug Quality & Safety Management ★ Patient Relation and Community Engagement ★	Drug Quality & Safety Management ★ Supply Chain Management ★
Possibilities/ Existing Management Mechanisms	• Each internal department shall undergo internal quality audit every year. • Foreign experts are invited to conduct quality audits when necessary.	• Ensure complete collection of safety information through various adverse drug event reporting channels, which are disclosed on the Company's official website. • Accurately report serious adverse events.	• Strictly control the packaging and transportation process to ensure the products are stored within 2℃ to 8℃ , and to regularly maintain the refrigeration equipment required. • Comply with the Good Distribution Process (GDP) for drugs and medications.
Likelihood of Occurence	● ○ ○ ○ ○	● ○ ○ ○ ○	● ○ ○ ○ ○
Severity	● ● ● ● ●	● ● ● ● ●	● ● ● ● ●
Actual Improvement Actions in 2021	• Deployed digitized document management, training, and quality management systems • Engaged in weekly online discussions with consultant in preparation for the U.S. FDA plant inspection. • Invited American consultants to conduct onsite quality audit and continued to optimize our quality system. • The U.S. FDA completed the GMP plant inspection at PEC's Taichung Plant in September, and we successfully obtained regulatory marketing approval in November.	• Toll-free Medical Information Consulting Call Center hotline set up by professional management/consulting company is used to announce/report relevant business activities with medical institutions and pharmacovigilance QA personnel from the plants. The electronic mailbox used for receiving drug safety reports has been announced on the website of PEC's Taiwan headquarters. • The electronic mailbox that represents PharmaEssentia at the drug safety CROs is used to receive safety/adverse events from all countries where PEC products have been launched. • Staff from clinical trials and business divisions all pay active attention to adverse events related to PEC's products. Any serious adverse event is reported to the competent authority within 15 days as required by the law. • Drug safety monitoring training is given to all new employees at PharmaEssentia.	• Utilized mean kinetic temperature (MKT) to evaluate temperature deviation risks in line with the United States Pharmacopeia (USP). • Completed audit procedures for 4 contracted transportation companies. • Built and deployed large-scale cold chain space, where the output of cold chain products is carried out; all output has met product temperature control requirements throughout the transportation process since the third quarter (Q3) • Verified by the TFDA and the U.S. FDA through plant inspection that all output operations and completeness of documentation process have met cGMP/GDP requirements.
Expected Improvement Actions for 2022 and Onward	• Deployed more digitized quality management procedures. • Continued to review quality and invited the EU consultants and experts to review and optimize existing systems in preparation for the EU plant inspection	• We actively engage in signal testing based on the safety signal management standards from GVP Module IX, in which we actively search for and identify safety signals from various sources, including individual case safety report (ICSR) and scientific papers and reviews. Safety evaluation on Signal Detection Report is conducted every three months. • Collaborate with QA department in Taichung Plant to handle product complaints related to adverse response. • Signed Safety Data Exchange Agreements (SDEA) with strategic partners abroad to exchange information related to drug safety from various countries to meet relevant legal requirements.	• While transporting output to the logistics center, our U.S. OEM used coolers to control the temperature on top of air freight and truck, and we are proposing to also deploy refrigerated trucks as a means of transportation. • Continue to execute external audit plan. • Besides maintaining existing compliance procedures, we will also continue to update relevant transportation and sales records in line with international laws and regulations to build a comprehensive drug traceability management system.

	Governance	
Risk Issues	R&D and business development directions are not closely aligned	Improper management of outsourced suppliers
Material Topics	R&D and Innovation of New Drugs★	Supply Chain Management★
Possibilities/ Existing Management Mechanisms	• R&D internal control rules and regulations and related management methods. • Due diligence mechanism and relevant training	• Establish supplier evaluation mechanism. • Perform various validation and verification. • External audit program. • Sign supply or quality contracts. • Provide outsourced CMOs with demand forecast and to update the forecast in a timely manner. • Establish channels of communication with outsourced vendors to achieve real-time review over relevant quality events and to determine subsequent actions. • Outsourced activities policy • Product packaging and labeling policy
Likelihood of Occurence	●●○○○	●○○○○
Severity	●●○○○	●●●●●
Actual Improvement Actions in 2021	• At the beginning of each new project, in-depth data collection should be conducted to understand the clinical progress of competitive drugs, PEC should conduct in-depth evaluation to tap into unmet drug needs and commercialization opportunities in the market and to guide the drug development progress through the development platform. • Engage in market analysis of existing drug development projects and coordinate with Marketing Department to understand market opportunities; dynamically report on the market's potential risk to the management team and to adopt rolling review over current R&D projects.	• Achieve bi-lateral communications with suppliers and maintain partnership to achieve timely support from suppliers in responding to production and market demand • Deployed 3 secondary sources of material while the supply chain was rendered unstable by the pandemic; supplies of all other materials continued to be normal
Expected Improvement Actions for 2022 and Onward	• R&D department will actively evaluate the feasibility of launching the new project using drug market database and to encourage other staff to engage in training related to market analysis. • Provide rolling adjustment and feedback on market trends to each project, and to regularly report to the management team during the bi-weekly R&D meeting to increase the project team and management team's market awareness and risk evaluation skills regarding R&D projects. • Formulate a R&D and marketing collaborative platform and procedures to promote inter-departmental facilitation and to increase the R&D team's market analysis skills.	• Continued to formulate Code of Conduct for Suppliers • Continued to develop and deploy secondary sources of material to reduce the risk of supply chain disruptions

	Governance	
Risk Issues	Unable to provide stable or timely supply of products	Violations of the code of business conduct and legal compliance
Material Topics	Supply Chain Management★, Access to Medicine★	Business Ethics & Compliance★, Access to Medicine★
Possibilities/ Existing Management Mechanisms	• Pre-plan and confirm production scheduling. • Establish safe inventory and secondary source of material. • Coordinate and arrange the transportation operation based on the drug's required temperature setting. • QA devision will confirm the relevant documents and operations meet the standards for product release. • Quarterly commercial and clinical development demand forecast. • Risk management policy • Raw material management policy • Drug safety reporting system and supply shortage notification system from the competent authorities in each country • PEC's drug complaint system	• PEC has formulated and enacted the "Corporate Governance Code" the "Principles of Ethical Corporate Management," the "Codes of Ethical Conduct," the "Procedures for Ethical Management and Guidelines for Conduct," the " Corporate Social Responsibility Best Practice Principles" and the "Operating Procedures for Handling Material Nonpublic Information and Preventing Insider Trading." • The Group has established internal control and internal audit management system and more than 40 operational management rules at the headquarters. The U.S. Subsidiary has also formulated more than 20 legal compliance policies. • From research and development to product commercialization, all business ethics and integrity of business conduct are required to comply with external regulations.
Likelihood of Occurence	● ○ ○ ○ ○	● ○ ○ ○ ○
Severity	● ● ● ● ○	● ● ● ○ ○
Actual Improvement Actions in 2021	• Maintain sufficient inventory and achieve timely supply of all drugs based on their respective demand by utilizing the production planning and raw material planning system and tools. • Build a large-scale cold chain space to increase the flexibility in storage and turnover of cold chain products. • Technological transfer is gradually completed for the new product's production line (PEG). • Expanded plant operations and office space in the fourth quater (Q4). • Improved the operational technology of biopharmaceutical manufacturing process and successfully passed the inspections from the U.S. FDA. • Actively maintain mutually trusting and beneficial relations with suppliers through increasing the frequency of communications to maintain stable raw material supplies, and to stay up to date on inventories of external suppliers in Taiwan, global supply, and demand status, and achieve inter-departmental collaborations on inventory preparations. • Deployed 3 secondary sources of material while the supply chain was rendered unstable by the pandemic; supplies of all other materials continued to be normal	• Promoted "Top Management Principles for Group Business Conduct and Ethics" and related detailed operational policies formulated by Headquarters. • Actively implemented the FSC's Corporate Governance 3.0 Blueprint of Sustainable Development Evaluation Index.
Expected Improvement Actions for 2022 and Onward	• Deployed more comprehensive corporate resource planning (ERP) system in January 2022. • Maintained functionalities of existing facilities and equipment. • Continued to maintain good interaction with suppliers. • Continued to develop and deploy secondary sources of material to reduce the risk of supply chain disruptions.	• Establish an inter-compliance committee within the Group and coordinate organizational procedures. Facilitate strategic decision-making processes by incorporating input from functional compliance representatives to achieve compliance with applicable laws and PEC's policies throughout all operational activities. • Ensure that operations comply with legal requirements both at home and abroad

	Governance		
Risk Issues	Inadequate quality assurance of clinical operating procedures	Attacks on network safety and private or confidential data ◎	Inadequate protection and control of intellectual property and defense against infringement of rights ◎
Material Topics	Drug Quality & Safety Management ★, Access to Medicine ★	Information Security and Cybersecurity, Human Rights ★	Intellectual Property, Business Ethics & Compliance ★
Possibilities/ Existing Management Mechanisms	• Implement management methods based on the existing QA department and QA system.	• Firewall, antivirus softwares • Update, strengthen software and hardware equipment	• Intellectual Property Rights Management and Utilization Regulations. • PEC's Legal Department and attorneys • Corporate Governance Best Practice Principles • Internal Control and Audit System and Management
Likelihood of Occurence	● ○ ○ ○ ○	● ● ● ○ ○	● ● ○ ○ ○
Severity	● ● ● ● ●	● ● ● ● ○	● ● ● ○ ○
Actual Improvement Actions in 2021	• Actively recruited clinical quality assurance (CQA) staff on talent recruitment websites. • Clinical Operations department has completed 20 SOPs related to clinical operations, including audit management and quality management system and more. • Clinical Operations personnel will temporarily assume drug safety monitoring QA functions	• Upgraded the firewall hardware from PA220 to PA820 • Completed the draft for information safety policy and procedures • Planned relevant information security protection measures to be enforced in 2022	• Since our patented new drug BESREMi® has obtained regulatory marketing approval at various countries, in addition to undertaking the basic IP protection around the world using our existing patent, we have also asked external pharmaceutical IP experts to facilitate the planning and filing for new patents.
Expected Improvement Actions for 2022 and Onward	• Completed recruitment of CQA staff. • Formulated annual QA plan for drug safety monitoring and implemented QA activities. • Amended clinical operations SOP related to quality assurance and drug safety monitoring SOP based on future legal updates and organizational adjustments.	• Completed the following measures in February 2022 – Information security advocacy and social engineering training – Replaced weaker thumb drive-based control with DLP total solution – Completed vulnerability scanning and improved major vulnerabilities – Phase 1 of data storage equipment management over major mainframes • Completed the draft for information safety policy and procedures and submitted the draft to the Board of Directors • Planned and executed the “data encryption system”, “data loss prevention (DLP) system”, and “cloud-based multi-factor authentication (MFA) mechanism” to strengthen information security and authentication mechanisms • Annual information security advocacy and social engineering training to be completed in October 2022	• Innovative reward system. • Forfeit the opportunity to enter certain markets if necessary. • Introduction and implementation of FTO (Free to Operate). • Deploy infringement detection mechanisms in our marketing system • Deploy due diligence mechanism and training for technologies that PEC is interested in acquiring • Increase the enforceability of contracts • Educational training. • Establish audit mechanism to allow for timely inspection • Data storage equipment management.

	Governance	
Risk Issues	Information disclosure is not in a time, transparent, or effective manner	International arbitration and litigation disputes
Material Topics	Corporate Governance	Corporate Governance
Possibilities/ Existing Management Mechanisms	• Procedures for Handling Material Inside Information and Prevention of Insider Trading • Material information as defined by the verification and public handling procedures of material information from TWSE or TPEx listed companies from the competent authority.	• Audit Committee • FSC corporate governance evaluation system indicators. • Board of Directors and director evaluation mechanism. • Internal auditing operations. • Comply with the relevant procedures enacted by the competent authorities. • Procedures for Handling Material Inside Information and Prevention of Insider Trading • For more information, please refer to the MOPS, PEC's website, 2021 Annual Report, and financial statements
Likelihood of Occurence	●●●○○	●●●○○
Severity	●●●●○	●●●●○
Actual Improvement Actions in 2021	• PEC complies with the information disclosure requirement for TWSE/TPEx listed companies from the competent authority, has acquired financial reporting competencies, and discloses financial information in a timely manner. • Amended PEC's Procedures for Handling Material Inside Information and Prevention of Insider Trading in line with the regulations from the competent authority and executes the Procedures in operations. • Third-party verification by an independent institution is conducted for the sustainability report.	• Optimized the internal control over procedures related to litigations monitoring the progress of PEC's major litigations to effectively manage and control over the contents of external legal documents • Reinforced the information relay between PEC's material information team to engage in more effective horizontal communications • The newly formulated "Management Procedures for Litigations and Material Disputes" from the Legal Department will strengthen the control over international arbitrations and litigations". • Continue to practice diversified policy and arrange diverse continuing education courses for members of the Board of Directors to enhance their decision-making quality and strengthen the functions of the Board.
Expected Improvement Actions for 2022 and Onward	• Continue to implement PEC's Procedures for Handling Material Inside Information and Prevention of Insider Trading and to advocate said Procedures to responsible personnel. • Implement and comply with disclosure standards from relevant laws and regulations from competent authorities both at home and abroad. • Adopted third-party verification mechanism for the sustainability report.	• PEC has made the material announcement on February 15, 2022, that, upon the final ruling from the Federal Court of Justice in Germany over the international arbitrary with AOP, that PEC does not need to pay compensations and interests from the previous arbitrary ruling (Documents related to legal case number: I ZB 21/21) • Legal Department plans to undertake the following control measures over litigations and non-litigious lawsuits: Optimize lawsuits and legal document management archive, formulate a lawsuit process monitoring system, and to set a process management model for similar cases in the future.

	Governance	Environmental
Risk Issues	Functions of the Board that require improvements	Climate Risk ◎
Material Topics	Corporate Governance	Climate Governance ★
Possibilities/ Existing Management Mechanisms	• Audit Committee • FSC corporate governance evaluation system indicators. • Board of Directors and director evaluation mechanism. • Internal auditing operations. • Comply with the relevant procedures enacted by the competent authorities.	• Contents of the Internal Greenhouse Gas Management Procedures • Carry out internal training, data collection, internal audit, and external verifications. • Corporate governance 3.0 evaluation system • Task Force on Climate-related Financial Disclosures (TCFD)
Likelihood of Occurence	●●●○○	●●●○○
Severity	●●●●○	●●●●○
Actual Improvement Actions in 2021	• Actively implemented the FSC's Corporate Governance 3.0 Blueprint of Sustainable Development Evaluation Index. • A Corporate Governance Officer has been set up; the role is served by Hsueh-Ling Chang, Deputy Divisional Head of Finance and Accounting Department from the Head Office, who will assist the Directors to perform their duties, provide needed information, and arrange continuing studies courses based on the Directors' needs. • PEC identified the non-financial ESG-related risks based on the corporate risk management framework co-published by the COSO and WBCSD. • Invited external evaluation agency to conduct external assessment over the Company's Board of Directors; please refer to disclosures on PEC's website for the assessment results.	• As a forefront in climate governance, the GHG reductions team has been formulated at Taichung Plant, and "Greenhouse Gas Management Procedures" has been formulated • Completed 2019 GHG inventories in October 2021 and received ISO 14064-1 third-party external assurance certification. • Introduced TCFD educational training course for the first time; total number of participants from the ESG functional groups was 40, reaching a 76.92% attendance rate. Gained awareness to the climate risks and opportunities in PharmaEssentia's value chain through the course and such knowledge will serve as important information for internal decision-making.
Expected Improvement Actions for 2022 and Onward	• PEC will formulate a nomination committee based on actual operational needs in order to continuously strengthen the nomination system of Directors. • Arrange continuing studies to enhance the professional functions of the Board of Directors based on the needs and willingness of the Directors. • Reinforced supervision of the Board of Directors over PEC's audit system practices, and regularly arranged for communications between the internal auditor and Independent Directors. • Regularly conducted the performance evaluation of the Board of Directors and the functional committees. Submitted evaluation reports and substantive improvement proposals to the Board. • In 2022, PEC expects to formulate a Sustainable Development Committee, which will be directly overseen by the Board of Directors. The Sustainable Development Committee will strengthen risk management and enhance contingency responsiveness, thereby achieving the goal of risk control.	• Taichung Plant will carry out 2020 and 2021 GHG inventories in 2022, and it will also implement ISO45001 Occupational Safety and Health Management Systems and ISO14001: 2015 Environmental Management Systems in 2023 • Information on climate governance is disclosed in the Annual Report and sustainability report in line with applicable laws and the Corporate Governance 3.0 Standards • Integrated potential effects from climate change in PEC's strategic planning, analysis, and risk management in line with the TCFD framework

Chapter 1

Innovation

Chapter 1 Summary of 2021

Innovation Highlights

Based in Taiwan, PharmaEssentia provides innovative and reliable drugs to improve the health of patients in every aspects of our operations, from innovation, testing and development, manufacturing, to marketing and sales in the international market after obtaining relevant regulatory marketing approvals. By using our original protein drug "PEGylation Technology Platform" as basis, we have successfully developed a new generation of PEG long-acting interferon alpha drugs. These have qualified for the GPM certificate from the EU's EMA, the GMP certificate from TFDA, passed the GMP review from South Korea MFDS, as well as the plant inspection from the U.S. FDA.

Our global business expansions are based on two major strategies, "establishment of multinational subsidiaries" and "licensed partnership model". Having recruited approximately 340 global talents, we are fully committed to the treatment of rare hematologic disease, MPN, which does not have a proper treatment method yet. Currently, the use of our proprietary Ropeginterferon alfa-2b (P1101) on the treatment of PV has obtained the regulatory marketing approvals from 37 countries around the world and is marketed under the product name BESREMi® to benefit PV patients. In addition, phase III multi-center clinical trials for using Ropeginterferon alfa-2b (P1101) to treat ET has also commenced in many countries around the world. We hope this product can be used to treat more patients, thereby realizing our goal of successfully entering the global market from our core R&D and production base in Taiwan.

Relevant Material Topics

R&D and Innovation of New Drugs

Relevant Stakeholders

Patients | Shareholders and Investors | CROs/Experiment units | Suppliers and Business partners

Performance Highlights

World's first long-acting alpha interferon drug approved for PV treatment

Makes up for the deficiencies in using existing drugs to treat PV

Phase III clinical trial of ET treatment is launched across the globe

Phase III clinical trials of using Ropeginterferon alfa-2b (P1101) for the treatment of ET has been carried out in multiple countries around the world

Global operations include 340+ top talents

Established operations in China, Hong Kong, Japan, South Korea, and the United States, and formed strategic partnerships in Europe

BESREMi® U.S. regulatory marketing approval expanded the PV patient groups

First long-acting interferon approved by the U.S. FDA for the treatment of PV after clinical trial and can be widely adapted to a range of adult PV patients

International GMP-certified manufacturer and passed plant inspection from the U.S. FDA

Qualified for GMP manufacturer by the EU EMA, TFDA, and Korea's MFDS. Further passed the U.S. FDA's plant inspection in 2021

Over 1,500 patients in 37 countries are currently using BESREMi®

Obtained regulatory marketing approval from the European Union, Switzerland, Liechtenstein, Israel, South Korea, and the United States and many more

Built stable global supply chain

Established a U.S. market supply chain from injection filling, stable third-party logistics, to product distribution

Total R&D expenditure exceeded NT$1.2 billion

Invested 83 R&D clinical personnel and NT$1.27 billion toward unmet medical needs

1-1 A Fully Integrated Innovative Biopharmaceutical Company

About PharmaEssentia GRI | 102-1~7

With our headquarter based in Taiwan, PharmaEssentia is not only equipped with manufacturing and production capabilities and cultivates local talents in the fields of biotechnology and pharmaceuticals, but also strives to expand globally and to develop strategic alliances and partnerships. PEC is a forerunner in the development of MPN treatment.

PEC has developed a highly regiospecific PEGylation technology, or referred to as "PEGylation coupling reaction technology platform" as well as small-molecule synthetic drug technology. It is superior to competitors in terms of side effects and maximum patient tolerance (MTD). Marketed under the product name BESREMi®, it is used to treat asymptomatic splenomegaly in adult PV. After obtaining the regulatory marketing approvals for multiple European nations, we further obtained the regulatory marketing approval for the treatment of general adult PV from Israel, Korea, and the United States in 2021. PEC is actively preparing for regulatory marketing approval applications for Japan, China, Singapore, and Hong Kong, and aims at effectively expanding the market share of Ropeginterferon alfa-2b (P1101) in the global market.

Mission and Vision

- Become a top-tier innovative protein biopharmaceutical company throughout the world
- Established the first fully integrated protein innovation biopharmaceutical company in Taiwan that has fully integrated the R&D, clinical trials, manufacturing and sales of new drugs

Operating Locations

- Headquartered in PharmaEssentia Corporation in Taiwan
- Global operations include the United States, China, Japan, Korea, Singapore, and Hong Kong

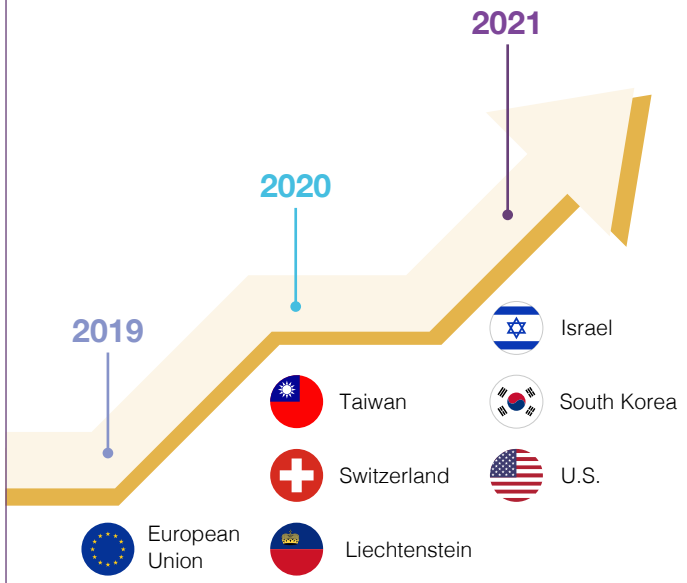
Total Number of Employees as of December 31, 2021

- 233 employees in Taiwan; 342 employees globally

Consolidated Revenue and Equity as of December 31, 2021

- Net operating revenues of approximately NT$656 million; equity of approximately NT$4.25 billion

Obtaining Ropeginterferon alfa-2b (P1101) Marketing Authorization Approval in the Global Market



Marketed under the brand BESREMi®, Ropeginterferon alfa-2b (P1101) is used to treat asymptomatic splenomegaly in adult PV while it is used to treat general adult PV in the United States. This is a type of indication for MPN, and severe cases could even develop life-threatening acute myeloid leukemia (AML)

Partners from the Value Chain

Upholding our mission, PharmaEssentia strives to give back to the society and to create values in Taiwan's biotechnology industry chain. We collaborate with every partner throughout our industry chain based on the spirit of "creating the common good and co-prosperity" and have developed individual collaborative strategies to strive toward mutually sustainable value.

Category	R&D of New Drugs	Pre-clinical Trial	Clinical Trial	Manufacture and Production
Partners	Academic or research institution (e.g., Academia Sinica, universities, and colleges in Taiwan or abroad), authorized domestic biotech companies, and authorized foreign partner Axis Therapeutics	CROs, authorized international biopharmaceutical companies, research foundations, international drug and medication logistics companies	Clinical trial hospitals, CROs, European strategic partner AOP Orphan, authorized partner Athenex	Suppliers/contractors, contract vendors, external consultants
Collaboration Modes	• Engage in industry-academia cooperation with universities in Taiwan and abroad to co-develop potential candidate drugs • Technical authorization for pre-clinical development with domestic biotech companies • Undertake clinical development of TCR-T technical transfer with authorized foreign partner Axis Therapeutics	• Collaborate with professionally qualified CROs that hold multiple international certifications • Actively interact with local research foundations, patients' right groups, and hospitals in various countries to understand the needs and trends of diease • Contract the execution of clinical trials to international biopharmaceutical companies • Maintain unimpeded channels of communication with international drug logistics companies and to enhance their operations through methods including internal audit in order to ensure timeliness and quality of drug transportation		• To ensure both parties have reached a clear understanding on product and quality requirements, PEC requires suppliers to sign a "Quality Agreement" that specifies PEC's rights and responsibilities for quality and technology-related issues • Collaborate with professionally qualified CROs that hold multiple international certifications • Collaborate with external vendors to optimize information security system and equipment • Invite external consultants to facilitate in preparing for plant inspection procedures
Results	• Please refer to Chapter 6, Section 6.2 for the development of potential drugs in specific cancers through industry-academia collaboration with domestic universities • Domestic biotechnology companies: Completed animal testing for studies on hepatitis B virus (HBV) • Authorized foreign partner Axis Therapeutics: Completed document, technology transfer, and equipment procurement	• Phase III clinical trial of Ropeginterferon alfa-2b (P1101) for treatment of hepatitis C virus (HCV) has been completed; we continue to enroll subjects in phase III clinical trial for ET • Completed Phase I clinical trial of KX-01 B14-201 on psoriasis • Drugs to be used by all clinical projects in Taiwan and abroad have arrived on time with acceptable quality		• All vendors on PEC's list of qualified suppliers have signed Quality Agreements based on our standardized operating procedures and standards; relevant agreements were all signed in 2021. • Information system optimizations: Enhanced the information system and infrastructure and strengthened the information security awareness in employees • Equipment optimizations: Introduced licensed agent for serialized equipment to respond to drug traceability and to meet plant inspection specifications • Completed simulation for the U.S. FDA plant inspection and successfully passed the on-site inspection

Category	Registration	Marketing and Sales
Partners	Partnership with authorized international biopharmaceutical companies/ CROs, local and foreign pharmaceutical companies	Authorized strategic selling partners/distributors, international drug logistics companies
Collaboration Modes	• Authorize international biopharmaceutical companies or CROs to conduct clinical trial and drug license application	• Strategic alliances with foreign partners or channel distributors familiar with the local market to jointly expand local market share • Maintain unimpeded channels of communication with international drug logistics companies and enhance their operations through internal auditing to ensure timeliness and quality of drug transportation
Results	• Completed document submissions to the U.S. FDA in 2021 and successfully obtained regulatory marketing approval in November • Regulatory marketing approval applications for Hong Kong and Macau are expected to be submitted in Q3 and Q1 of 2022 respectively	• BESREMi® is marketed in Europe, the MiddleEast, and the Independent States Association by authorized European partner, AOP Orphan. It has been approved for marketing and sales in 37 countries, including the EU, Switzerland, Liechtenstein, Israel, Korea, and the United States • Began supplying to third-party warehouse in the U.S. in December in line with operating procedures. Then prodcuts will be shipped to distribution channels, and finally delivered to end-users (patients)

1-2 Two Major Strategies for Global Markets

Strategic Approach for Expanding Globally GRI | 102-14

To enhance the efficiency of drug and market development, PharmaEssentia has formulated two major policies in terms of global market expansion strategies, including “establishment of multinational subsidiaries” and “licensed partnership model”. As of December 31, 2021, our product, Ropeginterferon alfa-2b (P1101), has obtained regulatory marketing approvals from various countries, enabling us to benefit patients around the world through promoting and expanding the drug accessibility for various indications.

Our 3 Major Strategic Objectives:

Strategy 1

Increase profitability through maximizing the value of technical platforms and products

- Building Ropeginterferon alfa-2b (P1101) into a leading brand for MPN and enhance patients’ loyalty in drug use
- By utilizing PEGylation as a technology platform, we can shorten the development timeline of new products, reduce the risks, and funding in product R&D. And successfully using the intellectual properties and R&D capacity accumulated from Ropeginterferon alfa-2b (P1101) to develop other innovative products for therapeutic trials of indications

Strategy 2

Recruit outstanding talents and sound operation management

- Through combining the global strategies of our subsidiaries around the world and recruiting local top talents from subsidiaries, we shorten the market entry
- Improve the comprehensiveness of services offered at our global subsidiaries to better serve the patients and reduce costs by achieving a more effective operation management

Strategy 3

Continuous innovation and development to create long-term value for PharmaEssentia

- Expand the Company’s diverse product lineup by developing or introducing potential new drug with strategic partners through licensed partnership agreement or permits.
- Sustainable development, risk management, and other functional committees have been established to plan, promote, execute, follow-up, and respond to corresponding sustainable management issues. As well as to optimize corporate governance and address the expectations of stakeholders

PharmaEssentia's Global Expansion Plan

Licensed Partnership Model

- Licensed the development and sales of Ropeginterferon alfa-2b (P1101) in Europe, Middle East, and Commonwealth of Independent States to our partner, AOP Orphan.
- Authorized the introduction of Athenex's Tirbanibulin ointment (KX 01) and collaborated on the development of the oral paclitaxel Oraxol® for cancer.
- Undertake clinical development of TCR-T technical transfer with authorized foreign partner Axis Therapeutics
- Authorize the strategic partners for Hong Kong, Macau, and other areas to assist in the regulatory marketing approval application of Ropeginterferon alfa-2b(P1101) in 2022
- Continue to increase PharmaEssentia's international visibility through strategic partnerships
- For more information on licensing partnership, please refer to section 6.3 in Chapter 6.

Strategies of Establishing Foreign Subsidiaries

- Established operations in the United States, China, Japan, Korea, and Hong Kong.
- Recruited local scientists and senior managers to communicate with local authorities on issues regarding clinical regulatory marketing approval applications and marketing strategies.

PharmaEssentia's Organizational Framework and Investments

* Amount invested (NT$ thousands)
** The aforesaid company has only completed company registration and PEC has yet to remit any funds.

1-3 R&D of Innovative Biopharmaceuticals

R&D Management Approach of New Drugs

Materiality Topic

In our management strategy for the development of new biologic drugs, in addition to expanding the application of the new generation of Ropeginterferon alfa-2b (P1101) to the field of MPN, PEC also conducts various exploratory research. Such as the inclusion of monoclonal antibodies for the development of immune checkpoint inhibitor PD-1 in line with long-acting interferon to enhance the patient's immune response against various cancers. In 2021, we invested nearly NT$1.27 billion in R&D expenditures, an increase of approximately 38% compared to 2020. We persist in creating the best new drugs and enhancing R&D capacity through technical expertise and the most rigorous quality management.

Policies

Internal Policy

From the early stage of basic research, product technology research, and preclinical trials to the middle stage of trial production, phase I and phase II human clinical trials, to the mature stage of product trials and phase III human clinical trials, PEC follows the internal control R&D cycle rules, intellectual property patent application protection and related regulations to seek new products with new technologies that are competitive in the market, and to explore the use of our own technology to develop new drugs that have not yet been met. We aim to seek new products with competitive technologies and to explore unmet needs for new drugs using our own technologies.

External Compliance

Rigorous compliance in clinical trial

- Declaration of Helsinki
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Good Clinical Practice (GCP) (ICH-E6-GCP)
- International Standards related to GCP, GLP, and GMP (GxP)

Commitments

We commit to comply with relevant and applicable regulatory requirements while focusing on four key disease areas, in which we innovate new biologic drugs with the best technology and highest quality, and contribute to improving the health of people around the world by providing innovative and reliable medicines

Responsibilities

- New drug discovery is coordinated by the New Drug R&D Division, the decision maker is the "Project Evaluation Team," which includes interdepartmental representatives and internal senior management executives. The resolutions discussed in the "Project Review Meeting" are jointly decided to establish a R&D project, where the project leader will coordinate its progress and regularly complete relevant reports
- Clinical Operations Department manages clinical trials
- Execution Center for Corporate Sustainability - Access to Medicine Team

Resources

The resources invested in the research and discovery management of new drugs will be allocated based on the importance of the project and the premise of "unmet-medical need." The planning of relevant labor and materials required by each project will be based on the needs of the individual project. PEC has a total of 83 R&D clinicians worldwide in 2021 with total R&D spending of NT$1.27 billion.

Goals & Targets

2022 Short-term Goals

- Expand clinical application of Ropeginterferon alfa-2b (P1101) to areas of MPN other than PV, such as ET and viral hepatitis disease (HBV/HDV).
  - Phase III clinical trial of Ropeginterferon alfa-2b (P1101) in ET in China, Hong Kong, Korea, U.S.A., Singapore, and Europe.
- Actively develop PD-1, PEG-EPO, PEG-GCSF and continue to develop a vaccine for HBV. As well as other PEG-Ad cellular stimulus drug and to launch clinical development plans for three new drugs
- Actively expand human clinical trials for cancer immunotherapy drugs (TCR-T), enter GTP production, and prepare to apply for the Investigational New Drug (IND).

2023~2025 Mid-term Goals

- Actively conduct clinical trials for cancer immunotherapy (TCR-T), enter GTP production, and prepare to apply for IND.
- Evaluate products related to immune targets and select one product for development.
- Actively implement PEGylation program for new target proteins and to apply for an IND.
- Introduce cell therapy-related technology cooperation projects, construct cell factories using imported technology, and continuously evaluate the direction of new drug development to apply for a cell therapy product clinical trial.
- Develop innovative process technology platforms to enhance production efficiency, reduce costs, shorten development time, apply new process technology platforms to new drug products, and apply for a clinical trial.
- Continue to promote multicenter, multination Ropeginterferon alfa-2b (P1101) ET phase III clinical trial and regulatory marketing approval applications.

2026 Long-term Goals

- Continue to seek licensing or permission to develop or introduce new drug candidates with strategic partners. Expand PEC's product lines by actively pursuing various drug development products with medical urgency.
- Accelerate the process of key clinical trials and the application of various regulatory marketing approvals in each country to maximize product benefits.

Evaluation of Management Approach

Mechanism of Evaluation

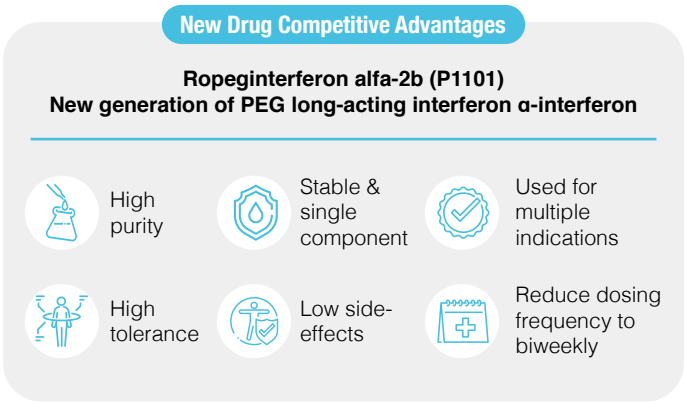
- All R&D projects have followed the internal R&D operation cycle, and project progress and execution efficiency are managed quarterly based on the financial information compiled by the Finance department. Cost control evaluation is also carried out for each project every six months. The members of the project team regularly and collectively make decisions on whether to continue the project according to the significant R&D results or milestones stated in the proposal.
- Large-scale projects and annual project budgets must be submitted to the Board of Directors for approval before relevant research and development could start.
- Audit unit performs audit operations of R&D cycle management mechanism in accordance with the annual audit plan each year.
- Clinical Operations Department reviews the Company's clinical trial progress during Medical Research on a bi-weekly basis.

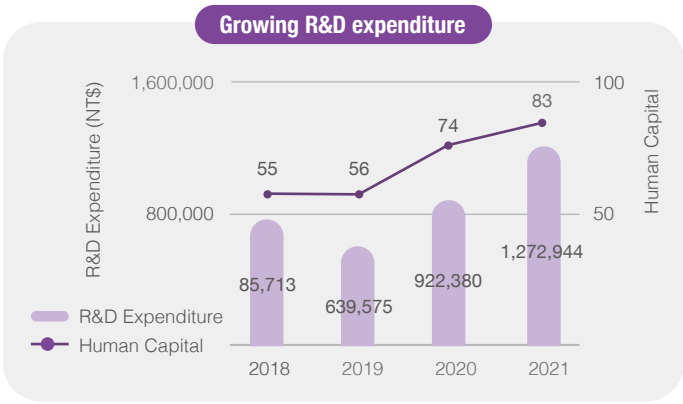
2021 Evalution Results

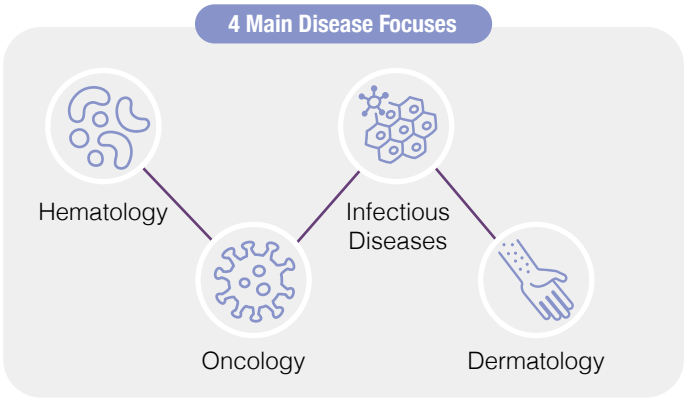
- The project team regularly evaluated and made decisions on various projects in R&D, the overall control evaluation was good.
- Phase I clinical trials of using Ropeginterferon alfa-2b (P1101) and then Anti-PD1 to treat Hepatitis B or Hepatitis D have already commenced at four medical centers in Taiwan in 2021.
- Clinical trials of using Ropeginterferon alfa-2b (P1101) on ET, viral infection diseases and neoplastic diseases have also commenced at various stages in number of countries.
- Phase I of clinical trial of the use of KX01 new drug, introduced from the U.S. based Athenex, on the treatment of actinic keratosis (AK), has also been completed in Japan, and a Phase III clinical trial has also commenced to meet regulatory requirements for regulatory marketing approval application in Japan.
- The application for regulatory marketing approval of using KX01 new drug, by Athenex, to AK has been filed to the TFDA in 2021.

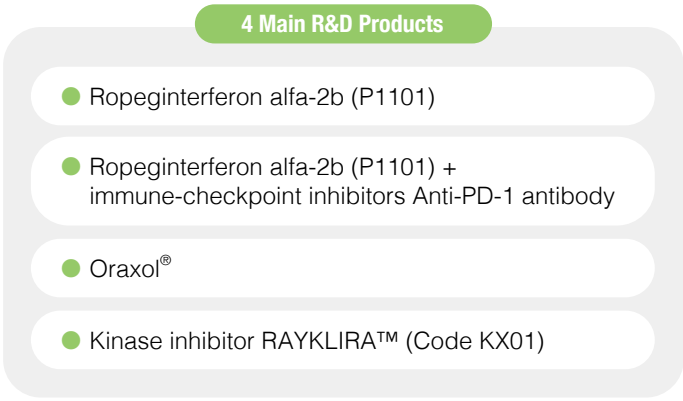
New Drug Discovery and Innovative Research

PharamaEssentia is focused on the four major disease types of rare hematologic diseases, viral infection diseases, neoplastic diseases, and dermatological diseases, and sees its PEGylation Technology Platform that significantly increases patient tolerance and convenience as its greatest competitive advantage. Applying the Company's self-developed PEGylation Technology Platform to different indications not only shorten the development timeline of new products and reduce the risk of new product R&D funding, but also create advantageous product portfolio for future business expansion and reduce possible competition risk of a single product. For more information on the Company's core function of R&D on new drugs for proximate social impact, please refer to Chapter 6, Section 6.2.









Note: 2021 R&D expenses came from consolidated financial data; R&D manpower data included PharmaEssentia's global R&D clinical units.

Pursue Animal Welfare in Preclinical Animal Experiments

PEC strives to ensure animal experiments are conducted in accordance with the relevant Institutional Animal Care & Use Committee (IACUC) regulations and tries to minimize the use of experimental animals as much as possible. Before engaging in pre-clinical animal experiments, we select GLP-certified CROs in Taiwan or abroad and frequently set up an animal welfare protection committee to conduct animal experiments in a humane manner. By conducting on-site inspection to examine the process of managing animal trials in the CRO operation, we strive to ensure the new drug being studied could pass the animal trial phase and proceed on to the next phase of human trials. For more information on our ethical and moral approach to managing preclinical animal studies, please refer to Chapter 2, Section 2.2.

PharamaEssentia's R&D Product Lines

SASB | HC-BP-000.B

Therapeutic area	Technology/product	Licensed to develop / Developed by the Company	Indication	Markets	Pre IND	Phase 1	Phase 2	Phase 3	Registration	Marketing
Hematology	Ropeginterferon alfa-2b (P1101)	Developed by the Company	Polycythemia Vera (PV)	Europe*, Switzerland, Israel, Taiwan, Korea, USA						
				Japan, China						
			Essential Thrombocythemia (ET)	Global						
			Adult T-cell Leukemia/Lymphoma (ATL)	Japan, Taiwan, China						
Oncology	Ropeginterferon alfa-2b (P1101) + Anti-PD-1 antibody (Note 1)	Developed by the Company	Hepatocellular Carcinoma	Global						
	Oraxol®	Licensed to develop	Breast cancer	Taiwan, Singapore, Vietnam						
	Oraxol® + Ramucirumab	Licensed to develop	Gastric cancer	Taiwan, Singapore, Vietnam						
	PEG-IL2	Developed by the Company	Solid tumors	Global						
	PEG-Gamma	Developed by the Company	Solid tumors	Global						
	Ropeginterferon alfa-2b (P1101)	Developed by the Company	Solid tumors	Global						
	TCR-T	Licensed to develop	Solid tumors	USA						
Infectious Diseases	Ropeginterferon aLfa-2b (P1101)	Developed by the Company	Hepatitis B/D	USA, Europe, Taiwan						
Dermatology	Tirbanibulin (Code KX01)	Licensed to develop	Psoriasis	Taiwan, China, Macau, Singapore, Japan, Korea						
	Tirbanibulin (Klisyri®, KX01)	Licensed to develop	Actinic keratosi	Taiwan, Japan, Korea						

Note: Investigator Initiated Trial (IIT) of Ropeginterferon alfa- 2b (P1101), has included primary myelofibrosis (PMF), chronic myeloid leukemia (CML), and adult T-cell leukemia/lymphoma (ATL).

Rigorous Human Clinical Trial Process

SASB | HC-BP-210a.1

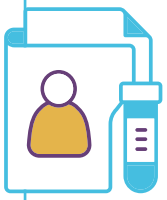
To maintain the quality of human clinical trials, PharmaEssentia has formulated more than 20 internal standard operating procedures for clinical operations. We have an audit and inspection mechanism in each clinical development phase and comply with the "Declaration of Helsinki," "International Council for Harmonisation of Technical Requirements - Good Clinical Practice (ICH-GCP)," and carry out phase I, II, and III clinical trials in line with approved investigational new drug application, and applicable laws and requirements from the local governments. During the clinical trial process, the principal investigator of the trial will regularly conduct health assessment on the subjects and monitor, report any adverse events. All adverse events will be treated appropriately. Follow-up periods are also set after the clinical trial process to ensure the safety of subjects.

PharmaEssentia's Human Clinical Trial Process

1 Phase I clinical trial: **Safety exploration**

2 Phase II clinical trial: **Preliminary study on the effectiveness of the drug**

3 Phase III clinical trial: **Large-scale treatment validity research**



Before each phase of the trial:

- Trial plan and relevant documents will all require review and approval from the health competent authority and human clinical trial committee
- Convene Chief Investigator Meeting for relevant training
- Obtain written informed consent from the subjects and strictly screen suitable subjects according to the inclusion and exclusion criteria of the investigational new drug (IND) application.

After each phase of the trial:

- Compile information on the clinical trial treatment effectiveness and safety
- Drug may only be approved and granted regulatory marketing approval upon written review and onsite inspection from the health competent authority, and after benefits and risk analysis

Launch Multi-Center, Multi-Nation Clinical Trials to Enhance Our Products' International Competitiveness

Launched multi-center across multiple nations for phase III clinical trial for the treatment of ET

Ropeginterferon alfa-2b (P1101) clinical trial has reached 900+ patients

Phase III clinical trials of using Ropeginterferon alfa-2b (P1101) for the treatment of ET has been carried out in Taiwan, Japan, South Korea, China, Hong Kong, Singapore, the United States, and Canada. The clinical trial plans in various countries have been approved by the competent authorities of participating countries. This trial is expected to enroll 160 subjects and is scheduled to complete a phase III clinical trial in 2022. Upon completion, we will file regulatory marketing approval applications to the respective competent authorities. The clinical trial plan has been granted approximately NT$32.92 million in special funding from Taiwan Ministry of Economic Affairs.

By the end 2021, PEC has benefited more than 900 patients worldwide through conducting clinical trials with Ropeginterferon alfa-2b (P1101). (This figure includes IIT but excludes healthy subjects). For more information on the Company's use of new drugs in trials for the treatment of MPN-related diseases, please refer to Chapter 6, Section 6.2.

1-4 World-Class Manufacturing and Production

Blueprint of Ropeginterferon alfa-2b (P1101) Production Certification

We have established a comprehensive, vertically integrated supply chain from production, quality control, filling, and shipping to global markets, thereby becoming a leading international pharmaceutical company.

2012 Completed construction of a biopharmaceutical manufacturing plant in Taichung.

▼

2013 Taichung biopharmaceutical manufacturing plant obtained GMP certification.

▼

2018 First protein pharmaceutical factory in Taiwan passed the inspection from EMA and obtained certificate for protein drug factory from GMP.

▼

2020 The newly established filling plant received GMP and Good Distribution Practice (GDP) certification from the Taiwan TFDA.

▼

2021
- Passed the MFDS GMP audit in Korea and obtained Korean regulatory marketing approval
- Passed the U.S. FDA plant inspection and obtained U.S. regulatory marketing approval in November

▼

Completed the blueprint of the full certification required for producing Ropeginterferon alfa-2b (P1101) by PharmaEssentia.

1-5 Global Commercialization Strategy

Deployment of a Local Team of Experienced Professionals

In order to serve local patients with the best execution skills and effectively comply with the market regulations in each country while marketing our pharmaceutical products, we have authorized our partner, AOP Orphan, to be in charge of the European, the Middle East and Independent States Association markets. Moreover, we have also set up subsidiaries in Asia Pacific and the United States with our own experienced professional teams to promote local sales.

European Market

SASB | HC-BP-240a.1 SASB | HC-BP-000.A

Used by nearly 1,000 patients in 30+ countries

As of December 31, 2021,
BESREMi® has been used by nearly 1,000 patients in more than 30 European countries

BESREMi® sold in Europe

In 2019, Ropeginterferon alfa-2b (P1101) was first marketed in the EU under the trade name BESREMi® through our strategic partner AOP Orphan. Currently, BESREMi® is now available in more than 30 European countries and it is used by nearly 1,000 patients. Looking forward, we expect our sales revenue and patient utilization in Europe to continue growing in 2022. We also expect to recover the costs we have invested in the development of new drugs year by year, which will be returned to our shareholders and investors.

Taiwan and Asia-Pacific Markets

Sales and distribution in Asia-Pacific

Headquartered in Taiwan, our team of professionals are expanding the sales and distributions in the Asia-Pacific region

百斯瑞明® sold in Taiwan

In May 2020, Ropeginterferon alfa-2b (P1101) was approved by TFDA to treat PV and granted a regulatory marketing approval under the product name BESREMi®. We are actively applying for the approval from the National Health Insurance administration to qualify BESREMi® as a NHI drug. Alternatively, we were granted our second BESREMi® regulatory marketing approval in Asia by Korea MFDS in 2021. We are also in the process of preparing for regulatory marketing approval applications in China, Japan, Hong Kong, Singapore, Malaysia, Vietnam, and other Asia-Pacific regions. Based in Taiwan, our professional marketing teams in Korea and Japan have formulated marketing strategies to increase our drugs' market visibility and sales in order to provide more effective treatment for clinical patients. As of December 31, 2021, a total of 27 patients in Taiwan, Korea, and Hong Kong (Note) have acquired and are using BESREMi® through product sales.

Note: The unmarketed product sales in Hong Kong were sold on a case-by-case basis as approved by the competent authority in Hong Kong

United States' Market

The PharmaEssentia USA Corporation (hereinafter refer to the U.S. Subsidiary) has also formulated its own marketing team to compete for market share. With its core senior management team in place, the U.S. Subsidiary has recruited hematology oncology professionals with more than 10 years of experience to form a strong marketing team. The team is experienced in launching oncology products and drug insurance negotiation, thereby allowing the team to fully engage in the marketing and sales strategies in the local market. Regulatory marketing approval of Ropeginterferon alfa-2b (P1101) for the treatment of PV was granted by the U.S. in November 2021. We have already prepared the expected volume of demand for the U.S. market for the following year through our stable and safe global supply chain. Local sales and delivery have also commenced in December 2021. Please refer to detailed descriptions on Sections 6.4 and 6.5 in Chapter 6. Additionally, we are accelerating the patient drug utilization rate of BESREMi® post-launch through local professional medical distributors and by serving the PV patients in the United States through SOURCE Program. These efforts will help realizing our sustainable philosophy of drug accessibility.

BESREMi® sold in the U.S.

Marketing Strategy	2021 Implementation and Performance
On the premise of compliance with marketing ethics, (please refer to PEC's commitment to marketing ethics) we actively communicate with clinicians to improve their understanding in the treatment of PV and their familiarity with BESREMi®.	In 2021, we participated in six seminars and workshops with a total of 290 participants to discuss the current situation and dilemma of disease and drug treatment in Taiwan and to share clinical experience in order to raise the brand awareness of PharmaEssentia and our drugs.
By increasing health education for patients, we can enhance the patients' understanding of the long-term effects of BESREMi® and the benefits of disease control.	• Maintain health education platform "MPNiCare", which integrates resources and unites patients to face diseases together. For more information about the Company's actions and achievements of patient care and education, please refer to Chapter 6, Section 6.5 • Commenced patient health care education SOURCE Program in line with medical personnel to serve patients in the United States.
Communicate with doctors, experts, and scholars worldwide by sponsoring annual MPN international seminars and conferences. As well as other annual conferences and activities related to the Company's disease fields.	• For 2021, PEC sponsored the MPN, MDS, and AML seminars in the United States, as well as MPN Research Foundation, Physicians Education Resource, and PV Reporter among other relevant activities. Please refer to Chapter 6, Section 6.4 for more details. • We continue to sponsor MPN Asia every year. For epidemic prevention measures and to avoid large gatherings, online video conferences were held in 2021. For more information on sponsoring MPN Asia, please refer to Chapter 6, Section 6.5.

Chapter 2

Business Ethics, Integrity, and Compliance

Chapter 2: Summary of 2021

Highlights

Established in 2019, PharmaEssentia's Execution Center for Corporate Sustainability has planned a 5-year sustainable governance development plan that is committed to promoting management strategies and action guidelines for various sustainability topics as we continue to work toward realizing the sustainable value of PEC and enhancing our culture of sustainability governance. Upon entering the third year of our sustainable development roadmap – ESG Performance Results, we implement the material topics and related risk management mechanism in line with the COSO Enterprise Risk Management Framework. Additionally, our ESG performance also includes internal trainings designed to facilitate employees' understanding of corporate ESG in the post-pandemic era and topics of concern to international institutions. To stay current, PharmaEssentia also needs to strengthen the correlation between the core strategies in our global operations with UN Sustainable Development Goals (SDGs). By building more diverse internal and external communication mechanisms, we can create even greater corporate sustainable values. At the same time, while planning short-, mid-, and long-term objectives and action plans, senior managers are also reminded that ESG risks may cause material losses to the Company; to achieve stable operations and fortify our corporate competitiveness among such uncertain changes, they shall properly re-allocate resources or even adjust their strategies and operating objectives.

Relevant Material Topics

Business Ethics and Compliance

Relevant Stakeholders

Patients | Employees | Medical Personnel | CROs/ Experiment units

Shareholders and Investors | Suppliers and Business Partners | Local Community | Government and Competent Authorities | Media

Performance Highlights

Voluntary sustainability reporting

Publishing 2021 Sustainability Report in English and Chinese. Obtained third-party assurance

TCSA Gold Medal in ESG Report

Received Gold Medal for ESG Report in medical healthcare sector of the 14th TCSA

Information disclosure in line with Sustainability Accounting Standards Board (SASB)

Disclose the evaluation of ESG performances in line with international standards to ensure the quality and consistency of disclosed information

Invited to participate in S&P CSA for the first time

Total score reached 92nd percentiles among global pharmaceutical companies, successfully propelling PEC onto the global market

Reached the Top 6%-20%

On the OTC corporate governance valuation scale

94.7% Attendance rate (Excluding attendance by proxy)

Board of Directors fulfilled due diligence in supervision

94 Trademarks

Number of valid trademarks

83 Patents

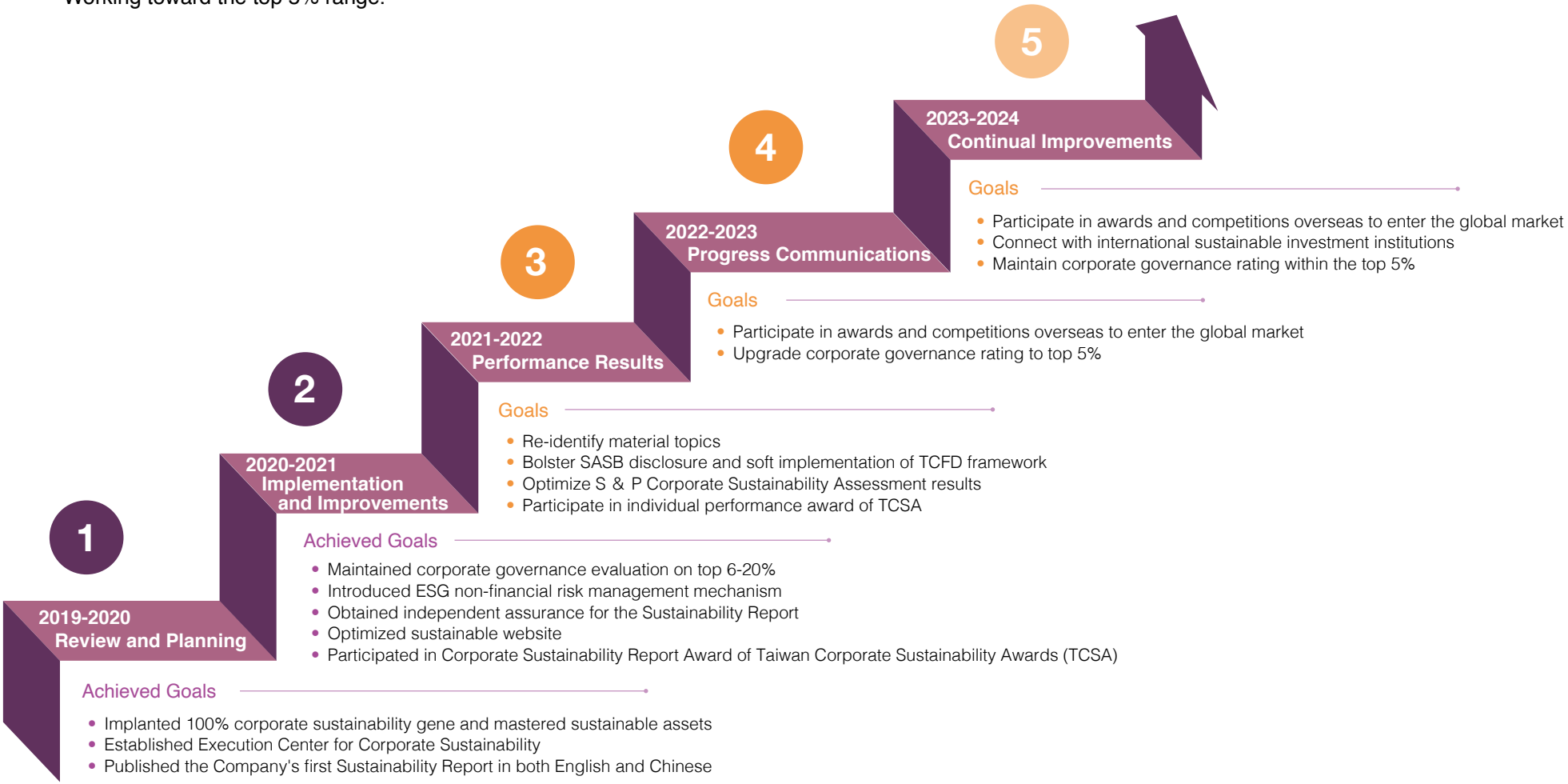
Number of valid patents

2-1 Corporate ESG Governance and Management Performance

Top 6%~20%

Reached corporate governance evaluation goal ahead of schedule in 2020. Working toward the top 5% range.

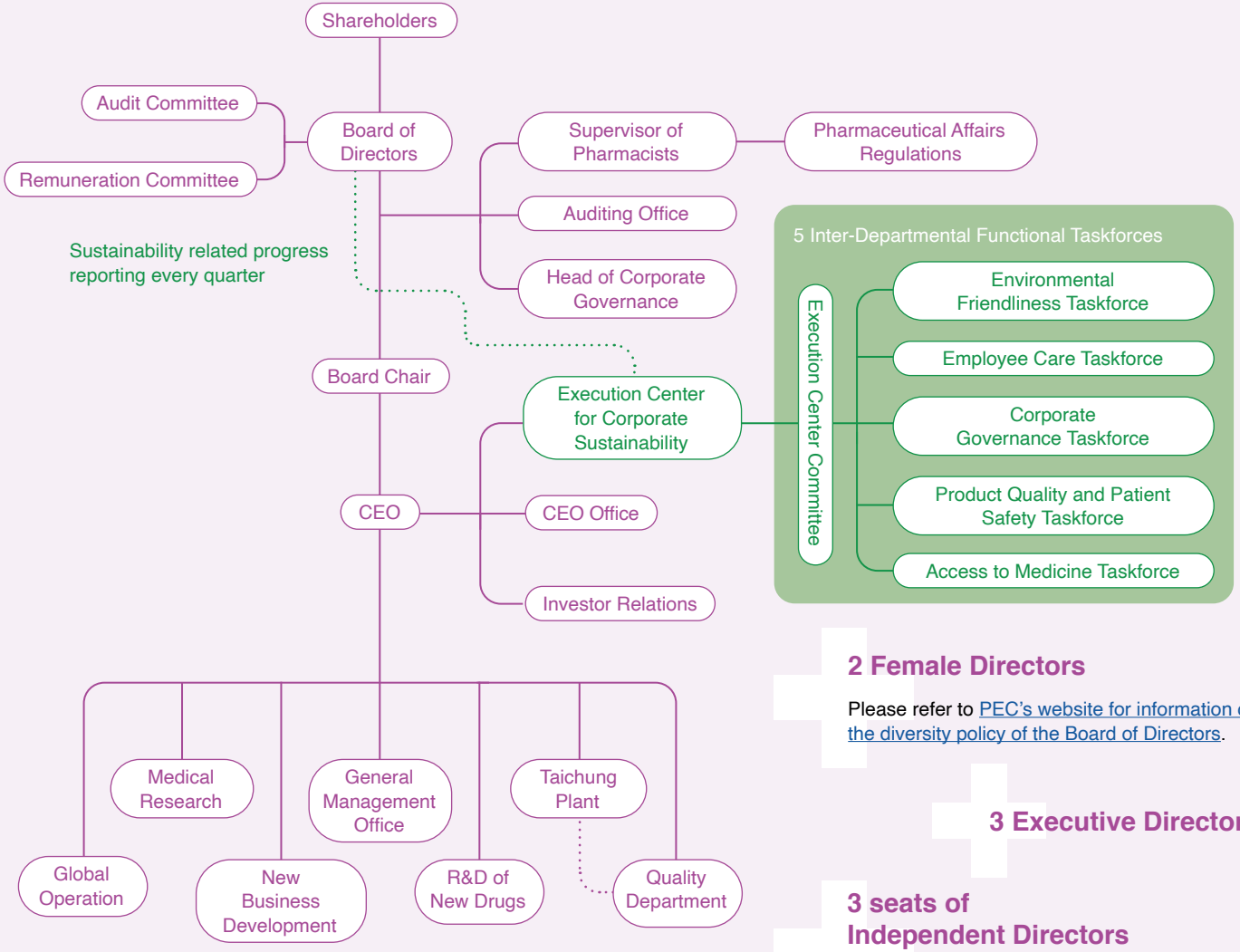
PharmaEssentia continues to strengthen and promote sustainable goals and is committed to co-creating long-term shared values with stakeholders. Besides reviewing our operations via the corporate governance evaluation, we have included sustainable development as a key development objective in corporate governance. And committed to realizing SDG 3 in the UN SDGs, Good Health and Well-Being, which is integrated with the ESG aspects in our sustainable development to formulate PharmaEssentia's blueprint for corporate governance development.



Professional and Diverse Board of Directors and Execution Center for Corporate Sustainability

GRI | 102-18~20 GRI | 102-31~33 GRI | 405-1

Board of Directors at PEC is the highest-ranking governance body. The Board currently has 11 Directors; the term of each Director is three years and currently lasts from August 5, 2021, to August 4, 2024. Please refer to PharmaEssentia Corporation Company Bylaws for detailed descriptions. PEC's Board of Directors meet at headquarters at least once a quarter, the managers and the accounting and finance managers are required to be present for consultation while the audit supervisor reports status on audits to the Board. A total of 12 Board meetings were held in 2021 with the attendance rate of 94.7%. Significant Board resolutions for 2021 can be found on PEC's website. PEC Subsidiary Panco Healthcare has three seats of Directors and one Supervisor with a term of three years, respectively. There were five Board meetings held in 2021 with a 100% attendance rate. The U.S. Subsidiary has four seats of Directors without any Supervisor and convened four meetings in 2021 with a 100% attendance rate. PEC set up the PharmaEssentia Execution Center for Corporate Sustainability and five functional taskforces in 2020. The Execution Center oversees compiling and reporting the ESG performance to the Board of Directors on a regular basis (please refer to the later Section, "PharmaEssentia's ESG Governance Goals and Organizational Operations," for details).



2 Female Directors

Please refer to PEC's website for information on the diversity policy of the Board of Directors.

3 Executive Directors

3 seats of Independent Directors

Please refer to PEC's website for the structure of the Board of Directors.

Board of Directors is a key player in setting the Company's sustainability strategy, overseeing management and being accountable to the Company and shareholders. PEC has a “Board Member Diversification” policy that aims to have members with different professional and industrial backgrounds to provide professional advice on operation judgment, accounting and analysis, operation management, industry knowledge, and international market outlook. Please refer to the Annual Report for professional experiences of each Director. The 11 seats of Directors include three seats of Independent Directors, accounting for 27.2% of the total number of Directors. It is expected to increase the number of Independent Directors to more than 1/3 of the Board in the future. All Directors and Independent Directors have fulfilled the required hours of continuing studies in 2021. Please refer to PEC’s website for details.

Board Member Diversity

Directors	Gender	Age				Specialized Knowledge and Skills			
		41~50	51~60	61~70	71~80	Biotech	Education	Accounting/ Law	Finance
ChingLeou Teng**	Female			✓		✓			
KoChung Lin**	Male				✓	✓			
ShenYou Gong	Male			✓					✓
BenYuan Chen	Male				✓		✓		
YenChign Hwang	Female		✓						✓
Chao Chung Kuo	Male	✓				✓			
ChanKou Hwang**	Male			✓		✓			
ShenYi Li	Male				✓			✓	
JinnDer Chang*	Male				✓			✓	
Patrick Y. Yang*	Male				✓	✓			
JienHeh Tien*	Male			✓		✓			

Note 1： * denotes Independent Directors
Note 2： Information is current as of December 31, 2021
Note 3： **denotes Board Members of Panco Healthcare Co., Ltd at the same time

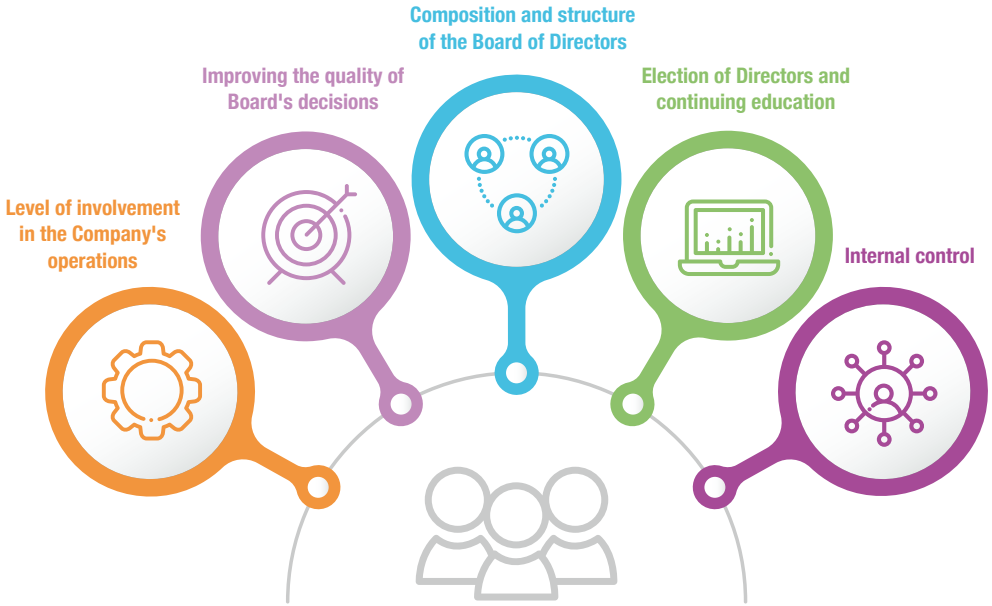
Functional Committees

Two functional committees have been set up under the Board of Directors, which are the Audit Committee and the Remuneration Committee. These committees comprise of the Independent Directors, which effectively realize the supervisory and the check and balance functions of the Independent Directors. In particular, the Remuneration Committee also has an external expert (Professor Ming-Chuan Hsieh). Based on the operational needs, PharmaEssentia may also promote the establishment of a Nomination Committee in 2022 to jointly review the composition of Directors and managers, improving the functions of the Board of Directors and strengthen the management mechanism.

	Audit Committee	Remuneration Committee
Responsibilities	Assist the Board to supervise the Company's performance quality and credibility in accounting, audit, financial reporting process, and financial control.	Assist the Board of Directors in formulating and reviewing the policies, systems, standards and structures of performance evaluation and remuneration for directors, supervisors, and managers.
Composition	Independent Director JinnDer Chang, Independent Director Patrick Y. Yang, and Independent Director JienHeh Tien	JinnDer Chang (Independent Director), Patrick Y. Yang (Independent Director), JienHeh Tien (Independent Director) and Ming-Chuan Hsieh (Professor)
Number of Meetings Held	11	5
Attendance Rate	90.91%	90%

Board Performance and Self-Evaluation

To implement corporate governance and enhance the functions of the Board, PharmaEssentia formulated the "Regulations for the Self-Appraisal or Peer Appraisal of the Board of Directors" to establish performance objectives and evaluation systems. The Board of Directors of PharmaEssentia shall perform internal Board performance evaluation at least once a year and appoint an external professional independent organization to conduct performance evaluation of the Board at the end of every three years. The performance evaluation measures include at least the following five major aspects:



Before the end of December 2021, PEC has appointed external entity "Taiwan Corporate Governance Association" to evaluate the performance of its Board of Directors from November 1, 2020, to October 31, 2021. The evaluation report contained four recommended improvements; PEC will strengthen the election mechanism of the Board, draft talent development plans for key management functions, build a comprehensive whistleblower mechanism and communication channels, and set up a corporate governance section on its website based on actual operating needs in the future.

Directors' Remunerations and Its Correlations with Sustainability Performance

Directors' remuneration at PEC complies with internal regulations and rules, and after offsetting cumulative losses, no more than 5% of the current earnings may be appropriated as remunerations for the Directors. Reasonable compensations and rewards may be given based on the level of individual Director's participation in PEC's operations and his/her performance and contribution and result of the performance evaluation of the Board of Directors. To reflect the Directors' efforts toward supervising the executions of sustainable development goals and strategies, the HR department is actively drafting relevant operating procedures to correlate the Directors' remunerations with PEC's sustainable performance in line with PEC's sustainable development progress.

Taxation Strategies and Governance

To strengthen the Group's compliance with relevant tax laws and to fulfilling corporate social responsibility, we abide by the following tax management approach. In order to reduce tax risks, optimize after-tax operating results, and to protect the rights and interests of shareholders. The Group has recognized current income tax expenses of NT$126,000 and NT$0 in 2020 and 2021, respectively.

- All operations are executed in line with relevant tax laws and regulations
- Related business transactions are conducted based on the arm's length principle and adhere to the internationally acknowledged transfer pricing principles announced by the Organization for Economic Cooperation and Development (OECD)
- Transparent financial reporting and tax-related disclosures adhere to applicable regulations and standards
- PEC does not engage in tax avoidance transactions
- PEC has formulated a mutually respecting relationship with the tax authority based on mutual trust and information transparency
- All important decisions considers the effects of taxes
- PEC analyzes operating environment and engages in tax risk evaluation via management mechanisms
- Strengthen professional tax competencies through continuous talent development

	2020	2021
Accounting loss before tax from continuing operations	$(1,948,016)	$(2,810,988)
Income tax expense at the statutory income tax rate	$(389,603)	$(562,198)
Tax effect of deferred tax assets/liabilities	389,629	562,198
Others	100	-
Total income tax expense	$126	$0

Unit: thousands in NT$

Internal Control and Internal Auditing

PEC's Taiwan headquarters has set up an Audit Office that directly reports to the Board of Directors. The Audit Office has two full-time auditors and deputy agents, and it prepares an audit report based on factual records of internal control deficiencies and abnormalities found in audit tasks. The audit supervisor reports to the Audit Committee and the Board of Directors on the execution of audit operations quarterly. They also report deficiencies found in the internal control as part of the annual Audit Plan, which are regularly followed up and reviewed to ensure that relevant departments have adopted proper improvement measures on a timely basis. To implement the corporate governance system, the auditors gain an understanding of the operating status and potential risks of internal control functions through routine and ad hoc inspections and assist the Board of Directors and the management to fulfill their responsibilities. Audit Office completed 50 audit reports and found one deficiency in 2021, and 100% of the deficiency has been improved. For the current period, auditors have also prepared two audit reports on PEC's global subsidiaries in line with PEC's "Operating Procedures for Subsidiary Supervision and Management," and no audit deficiency was found.

Annual Operation Performances

GRI 201-1

Operation Performances in the Last 3 Years			
	2019	2020	2021
Operation Revenue	305,692	557,257	656,506
Operation Costs	61,703	373,323	378,856
Total Operation Expenses	1,093,212	1,899,786	3,100,058
Loss Before Tax	-842,144	-1,948,016	-2,810,988
Total Tax Expense	850	126	0
Loss	-842,994	-1,948,142	-2,810,988
Other Comprehensive Income, net	926	-13,089	-19,879
Total Comprehensive Income	-842,068	-1,961,231	-2,830,867

Unit: thousands in NT$

Note 1: Above information is from the Company's consolidated financial statement.
Note 2: More information on the Board of Directors' performance and operation results, including CEO's remuneration structure, stocks hold by the government, stocks hold by the founding family, and disclosure on power to make decisions… etc. please refer to PharmaEssentia's year report.

50
Total number of audit reports completed by PEC

1
Audit deficiency

100%
Completion rate of improvement on audit deficiencies

PharmaEssentia's ESG Governance Goals and Organizational Operations GRI 102-19~20

The Execution Center for Corporate Sustainability and five functional taskforces have been formulated under the CEO, and they are responsible for planning and promoting cross-departmental and business group's sustainable development policies, goals, strategies, and implementation plans executed by the functional taskforces. The Execution Center will also regularly report the progress of various executions to the Board of Directors quarterly, as well as monitor and manage various ESG performance on a timely basis.

The ESG aspects and the SDGs to which the 5 taskforces corresponding to

Take the United Nations Sustainable Development Goals 3 as the core.

Address unmet disease needs through PharmaEssentia's science and innovation to deliver access to medicines for patients worldwide.

E

- Ensure the health of PharmaEssentia's employees and the residents around the plant through actions to reduce chemical, air, water, soil and other pollution.
- We examine the management of waste and toxic chemicals from a life-cycle perspective to prevent environmental pollution from harming human health.
- We are committed to reducing energy consumption intensity through a number of energy efficiency initiatives. We are progressively using the Task Force on Climate-related Financial Disclosures (TCFD) as a framework for disclosing climate change risks and opportunities to implement climate action.

S

- Prepare for possible future public health emergencies, we continue to promote and collaborate on the development of vaccine candidates.
- We regularly report on the proportion of women on boards and in management-level roles, and support the career development of women managers to promote a gender-balanced and inclusive workplace.
- In order to ensure that our colleagues interact with healthcare professionals in a reasonable manner and in accordance with relevant drug and medical regulations, we comply with WHO and national ethical standards for pharmaceutical marketing. In 2020, we established three major supplier management priorities to ensure a stable procurement supply with our supply partners.
- To support the health and well-being of our employees, we provide them with quality compensation and benefits, and ensure that they have appropriate career development plans through comprehensive education and training, regular performance appraisals, and the promotion of employment and overall economic growth.
- Our greatest impact on health is the successful development of innovative products. Through our science and innovation, we develop differentiated, high quality medicines to improve the health of patients worldwide.
- We have built diverse partnerships among academia, strategic alliances, and intellectual property sharing companies to pursue breakthrough innovations in support of global goal SDG 3.

Environmental Friendliness Taskforce

Identifying and managing the product life cycle that may have an impact on the environment, such as energy use, water resource use, greenhouse gas emissions, medical waste management, chemical substance management… etc.

Employee Care Taskforce

Managing the topics of each stage in the human resource cycle, including recruitment, appointment, compensation assessment, rewards, training, performance assessment, employee assistance, workplace health and safety, resignation and retirement… etc.

Product Quality and Patient Safety Taskforce

Managing topics related to the product life cycle. Including R&D, clinical, manufacturing, and sales, safety, effectiveness, ethics and morals of products.

Access to Medicine Taskforce

Ensuring patients' access to medicine. Including policy participation, innovative technologies, ability building, and other aspects. Considering ways to assist patients in obtaining the drugs they need and formulating relevant action plans to exert social influence in the pharmaceutical industry

Manage 11 Material Topics

- ★ Waste Management
- ★ Hazardous Substance Management
- ★ Climate Governance
- ★ Talent Attraction and Retention
- ★ Human Rights
- ★ Drug Quality & Safety Management
- ★ Supply Chain Management
- ★ Access to Medicine
- ★ Research and Development Innovation of New Drugs
- ★ Patient Relation and Community Engagement

G

Realize our business opportunities while providing patients with reasonable, affordable, correct and easy access to the medicine they need, through an approach to proximate drug governance that is closely aligned with our business development strategy from our core competency.

We are committed to upholding the spirit and fundamental principles of human rights protection as set forth in the "United Nations Global Compact," the "United Nations Universal Declaration of Human Rights" and the "ILO Declaration on Fundamental Principles and Rights at Work." We have a zero-tolerance approach to bribery and any form of corruption and have developed an anti-bribery and anti-corruption action plan.

We believe that a multi-faceted partnership between corporations, governments and NGOs that effectively harnesses each party's unique expertise will help develop and deliver the medicines in a timely manner to people around the world to meet the healthy lives.

Corporate Governance Taskforce

Facilitate effective management from the Board of Directors:

- Ensure compliance and business integrity.
- Monitor operational risks.
- Enhance the transparency and timeliness of public information.
- Maintain robust financial performance.
- Protect privacy and information security of the patients.
- Construct a system of application, acquisition, management, and operation of intellectual property

Manage 11 Material Topics

★ Business Ethics and Compliance

2021 PharmaEssentia ESG Performances

5 ESG functional training sessions

To promote the awareness and practice of senior managers and employees on the correlations between core functions and sustainable performance

Comprehensively identified and addressed stakeholders' expectations

Information disclosed on 11 ESG material topics from both domestic and foreign investors

Voluntarily published the third Sustainability Report in English and Chinese

Reporting boundaries have been extended to include the U.S. Subsidiary

Participated and completed the submission of S&P CSA for the first time

Ranked in 92 percentiles among global pharmaceutical companies

Completed ESG risk evaluation from international independent Sustainlytics for the first time

Ranked top 15% among all global pharmaceutical companies.
ESG risk was reduced to moderate

Received TCSA Gold Medal in CSR Report

Honored with Gold medal in medical industry sector in 2021

Risk and crisis management framework and executions

Formulated management mechanisms and action plans for the ESG non-financial risk topics

Further engaged in training of existing material topics using SMART principle, enabling departments to formulate clearer and measurable short-, mid-, and long-term ESG goals to reinforce the evaluation mechanism and to achieve KPI performance. Subsequently, PEC also deployed COSO enterprise risk management framework to identify 19 non-financial ESG risk topics and re-identified material topics in 2021 to comprehensively examine our management objectives and performance goals in order to promote PEC toward sustainability on a rolling basis (please refer to Appendix 4 for the status in achieving 2021 material topics).

2021 PharmaEssentia ESG Performances

Plans Executed		Results
Organization establishment and education training	Sustainability project initiation meeting and education training.	• Completed the first COSO ERM non-financial ESG risk issue training in January 2021 • Completed the second COSO ERM non-financial ESG risk issue training in March 2021 • Organized TCFD training in August 2021 • Organized ESG investment score training in September 2021 • The third "PharmaEssentia Sustainable Development Project Initiation Meeting and Education Training" was held in December 2021, in which 24 executives and nearly 40 employees participated in the offline conference
eview of the sustainable assets and issues	Identifying stakeholders and major concerns.	• Identified 10 types of stakeholders through interviews with senior management and departmental supervisors. • Identified 11 material topics of priority concern through 332 online questionnaires.
	Identifying non-financial risk topics.	• Conducted one training session on workplace unlawful infringement and one session on identification of legal risk topics arising from unethical conduct, with more than 30 participants from senior management and department heads, and nearly 200 employees. • Identified 19 ESG non-financial risk topics.
Disclosure of sustainable information	Prepare and publish sustainability reports.	• The second Chinese version of PharmaEssentia Sustainability Report was published in July 2021. • The second English version of PharmaEssentia Sustainability Report was published in September 2021. • Obtained sustainability report assurance from BSI for the first time
	Deployed and participated in international standard assessment	• Introduced COSO ESG risk management framework development and utilization for the first time • ESG risk evaluation from international independent Sustainlytics was reduced to moderate for the first time, and ranked top 15% among all global biotech companies • Participated and completed the submission of S&P Global Corporate Sustainability Assessment for the first time and ranked in 92 percentiles among all global pharmaceutical companies • Awarded Gold medal in medical industry sector in 2021 TCSA

2-2 Compliance and Business Ethics

Management Approach of Compliance and Business Ethics

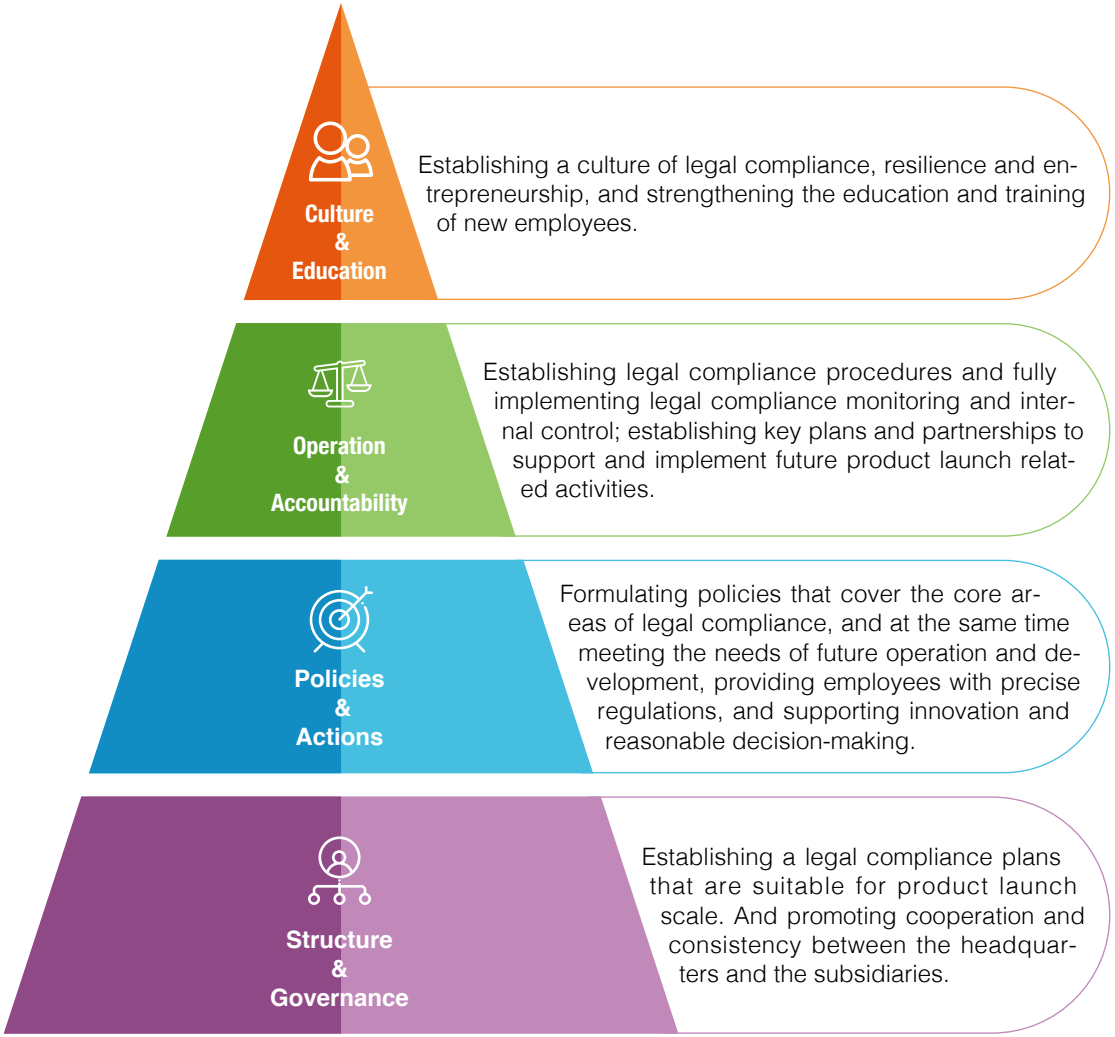
Materiality Topic

PharmaEssentia's product sales span across European, American, and Asian markets. We keep abreast of any domestic or foreign policies and laws that may have a significant impact on our operations. We have drafted a compliance strategy framework founded on four major principles of Structure and Governance, Policies and Actions, Operation and Accountability, and Culture and Education, for our global operations in order to reduce operational risks caused by legal violations. To ensure the conduct of PEC's subsidiaries and employees around the world all comply with regulatory and ethical standards and rules, we plan to establish an inter-subsidiary Compliance Committee within the Group in the future. In addition, to set our foundation toward sustainable management, each functional department engages external professional consultants to provide guidance on legal compliance policies in accordance with the Group's development needs. Currently, the Compliance Committee has been set up at our U.S. Subsidiary and stipulates ethical and integral business conduct through "Compliance Policy Book-A Guide." Please refer to "Global Legal Compliance Strategies - Legal Compliance in the United States" for more descriptions.

GRI | 103-2~3

Vision

Providing employees with relevant knowledge and tools to enable all employees worldwide to follow the laws and codes of ethics.



Policies

Internal Policy

- Based on our mission to provide effective, safety and cost-effective medical products to treat human diseases, the Group continues to engage in and to actively strengthen legal compliance management, as well as to formulate a culture of regulatory compliance. Besides formulating various standardized operating procedures in line with laws from the competent authority, we have also formulated procedures including the "Principles of Ethical Corporate Management" and the "Procedures for Ethical Management and Guidelines for Conduct." By actively engaging in employee advocacy and training, we can ensure that all business and operating activities are in line with relevant laws and PEC's management policies.

External Compliance

- Biopharmaceutical is a highly regulated industry, and all business conduct and products of the Group, from R&D, clinical trials, drug manufacturing and production, regulatory marketing approval review, to post-marketing safety monitoring, shall comply with relevant regulations from various countries.

Commitments

The Group places immense importance on compliance and monitoring at all stages of the industry value chain and expects its employees around the world to implement the following four major principles as a commitment to sustainable development:

- Structure and Governance: Establish a global pre- and post-market compliance program for products.
- Policies and Actions: Develop core areas of compliance and sound policies.
- Operation and Accountability: Establish legal compliance procedures and fully implement control and accountability management.
- Culture and Education: Continuously conduct employee education and promotion to deepen the corporate spirit.

Responsibilities

Legal compliance is a core requirement to enterprise management, and all internal organizations, subsidiaries, and all employees need to make sure that relevant business conduct and actions comply with regulatory requirements and PEC's policies and regulations, including:

- Board of Directors of the headquarters, the pharmaceutical legal affairs unit, the legal affairs unit, the human resources unit and each functional department, as well as the management team and the legal compliance team of each subsidiary.
- Execution Center for Corporate Sustainability-Corporate Governance Taskforce

Resources

Personnel / operational invested

- Board of Directors of the headquarters, the pharmaceutical legal affairs unit, the legal affairs unit, the HR unit and each functional department, as well as the management team and the legal compliance team of each subsidiary.

Expense invested

- Each functional department of the Group's headquarters and subsidiary shall prepare the annual budget related to the compliance plan, which shall be reviewed by the finance department of the headquarters and submitted to the Board of Directors for approval.
- Each functional department engages external professional consultants to provide guidance on legal compliance policies in accordance with the Group's development needs.

Goals & Targets

2022 Short-term Goals

- PEC will formulate a Nomination Committee based on actual operational needs, in order to continuously strengthen the nomination system of Directors.
- Reinforce the channel on PEC's website designed to directly or synchronously communicate or file grievances with the Independent Directors (Audit Committee).
- Optimize information related to corporate governance on the existing PEC website to allow internal and external stakeholders to inquire needed information with greater efficiency and as needed, as well as to facilitate positive interactions and communications.
- Strengthen training on legal compliance management by building a clear and adequate systems for transmission of, and consultation, coordination, and communication with respect to, acts and regulations so that legal compliance could be achieved on all levels of the Group.
- Headquarters has formulated the Group's "Top Management Principles for Group Business Conduct and Ethics" and related, detailed operational policies.
- Include legal compliance standards and rules in the annual Audit Plan and regularly carry out internal audits.

Goals & Targets

2023~2025 Mid-term Goals

- Formulate a cross-subsidiary Compliance Committee within the Group to facilitate strategic decision-making processes that incorporate input from functional compliance representatives to achieve compliance with laws and company policies in every operational activity.
- Advise senior management team to promote the formulation of a global Compliance Committee to oversee the implementation effectiveness of the global compliance program under the compliance committee and establish a reporting and management mechanism to manage the headquarters and subsidiaries.
- Establish an integrity management supervisory unit under the headquarters Compliance Committee.

2026 Long-term Goals

- Establish a global compliance committee.
  - Provide a global view of the compliance risk profile for each subsidiary.
  - Facilitate cross-region identification operations and prevent duplication of effort.
  - Make decisions and develop the Group's global risk management strategy.
  - Facilitate in the management of global risk oversight of compliance between branches.

Evaluation of Management Approach

Mechanism of Evaluation

Internal audit mechanisms:

- Comply with the relevant procedures enacted by the competent authorities, for instance, the headquarters has formulated the internal control and internal audit management system and more than 40 operating management procedures.
- Annual internal audits and feedback, and regular quarterly reports to the Board of Directors on the results of implementation.
- Employee training.
- Performance evaluation of Directors and managers.

External audit mechanisms:

- Financial Supervisory Commission's corporate governance 3.0 evaluation system
- External professional agency is invited to conduct performance evaluation of the Board
- Reporting and complaint channels and mailbox

Evaluation of Management Approach

2021 Evaluation Results

- Include legal compliance standards and rules in the annual Audit Plan and regularly carry out internal audits. In terms of compliance with ethical business conduct and ethics, no significant deficiency was found in 2021.
- No incidents of corruption or harm to customer privacy was found in 2021.
- After external professional agency completes performance evaluation of the Board, a report will be issued and disclosed on PEC's website.
- Auditing Office organized one session of internal legal compliance training and external practicing attorneys were invited to give one training on legal risk topics arising from unethical business conducts.
- Two incidents of violations against relevant operating procedures from the Taipei Exchange in 2021; conference with professional attorney and CPA was already held to jointly propose substantial improvement measures and system optimizations.

Continue to Promote and Deepen Integrity Management.

Due to the nature of PEC's industry, our products are vital to human safety and health; therefore, it is crucial for us to adhere to the Principles of Ethical Corporate Management. PEC's Procedures for Ethical Management and Guidelines for Conduct focused on: specific rules concerning anti-corruption, corporate social responsibility, business secrets, and conflicts of interest. There will also be corresponding authorities and departments in each rule to improve departmental organization and development, thereby executing and supervising the Procedures for Ethical Management and Guidelines for Conduct. The "Rules of Procedure for Board of Directors" also clearly stipulates the recusal system for the Board of Directors and other relevant parties and matters. Going forward, we will also establish an integrity management supervisory unit under the Compliance Committee to strengthen legal compliance and ethical business management.

To comprehensively ensure the practice of ethical corporate management, PEC will also propose a whistleblower system to protect whistleblowers and to provide a confidential reporting hotline available to suppliers, customers, and other third parties via their local language. The number of reports received, types of improper conduct, and measures adopted will also be disclosed. This system will strengthen risk detection, fulfill our commitment, as well as protect our reputation.

Anti-Corruption

Focused on prohibiting any form of bribery, improper monetary transaction, or insider trading, money laundering, or illegal political donations to implement PEC's anti-corruption implementation plan.

Corporate Social Responsibility

Focus on sponsorship and corporate social responsibility, including all financial activities of the Company related to sponsorship or charitable activities, including drug donations, research sponsorship programs.

Trade Secrets

Business secrets are important assets of rsesearch and development enterprises, and they must be proactively protected and managed to a level no less than intellectual property or patent protection.

Conflict of Interest

PEC shall conduct its business activities in accordance with the Fair-Trade Act, the Company Act and the Securities and Exchange Act, and other applicable laws and regulations. And shall not engage in unfair competition or monopoly or harm the rights and interests of consumers or other stakeholders.

Guidelines on Corporate and Employee Business Conduct and Ethics

GRI | 102-17

PharmaEssentia and all employees are required to abide by the six major business conduct and ethics regulations set by PEC. The HR department will promote the precautions related to professional ethics during the education and training of new employees. In addition, a specific reporting system on illegal (including corruption) conduct have also been formulated for internal and external personnel. In December 2021, PEC also invited external practicing attorneys to give one seminar on "legal risk topics arising from unethical business conduct" to strengthen the awareness of employees from the headquarters and subsidiary Panco Healthcare concerning ethical business management policies that shall be followed by companies listed on the Taipei Exchange. Total number of participants reached 198 persons, accounting for 85.71% of all employees in Taiwan.

Our employees are required to follow our business guidelines and codes of ethical conducts

Global Legal Compliance Strategies -
Legal Compliance in the United States

Signed PharmaEssentia USA "Compliance Policy Book"

Policies that specify PEC's ethical business conduct and legal compliance

Formulated standardized operating procedures related to legal compliance

Operational Guidance Document covering legal and compliance operating procedures are being finalized

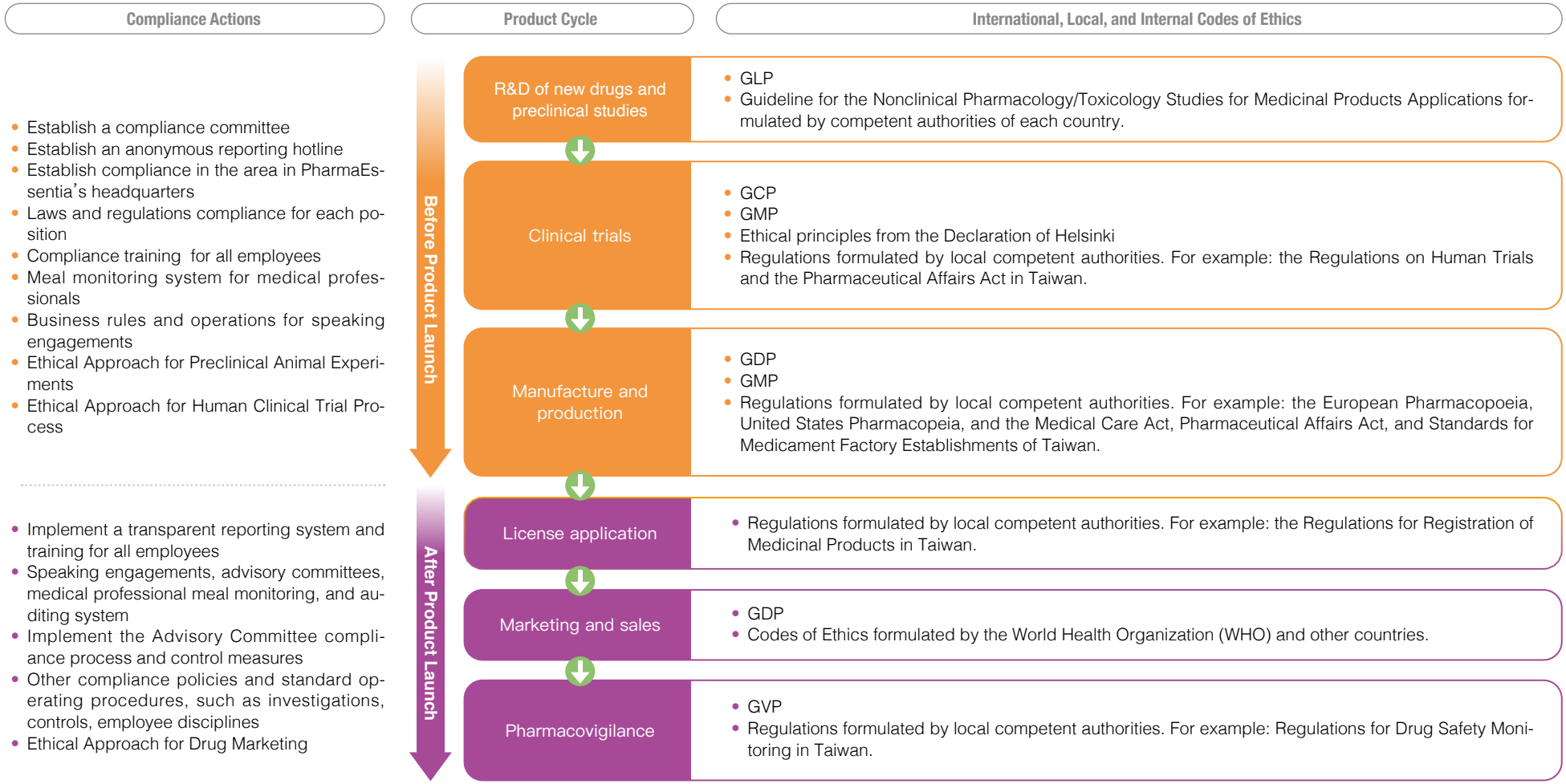
Organized multiple employee training sessions

Established Compliance Committee

PharmaEssentia's U.S. Subsidiary is committed to complying with the highest ethical standards and all applicable laws, regulations, industry standards, and PEC's policies and procedures. The US Compliance Committee assists the Head of US Compliance in implementing and enhancing our US compliance program. And the PharmaEssentia USA Compliance Policy Book has been enacted to provide the policies that guide and govern the conduct of the US subsidiary's business and reflect its commitment to compliance. Corruption, interactions with patients and their representatives, Fee-for-service, privacy, and ethical and moral standards specific to the biopharmaceutical industry are specified in the Compliance Policy Book-A Guide.

Requirements and Specific Actions Taken at Each Stage of Product Life Cycle SASB | HC-BP-270a.2

Rigorous regulatory requirements are found throughout each stage of the biotech and new pharmaceutical industry chain, and arbitrary experiments, manufacturing, sales, and advertising are strictly prohibited. In terms of ethical and moral issues specific to the biopharmaceutical industry, we pay special attention to the implementation of ethical and moral regulations in the three stages of the product life cycle, including ethics on pre-clinical animal testing, clinical human trial, and drug marketing.



SASB | HC-BP-270a.2

	Code of Ethics	Our Actions	Our Purpose
Preclinical Studies Ethics	• Guideline for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications formulated by competent authorities of each country.Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals formulated by the ICH. • GLP	• Establishing the Institutional Animal Care and Use Committee (IACUC) to review and supervise the situation of animal experiments and animal husbandry conducted by the institutions. • All CROs for animal experiments must pass domestic and foreign GLP certification. • Animals used in experiments must be healthy, free from sources of infection animals that meet the requirement level of Specific Pathogen Free (SPF), to prevent interference to trial results for certain diseases. • Actively implementing the 3Rs of laboratory animals: “Replacement,” “Reduction” and “Refinement.”	Ensuring that researchers follow relevant laws and regulations during animal experiments and minimize the use of laboratory animals.
Clinical Trials Ethics	• Clinical Study Policy formulated by the Company • Declaration of Helsinki • GCP • Investigational new drug (IND) applications and local laws and regulations	• Establishing standard operating procedures for the formulation and approval of IND indications and subjects’ informed consent. • All IND indication and informed consents of subjects must be reviewed and approved by the health authority and the “Institutional Review Board” before the start of the trial. • Subjects of clinical trials led by PharmaEssentia are insured with clinical trial insurance to protect their personal rights. • Personal data and privacy will be protected during the clinical trials. • Regular monitoring and auditing are also conducted during the clinical trials.	Ensuring that the safety, privacy, and other rights of clinical trial subjects are not violated, showing that the Company is a trustworthy biopharmaceutical company among patients.
Drug Marketing Ethics	• Code of Ethics formulated by the WHO, the National Council for Prescription Drug Programs (US), International Research-Based Pharmaceutical Manufacturers Association (Taiwan), National Council for Prescription Drug Programs (US), and the Foreign Corrupt Practices Act (US). • The HCP& HCO Interaction Policy and the Promotional Material Policy formulated by the Company.	• All employees must follow the aforementioned ethical standards when interacting with people or organizations related to healthcare. • Marketing activities must be transparent, ethical, correct, balanced, and must not be misleading. • Marketing materials must include correct product risks and benefit assessments and appropriate usage methods. • It is not allowed to sell and market products in the name of clinical trials	Ensuring that medical staff obtains the necessary information, protect the medical care and wellbeing of patients, and implement the Company’s mission and responsibilities in an ethical manner.

Incident Relating to Corporate Governance and Method of Improvement

Incidents

In 2021, Taipei Exchange found that PEC failed to comply with the "Procedures for Verifying and Disclosing Material Information”. Furthermore, in December 2021, PEC also failed to comply with the "Procedures for Verifying and Disclosing Material Information” and "Information Reporting Procedures" for companies listed on the Taipei Exchange. PEC was fined twice, for a cumulative sum of NT$1.5 million.

Method of Improvements

To address these incidents, PEC met with professional attorney and CPA to jointly propose substantial improvement measures and system optimizations. Besides clearly specifying existing internal standardized control processes and adding relevant operating procedures, an improvement plan to the internal control system has also been drafted. After review, the attorneys and CPA have expressed the opinion that the aforesaid improvement plan and procedures are both appropriate and feasible. As of the publication of this Report, there have been no further incidents of negligence or penalties.

2-3 Data Security and Privacy Protection

PEC is cautious in the management of information security and has established an information system cycle in the internal control system. And entrusts a professional information company that complies with the ISO 27001: Information security management for the planning, implementation, maintenance, management, and support of the Company's information system.

Data Security

- Information Security Committee was formulated in 2022
- Adopt ISO 27001 Information Security Management System in 2025

Privacy Protection

- Follow the EU General Data Protection Regulation (GDPR) to protect the personal privacy information of patients in clinical trials
- Regarding the privacy and personal information of patients and employees, PEC abides by relevant policies and laws to ensure their rights and interests

Future Action Plans to Ensure Information Security

PEC has planned to build an IT team and will recruit relevant professionals. Initially, internal information security, anti-hack policy and specific management measures will be formulated. We expect to establish an Information Security Committee in 2022 to strengthen information security risk control, complete ISO 27001 certification in 2025, formulate an effective information security management mechanism, and establish an effective information security management mechanism to enhance the information security awareness of all employees.
And strengthen the overall information security of PEC through the items listed in the table below.

PharmaEssentia's Measures on Information Security and Hacking Prevention

Stage 1 (Completed)	Stage 2 (In process)
✓ Bolstered core information system backups (Ex, ERI) *2021/12*	• Bolster information system and network vulnerability *2022/4*
✓ Drafted information security policy (complied with TPEx's Guidelines on Information Security Management) *2021/12*	• Plan and execute files encryption system *2022/6*
✓ Planned and executed information security annual checkups (execute annually) *2022/1*	• Protect information on terminal equipment with data loss prevention (DLP) *2022/8*
✓ Planned and executed employee training on social engineering (execute annually) *2022/2*	• Bolster information security with O365 Multi-factor authentication (MFA) *2022/10*
✓ Conducted vulnerability assessment on information system and network (execute annually and internally) *2022/2*	
✓ Conducted penetration testing on information system and network (execute annually and externally) *2022/2*	

Besides enhancing both software and hardware, PEC also regularly promotes its information security policy, organizes training, audit, and review every year in order to formulate employees' awareness of information security and to practice such awareness in our day-to-day operations. Employee feedback is used to ensure employees' recognition and responsibility to information security management.

Implementation of Personal Privacy Protection

PharmaEssentia's privacy policy focuses on protecting private information and the collection and further processing of private information from patients, health care professionals, and other individuals with whom PEC does business, and all employees must adhere to this policy. Privacy protection is mainly divided into the clinical trial stage and the post-product-launch stage, both of which must comply with relevant internal and national regulations to improve our responsibility for the protection of personal information.

Clinical Trial Stage

- Entrusts qualified CROs to conduct human clinical trials and ensures that the CROs adopt strict confidentiality measures for the collection, processing, and utilization of subject data.
- Complies with the GDPR, Good Clinical Practice (GCP), "Declaration of Helsinki," and relevant laws and regulations of various countries, such as Taiwan "Human Research Ethics Policy Guidelines" and "Medical Care Act."
- The principal investigator of the trial plan must keep the results of the examinee's examination and the physician's diagnosis confidential and replace the subjects' names with numbers. Other forms of privacy protections are required by individual clinical trial hospitals for relevant researchers participating in clinical trials. PEC has no way to identify the personal information of the subjects and has no access to other personal information.

Post Product Launch

- Conducts Post-Market Surveillance (PMS) before obtaining patient information, we will provide a patient consent form to ensure that we have the patient's consent and explain to the patient how we handle the information and protect the privacy of the patient.
- Ensure that pharmacists in medical institutions, community pharmacies, and other primary care practices incorporate the concept of privacy protection in their daily practice when providing pharmacy services to the public and medical personnel, and actively protect and ensure that patients' privacy rights are not violated.

2-4 Comprehensive Management of Intellectual Property Rights

PharmaEssentia has formulated the "Intellectual Property Rights Management and Utilization Regulations," which includes intangible rights and property including patents, trademarks, copyrights, and trade secrets. To make our intellectual property (IP) management system more comprehensive, we are committed to patent application during the product life cycle management, risk control of IP, and new drug IP utilization strategies. Besides closely following the regulations for R&D cycle and complementing the Operational Procedures for Acquisition and Disposal of Assets to protect PEC's R&D personnel's intellectual property from infringement, we can also ensure that an innovation becomes PEC's intellectual property and that our intellectual property can be widely applied for and registered internationally. So that more people in need can know about and have access to the new drugs, and that the IP rights of others will not be infringed upon.

Management and Statistics of Patents and Trademarks

83 patents
Number of valid patents

96 trademarks
Number of valid trademarks

81 countries
Valid patents are available at 81 countries (sovereignties)

31countries
Valid trademarks are available at 31 countries (sovereignties)

Known for our innovative R&D competencies, PharmaEssentia applies for types of development patents in line with the R&D progress of each project to plan our global technical strategies. We realized our global intellectual property strategies early on, in as early as our startup period since our product Ropeginterferon alfa-2b (P1101) has realized the goal of applying for multinational regulatory marketing approvals. PEC has obtained patent certifications from around the world; as of 2021, we hold 83 valid patents (9 new patents were added in 2021) from 81 countries (sovereignties); in terms of countries (sovereignties), we have obtained as many as 164 patents. As for trademarks, we have received an additional 19 in 2021, and cumulatively, we hold 96 valid trademarks in 31 countries/regions. In line with the indices from Corporate Governance 3.0 evaluation, PEC's Intellectual Property department regularly reports annual executions of the Intellectual Property Management Plan, which is correlated with our business objectives, to the Board of Directors on an annual basis. Furthermore, to demonstrate our determination to practice intellectual property management as well as our commitment to intellectual property as a leading new pharmaceutical company, the newly added rules related to intellectual property rights management in the Corporate Governance Best Practice Principles for TWSE/TPEx Listed Companies have also been incorporated into PEC's internal control procedures. Executions of the Intellectual Property Management Plan in 2021 has been reported to the first Board of Directors meeting convened on March 1, 2022 and have been acknowledged and approved by all Directors.

Chapter 3

Product Quality and Patient Safety

Chapter 3: Summary of 2021

Highlights

Our entire supply chain includes from upstream raw material suppliers, outsourced manufacturing or distribution partners to downstream customers and users. The entire supply chain is required to comply with external laws and regulations and rigorous internal quality management system. It is regularly reviewed and evaluated for performance to reduce risks and to improve management continuously. Therefore, it is ensured that the drug supply chain management policy is implemented and that our drug supply meets the needs of our patients.

Relevant Material topics

- Supply chain management
- Product quality and safety management

Relevant stakeholders

- Patients
- Suppliers and Business Partners
- Government and Competent Authorities

Performance Highlights

4,000+

Comprehensive quality and safety management, standard operating procedures and various plans and reports.

Taichung Plant passed the U.S. FDA's plant inspection

54,168 hours of training
2,234 participants

Good Manufacturing Practice (GMP) for Medicinal Products training

Stable and safe transnational supply chain

Established a US market supply chain from filling injections, stable third-party logistics, to drug distribution

Top 3 sustainability management priorities for suppliers

Advocated to 177 suppliers

100% for 3 consecutive years

All the vendors that required to sign quality agreements, internal assessments and on-site audits were completed.

Pharmacovigilance

Set up real-time global reporting mechanism and adverse event reporting emails: Safety@pharmaessentia.com
PharmaEssentia.drugsafety@labcorp.com

Second BESREMi® Periodic Safety Update Report (PSUR)

Regularly issues safety reports (PSUR/PBRER) in line with the requirements from competent authorities of various countries

3-1 Constructing a Comprehensive Supply Chain System

Stable and Safe Supply Chain Management Approach

Materiality Topic

PEC has established a legal and comprehensive global supply chain management mechanism in line with PIC/S Guide for Good Distribution Practice (GDP). More than 4,000 internal quality and safety management, standard operating procedures, and various plans and reports have been formulated to verify the compliance of operating processes and the accuracy and completeness of records and information. These help us to ensure the quality and safety of drugs from manufacturing output from our Taichung Plant to patient use, and to protect the drug use safety of all patients around the world.

GRI 103-2~3

Policies

Internal Policy

- Quality management policy
- Risk management policy
- Raw material management policy
- Storage and distribution policy
- Outsourced activities policy
- Product packaging and identification policy
- Supplier Management Policy

External Guidelines

- WHO Good Storage and Distribution Practices for Medical Products
- Strictly comply with legal and external GxP regulations for all phas

Commitments

PharmaEssentia is committed to building a stable, safe and high-quality pharmaceutical supply chain, and is committed to improving the accessibility, affordability and availability of pharmaceutical products, and continuously enhancing the safety and stability of the overall supply chain and to reduce the supply chain disruptions from COVID-19.

Responsibilities

- The Supply Chain Management (SCM) under the headquarters includes business units, purchasing units, production management units, logistics units, production and manufacturing units, QA units and SCM units of each subsidiary.
- Execution Center for Corporate Sustainability - Product Quality and Patient Safety Taskforce

Resources

Personnel/operational input

- Professional delegation of duties and execution of tasks to the responsible personnel:
- Continued on-the-job employee training
- Investments toward large-scale digitized projects (e.g., ERP system, drug traceability management software)
- Tasks related to negotiating costs, lead time and materials preparations, and notifications of change with suppliers in response to effects from COVID-19, leading to an extra 30% to 40% time investment

Expense invested

- Costs of raw materials, delivery materials and transportation

Goals & Targets

2022 Short-term Goals

- Meet the needs of drug users in time.
- Global economic activity will continue to be impacted by the COVID-19 pandemic in 2022. All business units covered by the supply chain have adopted short-term feasible strategies to reduce the risk of supply chain disruptions, building on the experience gained in 2021.

2023~2025 Mid-term Goals

- Enhance customer satisfaction by improving delivery reliability and flexibility and plan for potential market demand.
- As the COVID-19 vaccines become more widely available, though the supply chain is unable to resume its past stability; however, the economy is expected to gradually recover. After meeting the needs of drug for users, the next step is to improve the satisfaction of drug users. From the supply chain team's point of view, this level of satisfaction goes beyond quality issues and includes satisfaction in business activities, creating maximum benefits for both the Group and the patients.

Goals & Targets

2023~2025 Mid-term Goals

- As PEC's drug is launched in the U.S. Market and we continues to obtain regulatory marketing approvals in different countries, we should anticipate the expected demand from each country early to plan and prepare for immediate and stable supply to potential markets, which will be an important mid-term goal for the supply chain team.

2026 Long-term Goals

- Optimize the internal process of the Group (e.g. value flow), integrate the needs of various subsidiaries/countries, and reasonably control, allocate, and manage the required resources to enhance effectiveness.
- As stated in the mid-term goal, because drugs will be successively marketed in different countries, due to their criticality and particularity, the competent authorities of various countries have formulated strict laws and regulations to regulate the inspection specifications, packaging labeling, and shelf life of drugs. The supply chain team is also committed to integrating these requirements to make the most efficient use of resources within the Group.

Evaluation of Management Approach

Mechanism of Evaluation

- "Supplier Management Practice Standards" and "Supplier Management Procedures"
- "Procurement Management Practice Standards" and "Procedure for Supplier Audit"
- "Corporate Social Responsibility Best Practice Principles"
- Drug safety notification system of the competent authorities of each country.
- Drug supply shortage notification system of competent authorities in various countries
- Drug complaint system established by PharmaEssentia
- Regular management meetings of PharmaEssentia and product quality review

2021 Evaluation Result

- After obtaining the drug license for BESREMi® in Taiwan in June 2020, the Company had continued to provide stable supply to patients.
- COVID-19 continued to rage in 2021 and severely disrupted the supply chain. Besides successfully negotiating with suppliers to control and reduce our costs, we also deployed secondary material sources and achieved stable partnership with our suppliers.
- The number of complaints from the hospitals and patients reported in 2021 was 0.
- Established sufficient stock inventory according to the number of drug users.
- The number of cases of product failure or safety concerns due to transportation and storage activities in 2021 was 0.
- BESREMi® obtained regulatory marketing approvals from the U.S. And Korea in 2021, and we have begun to supply the drug to patients in the U.S.

SASB | HC-BP-260a.1

Global patients with rare diseases highly rely on pharmaceutical companies for continuous supply of safe and reliable medicines to sustain their lives and improve life quality. Therefore, the establishment of a comprehensive, stable, safe and high-quality pharmaceutical manufacturing and transnational supply chain is a mission cannot be ignored by all PharmaEssentia's employees and upstream, downstream supply chain partners.

Integrating and planning drug supply and demand

- Inter-departmental distribution meetings held between the HQ and subsidiaries are used to integrate the drug's commercial needs from clinical and external parties
- Confirm the production schedule with the supply side and the production side to mediate the supply and demand throughout the value chain

PharmaEssentia

- Taiwan HQ
- United States
- Japan
- South Korea
- China
- Others

Responsible purchasing and supplier management

- Rigorously monitor the selection, evaluation and approval of suppliers of raw materials, materials and instruments/equipment and prioritize the use of local suppliers.
- A safe inventory volume has been formulated to obtain real-time understanding on lead time of raw materials and we actively establish second source to reduce the risk of raw material disruptions
- Use three major supplier management practices to communicate our sustainability philosophy and practices to our procurement partners, jointly build a stable procurement supply and ensure patients' right to medication

Raw material, input, and equipment procurement

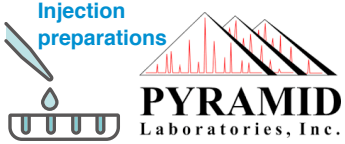
Statement to Supplier Sustainability

High-quality manufacture and production

- All production and delivery procedures cply with current regulations including GMP, ICH, EMA, FDA, and more than 4,000 internal standard operating procedures.
- Quality, safety and product release are jointly managed and supervised by the QA and QC departments of the quality system to strictly control product safety.
- In the US, US subsidiary has formed an in-house marketing team and outsourced relevant processes to local injection preparation OEM Pyramid Laboratories Inc.

DS Manufacturing Plant

Injection preparations



Drug preservation and transnational logistics

- In terms of logistics, we rigorously control packaging and transportation process as well as maintenance of refrigeration equipment.
- In Taiwan, our in-house sales and logistics teams are in charge of drug supply and marketing.
- Outsourced injection preparations and transportation partners have been set up for the U.S. market. After Pyramid Laboratories Inc. completes injection preparations, the drugs are dispatched to third-party logistics company Cardinal Health for warehousing and transportation to dedicated distributors and specialty pharmacies, and from there the drugs are delivered to the patients.

PharmaEssentia

CardinalHealth

Third-party logistics

Dedicated distributors and specialty pharmacies

Effective pharmacovigilance and recall mechanism

- CRO will formulate a pharmacovigilance system, and Taiwan HQ has also established a pharmacovigilance team responsible for coordinating the information of ongoing clinical trial information from all subsidiaries.
- Build a drug safety database to integrate drug safety-related information, and preparing and providing safety reports required by regulatory agencies on a regular basis.
- A product serial number tracking management system and a drug recall policy and system have been formulated to ensure that when a product quality problem occurs, the product can be recalled and the related inventory disposed of within the time limit regulated by the competent authorities.

PEC headquarters' adverse reaction reporting mailbox
Safety@pharmaessentia.com
PEC headquarters' adverse reaction reporting mailbox
PharmaEssentia.drugsafety@labcorp.com

Drug safety reporting hotline from Taiwan
0800-818-886
Dedicated reporting and management center for the U.S. market
PEC U.S.Call Center (800) 999-2449

3-2 Accountable Supplier Management

3 Key Points to Strengthen Supplier Sustainability Management

Impacts of COVID-19 to the upstream suppliers of global enterprises continued to spread throughout the world. PEC continues to uphold our philosophy for co-prosperity with suppliers, and we collaborate and realize our vision for sustainability with suppliers and contractors to create stable long-term value for pharmaceutical industry and patients.

Sustainability Proclamation

To work with our supplier partners for mutual benefit and prosperity, our plan is:
- Declaration: To convey the corporate sustainability philosophy and practices of PharmaEssentia.
- Action 1: Promote the "Code of Conduct for Suppliers."
- Action 2: Sign the "Code of Conduct for Suppliers."

Improved Management

In the face of a changing world, our strategy to enhance our management and response capabilities is:
- Information mastery.
- Enhance supplier management capabilities.
- Strengthen the interaction with suppliers.

Building Substitutional Resources

In order to ensure stable supply, our approach is:
- Identify critical material.
- Screen out candidate raw materials.
- Quality confirmation, experimental confirmation.
- Manufacturing trial mass production
- QA monitoring and regulatory compliance.

Sustainability Declaration: Suppliers / Contractors Co-prosperity

PEC continuously conveys formal or informal sustainability proclamation to supplier partners in order to create positive long-term impact. Procurement and other relevant departments began to draft “Supplier Code of Conduct” to advocate and to urge for signature of acknowledgement. We carried out PEC CSR Report advocacy to 177 suppliers in 2021. We are now in the progress of completing the amendments to “Supplier Code of Conduct” and revising the “Supplier Management Operating Principles”. We are about to proceed signing these documents with our suppliers since 2023. We expect to grow and prosper with all partners throughout our supply chain, and to be committed to corporate social responsibility.

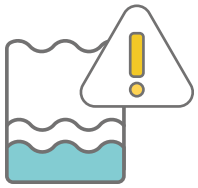
Strengthen Supply Chain Management and Resilience

To prevent the impacts of COVID-19 on the supply chain, PEC continues to enhance supply chain management and our response capacity by maintaining a safe inventory volume and to establish alternative sources of raw materials. By obtaining a balance between cost consideration, long-term raw material preparations and through quick response, we can actively reduce the risk of input disruption from the inability to obtain timely and stable supply.

1. Timely grasp of factors that may affect the supply chain (disease, climate change, natural disasters, etc.).
2. Enhance supplier management capabilities.
3. Strengthen the contact and interaction with suppliers, grasp the changes of suppliers in real time, and continuously monitor the information related to material delivery to ensure the overall information of transportation and logistics in a timely manner.
4. Update the lead time of raw material procurement from suppliers.
5. Enhance safety stocks and monitor changes in demand at customer front-end medical facilities and patients.
6. Investigating the situation of pandemic in the countries producing raw materials, and evaluating the risk and possibility of material breakage.
7. Actively establishing a second source of raw materials to reduce the risk of supply chain disruption.

Establishment of Alternative Sources

We conducted a comprehensive survey of raw materials and determined the priority of materials to be introduced into secondary sources in accordance with our internal standard operating procedures. For materials with immediate risk of input disruption, we have established secondary sources, and for materials with potential risk of input disruption, we will reduce such risk by increasing the inventory of relevant materials to safety stock levels.



Review of raw materials that need to be established as an alternative source, the basis for judgment is:

- The manufacturer informed that the production is about to be suspended.
- Compliance requirements.
- Conduct material risk assessment and evaluate the material criticality according to the procedure of "Material Criticality Assessment."

Perform quality confirmation.

The process development is verified by the process development experiment and the trial production is carried out. The tested raw materials will then enter the GMP control procedures (e.g. supplier evaluation, specification inspection and method establishment, etc.), and after completing the relevant procedures, they will enter the reserve list.

All test data and documentation are continuously monitored by QA at each stage of alternative source development to ensure that the overall process is fully compliant with regulatory standards.

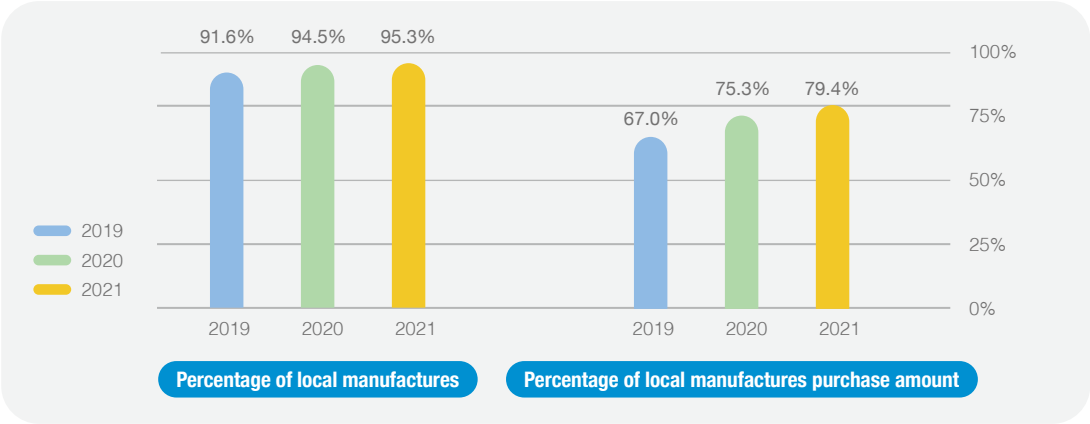
Management Process of Supplier/Contractor

GRI 102-9 GRI 204-1 SASB HC-BP-430a.1

100% of the Suppliers Signed Quality Agreements

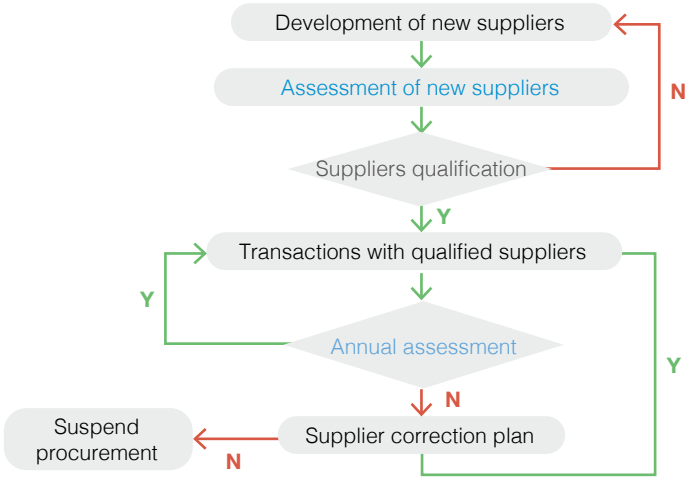
All the Suppliers Required Signing have Completed

PEC ensures that our suppliers and their raw materials and equipment provisions meet our quality, lead time, and Good Manufacturing Practice (GMP) regulations through the “Supplier Management Practice Standards" and "Supplier Management Procedures” formulated by the QA department. These documents serve as the approved standards and contents of suppliers’ and contractors’ verification procedure and job description. By rigorous monitoring procedures, we can closely supervise the selection, evaluation, and approval of suppliers of raw materials, materials, instruments and equipment. Furthermore, the Company requires suppliers to sign a “Quality Agreement,” which clearly sets out the Company’s rights and responsibilities for quality and technology-related issues, to ensure that both parties have a consensus on the requirements of products and quality. All suppliers that required to sign the quality agreement have signed the agreement. The ratio of local suppliers continued to increase to 95.3% in 2021, while the ratio of procurement from local suppliers has been increased to 79.4%.

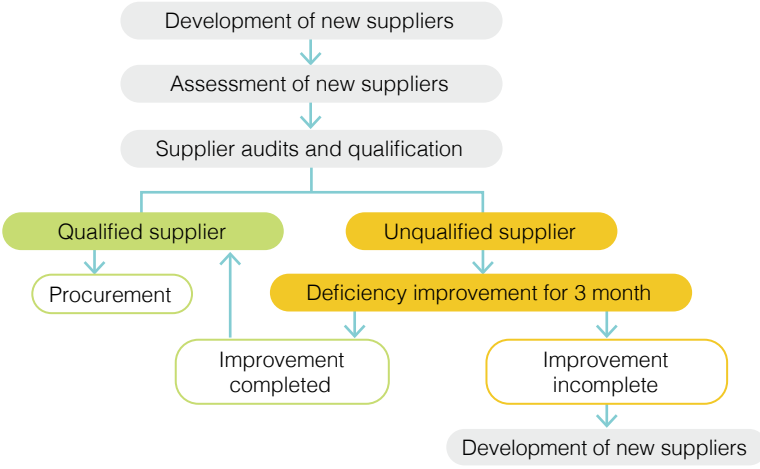


Note 1: The scope of information disclosure for 2019 and 2020 only includes PEC headquarters.
Note 2: The scope of information disclosure includes PEC headquarters and Panco Healthcare.

PEC supplier management operating process at the Taiwan headquarters



Supplier management operating process at Panco Healthcare



2021 statistics of procurement and number of supplier of PEC headquarters and Panco Healthcare

Procurement category	Local Taiwanese suppliers*			Non-local Taiwanese suppliers		
	Percentage of amount of local consumption	Number of suppliers	Percentage of number of suppliers	Percentage of amount of non-local consumption	Number of suppliers	Percentage of number of suppliers
Raw materials	100.0%	7	100.0%	0.0%	0	0.0%
Packaging materials	100.0%	5	100.0%	0.0%	0	0.0%
Consumables	100.0%	72	98.6%	0.9%	1	1.4%
Agents	99.1%	15	88.2%	1.4%	2	11.8%
Instruments/ equipment	91.7%	90	98.9%	8.3%	1	1.1%
Contracted services/ manufacture	37.0%	94	89.5%	63.0%	11	10.5%
Engineering construction	100.0%	15	100.0%	0.0%	0	0.0%
Drugs	100.0%	7	100.0%	0.0%	0	0.0%
Total	79.4%	305	95.3%	20.6%	15	4.7%

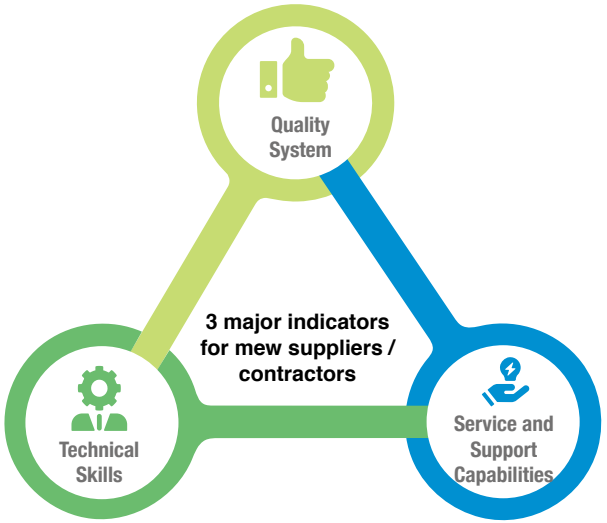
Note: Local supplier refers to vendors who provide products and services within Taiwan. This includes production, manufacturing, and licensed agency in Taiwan.

Selection and Assessment of New Suppliers/Contractors

58% +

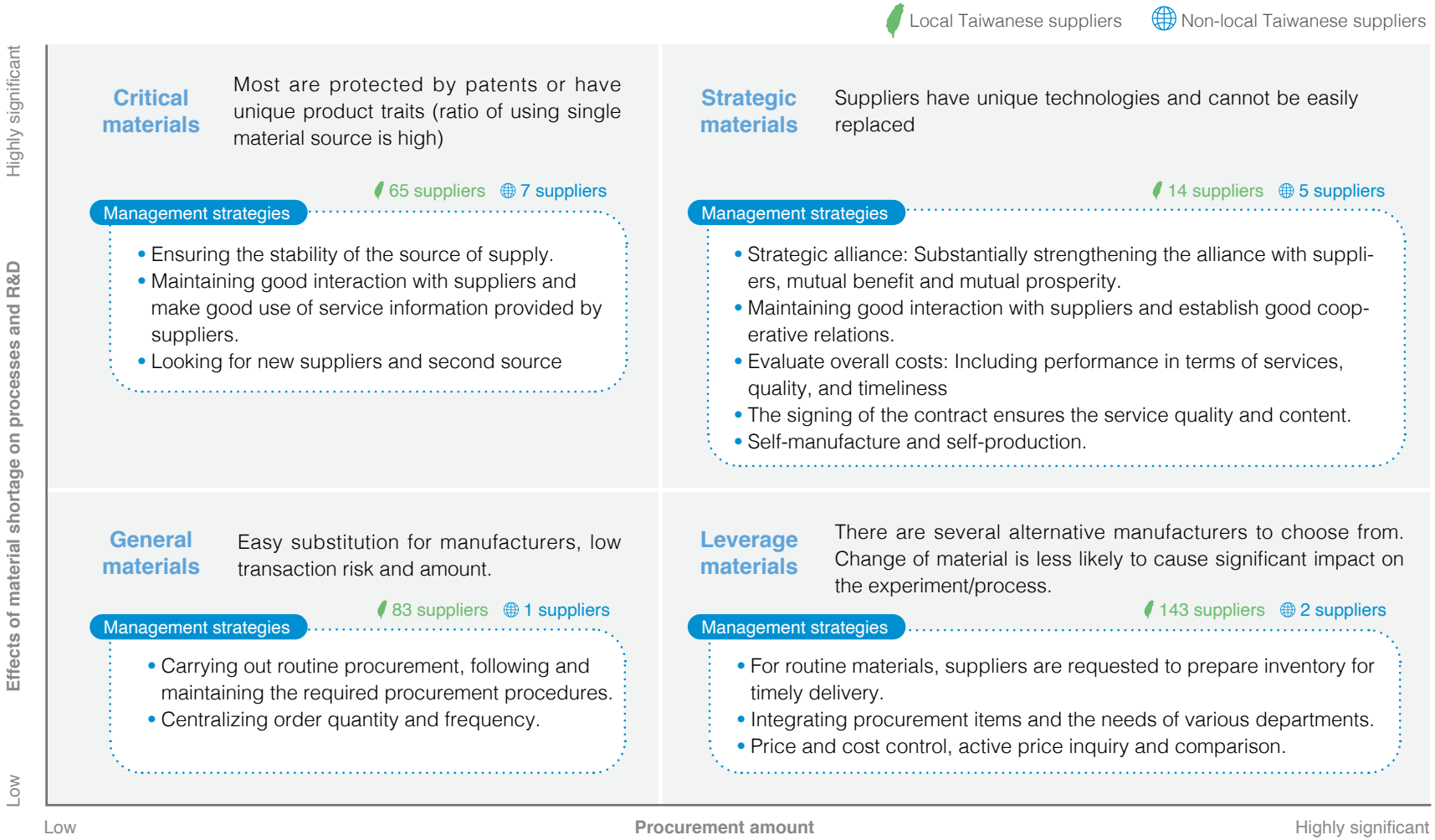
Of the 77 new suppliers, 45 of them are local suppliers, accounting for 58.4% of all suppliers.

The selection and assessment of new suppliers/contractors are based on 3 major indicators covering the aspects such as quality system, technical capabilities, delivery time, service and management. All potential new suppliers/contractors who intend to transact with PEC are required to be evaluated by the relevant requesting departments, QA department and procurement unit according to the "Supplier Management Practice Standards" and "Supplier Management Procedures" before initial procurement could be achieved. In 2021, there were 77 new suppliers. 45 of them are local suppliers, accounting for 58.4% of all suppliers.



Management Strategy of Supplier/Contractor

To improve the efficiency of supplier management, PharmaEssentia classifies materials or services purchased from suppliers into four categories, including "strategic," "critical," "leveraged" and "general," based on their respective risk and purchase amount. Subsequently, corresponding management strategies are drawn up according to the market characteristics and product attributes of each type of material or service.



Annual Assessment of Suppliers / Contractors SASB | HC-BP-430a.1

186 suppliers

Suppliers under internal assessment in 2021

100% for 3 consecutive years

Completed 100% of internal audits

16 suppliers

Suppliers underwent on-site audit in 2021

100% for 3 consecutive years

100% completion of on-site audits

PharmaEssentia conducts supplier and contractor assessments annually in line with the "Supplier Audit Procedures" to ensure the quality of suppliers' products and services. The assessments are executed via internal assessment and on-site audit. If there is a high risk, we will increase the frequency of re-examination and take actions for improvement. If there are major deficiencies, the procurement will be suspended immediately.

Of the 16 suppliers that require on-site audit in 2021, on-site audit could not be completed for certain foreign suppliers due to COVID-19. Alternatively, assessment was conducted via questionnaires and document review. On-site audit was completed for all other suppliers in line with the "Supplier Audit Procedures". To conclude the audit results in 2021, 186 companies that required to perform internal assessment and 16 companies that required to perform on-site audits have all completed the assessment and on-site audits. No high-risk supplier was identified.

List of 2021 assessment of suppliers/contractors of PEC headquarters and Panco Healthcare

Types of assessment / Stage of value chain	Internal assessment (Note)		On-site audit	
	Number of suppliers to be assessed	Actual number of suppliers assessed	Number of suppliers to be audited	Actual number of suppliers audited
R&D of new drugs	99	99	0	0
Pre-clinical trial	0	0	0	0
Clinical trial	3	3	2	2
Manufacture and production	76	76	13	13
Regulatory marketing approval application	2	2	0	0
Marketing and sales	6	6	1	1
Total	186	186	16	16

Note: Suppliers assessed are those who have business dealings with the Company from July 1, 2020, to June 30, 2021. If the supplier reached Level A or B in the internal assessment in the previous year, it might be exempted from the evaluation for the current year.

3-3 Ensuring the Quality and Safety of Drugs

Management Approach of Drug Quality and Safety

Materiality Topic

Throughout PEC's value chain, from R&D, clinical trials, commercial mass production, to patients' use, we use standardized operating procedures, comprehensive quality management and complete product traceability systems, ensuring the safety, effectiveness, and quality of the drugs used by patients.

GRI | 103-2~3 SASB | HC-BP-250a.1~a.5

Policies

Internal Policy

- In terms of quality management, the "Quality Handbook" has been formulated internally along with approximately 20+ relevant policies that comply with international standards, such as the "Quality Management Policy," "Raw Material Management Policy," "Production and In-Process Control Policy," "Quality Assurance Policy", and the "Complaint and Recall Policy" etc.
- Pharmacovigilance Policy
- Standard operating procedures for drug safety, functions, and training
- Standard operating procedures for post-listing safety data collection

External Guidelines

- We comply with regulations formulated by local competent authorities, including the European Pharmacopoeia, United States Pharmacopeia, Guidance from the U.S. FDA, international standards related to GxP, and various laws including the Medical Care Act, Pharmaceutical Affairs Act, Detailed Implementations of the Pharmacist Act, Regulations for Drug Safety Monitoring, and Regulations for Reporting Serious Adverse Reactions of Medicaments.

Commitments

- As we obtain more and more regulatory marketing approvals from various countries, we commit to comply with the relevant regulations from local competent authorities to meet the local standards of sales of medicaments.
- The concept of "quality first and patient safety" is deeply rooted in the day-to-day operations and the lives of all PEC employees, allowing us to prioritize quality and safety to implement drug risk management and to ensure the safety of patients' drug use.

Responsibilities

- Doctors and pharmacovigilance personnel, and pharmacovigilance QA personnel from Taiwan headquarters, and subsidiaries in U.S., China, Japan, Korea, Hong Kong, and Singapore.
- QA department and QC department in headquarters are responsible for the quality of commercially available drugs and clinical drugs, while clinical trial QA and pharmacovigilance functional group are also involved in this process.
- Execution Center for Corporate Sustainability - Product Quality and Patient Safety Taskforce

Resources

Personnel/operational resources

- A pharmacovigilance functional group (3 persons from Medical Research department) has been set up at the Taiwan headquarters to be in charge of pharmacovigilance and management tasks.
- To meet the relevant laws and regulations on pharmacovigilance and reporting from marketed countries or regions, PEC has set up dedicated physicians or pharmacovigilance personnel to be in charge of relevant tasks at our Taiwan headquarters and subsidiaries in the U.S., China, Japan, Korea, Hong Kong, and Singapore.
- Presently, PEC has already commissioned a pharmacovigilance CRO to form a project team to manage and maintain the safety information database of PEC's BESREMi®, the collection and exchange of drug safety information, and reporting to legal competent authorities.

Expense invested

- In 2021, we invested over NT$10 million for pharmacovigilance related tasks around the world.

Goals & Targets

2022 Short-term Goals

- Amend PEC's standard operating procedures related to pharmacovigilance in line with regulatory updates and actual operating needs.
- Draw up a drug safety monitoring plan.
- Reach 100% completion rate of pharmacovigilance training for new employees.
- Update and maintain drug safety database (Argus) and provide accelerated and periodic reports on pharmacovigilance.
- Reach 100% execution rate on timely drug safety information reporting from the headquarters. Reach 100% execution rate on timely drug safety information reporting across all subsidiaries.
- Continue to collect drug safety information from academic publications and continue to identify and analyze drugs and adverse reactions, as well as to complete safety signal monitoring reports on a regular basis.
- Set up QA personnel at the headquarters to be in charge of quality assurance and auditing activities of procedures and documents related to pharmacovigilance.
- Obtain regulatory marketing approval from Japan by passing the PMDA inspection; also aim to pass inspection from competent authority in Turkey.
- Complete deployment of all processes from the quality management system (QMS).
- Evaluate the deployment of electronic equipment management system.

2023~2025 Mid-term Goals

- Continue to update or amend PEC's standard operating procedures related to pharmacovigilance. Standard operating procedures related to localized pharmacovigilance will be formulated by respective subsidiary.
- Continue to amend the drug safety monitoring plan.
- Continue to optimize the drug safety database (Argus), and to update the database based on actual practices.
- Continue to require submission of pharmacovigilance reports in line with requirements from the competent authority. Reach 100% execution rate on timely drug safety information reporting at the headquarters and across all subsidiaries.
- Continue to collect safety information from post-marketing safety reports or academic literature, and to reach 100% implementation rate on identifying and analyzing drugs and adverse reactions.
- Introduce 1 to 2 additional staff to the pharmacovigilance personnel at the headquarters, and continue to organize pharmacovigilance training for all new employees and all members of PEC.
- Pass the regular drug good practice inspections for every 2~3 years performed by the EMA, TFDA and FDA. The estimated inspection will be carried out in the following schedule:
  - 2022: EMA
  - 2023: TFDA and FDA

Goals & Targets

2026 Long-term Goals

- Continuously review the drug safety monitoring management standards and drug safety monitoring standard operating procedures and update or revise the content according to the actual situation.
- Coordinate IT and relevant personnel to develop a drug safety database autonomously managed by PEC.
- Continue to develop the pharmacovigilance team and to train new pharmacovigilance staff at the headquarters, as well as to acquire in-house execution and management over global safety data collection, analysis, and reporting.
- Pass the regular inspection by the competent authority of the country where PEC has obtained the drug certificate.

Evaluation of Management Approach

Mechanism of Evaluation

- Post-marketing pharmacovigilance will be conducted by Contract Research Organization (CRO) and physicians designated by PEC.
- Physicians or dedicated pharmacovigilance personnel at the headquarters and subsidiaries will be in charge of their local pharmacovigilance tasks.
- Internal audits: audits by QA department or commissioned by a third party.
- External audits: Drug safety inspection from both local and foreign competent authorities
- Evaluate the operations of immediate reporting mechanisms:
  - PEC Taiwan headquarters' adverse reaction reporting mailbox:
    Safety@pharmaessentia.com
  - CRO adverse reaction reporting mailbox:
    PharmaEssentia.drugsafety@labcorp.com
- Evaluate the operations of the drug safety reporting hotline (in Taiwan, the U.S., Korea, and Japan).
- Regularly monitor the status of submitting Periodic Safety Update Reports (PSUR) or post-marketing product safety reports to the U.S. FDA, the EU EMA, TFDA in Taiwan, PMDA in Japan, and MFDS in Korea.

Evaluation of Management Approach

2021 Evaluation Result

- Post-marketing safety monitoring: announce immediate reports and maintain the normal operations of our immediate reporting mechanism in line with regulations from competent authorities.
- Periodic Safety Update Report (PSUR) We regularly submit the Development Safety Update Report (DSUR) and the Periodic Safety Update Report (PSUR) to the competent authorities of respective country.
- No competent authority on drug safety has conducted inspections related to pharmacovigilance in 2021.
- All plants passed TFDA's routine Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) inspections.
- All plants passed MFDS's GMP audit certification in 2021, and regulatory marketing approval has been obtained.
- Our API manufacturing plant passed the U.S. FDA's pre-license GMP plant inspection in 2021, and regulatory marketing approval has been obtained.
- No critical violation of relevant GxP laws and regulations have been found in external official inspections.
- Results of internal quality audit: A total of 12 internal audits were carried out in 2021, and 43 minor deficiencies were found. No critical or major deficiency was found, and improvement and preventive plans have been drawn up for all 43 minor deficiencies within the deadline.
- No product-quality incident that required reporting to the competent authority has occurred.

Comprehensive Quality and Safety Operation Management and Operation Process Guidelines

PEC's Taichung Plant has a detailed organization and operation chart. It is equipped with sufficient and experienced qualified personnel, and the QA and QC departments of the quality system are responsible for the management and supervision of the manufacturing process. The Company has the internal "Quality Handbook" and over 4,000 related standard operating procedure specifications, and plans and reports, to ensure the quality and safety of products.

4000+

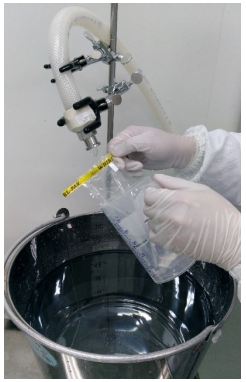
Comprehensive quality related standard operating procedures and various plans and reports

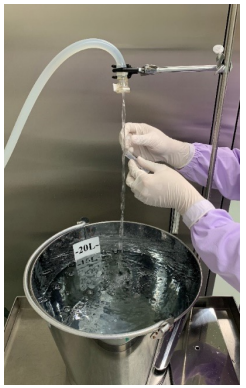
Maintenance of Manufacturing Quality

To ensure that the quality inspection of the environment, raw materials, intermediate products, APIs and finished products of the PharmaEssentia's Taichung Plant are in compliance with Good Manufacturing Practice (GMP) requirements, PEC has established the "Manufacturing and Process Control Procedures" to standardize process control, monitor labeling, inspect and control basic operation procedures. The QA department has implemented layers of controls prior to manufacturing, as well as formulated the "Cross-Contamination Prevention Management Procedures" to oversee the basic operation procedures at the manufacturing areas to reduce the risk of cross-contamination.

Monitoring Environmental Quality

The QC department is in charge of environmental quality monitoring, as well as the quality inspection of the cleanliness of raw materials, intermediate products, active pharmaceutical ingredients (APIs), products, and production equipment. PEC has formulated the "Environmental Monitoring Program Standards," " Water System Monitoring Standards" and "Microbiological Identification and Statistics Standards," etc., to ensure effective monitoring of environmental microorganisms, and timely response measures to greatly reduce the risk of microbial contamination of products. We also conduct trend analysis based on the results from environmental quality monitoring and meet annually to discuss the analysis report. Results of the 2021 monitoring trend report on the production environment (air conditioning), water system, compressed air and biosafety operation cabinet show that all systems meet their respective design requirement and comply with laws and regulations.



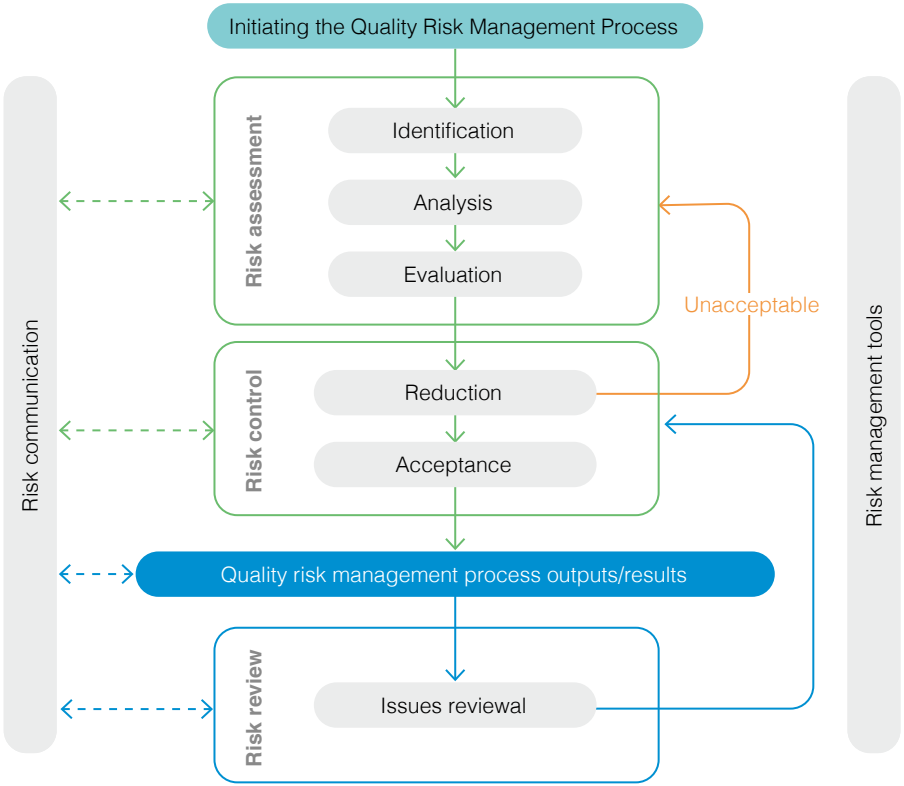


Monitoring personnel perform water system monitoring and sampling, using different fittings according to different water quality sampling points.

Management and Assessment of Quality, Safety and Risk GRI 102-15

Quality risk management is implemented throughout the product's life cycle. PEC's Taichung Plant has formulated the "Quality Risk Management Procedures" in line with ICH Q9. Protect patients' health and effectively control and reduce the risk of patients' drug use through practicing good manufacturing quality risk management.

Flow chart for quality risk management



Risk Assessment and Maintenance of Clinical Trial Quality

The risk assessment of clinical trials is performed by contract research organizations (CROs). In line with regulations from our internal operating procedures, internal and external training regarding trial product safety is held before and during the clinical trial, as well as implementing quality assurance and quality management in clinical trials. Going forward, PEC plans to formulate reasonable drug safety risk assessment SOP that complies with relevant laws and regulations, and to have internal dedicated clinical trial QA staff conduct inspections based on the SOP.

Before clinical trial:
Assessing the degree of risk that may be encountered during the trial process according to the characteristics of the trial drug and the difference in the trial design.

Key points in evaluation

Specific "Monitoring Plan" and "Audit Plan" are developed to perform QA and QC activities based on the levels of risk. Ensure that the rights and welfare of the subjects are protected and that the clinical trial is conducted and the data generated, recorded and reported in compliance with the trial plan, GCP and related regulatory requirements.

Implementation Process

Quality Assurance (QA) activities

Include an independent audit system where problems identified are properly evaluated and tracked, and CAPA is developed.

Quality Control (QC) activities

Include monitoring and assisting in monitoring tasks

Risk Management of Manufacturing Quality

PEC's Taichung Plant has formulated the "Quality Risk Management Procedures" in line with ICH Q9. To reduce the risk of quality hazards when operating equipment, the "Equipment Risk Evaluation Procedures" has also been formulated in line with the regulations on instruments and equipment from the U.S. Pharmacopeia (USP), and conducts categorized risk management accordingly. And the Company has introduced risk management to control the production process, environmental control, material supply and other matters to minimize quality hazards. Besides inspecting the risk issues within the plant via inter-departmental risk assessment team meetings, PEC also meets with global subsidiaries via video conference to coordinate information on quality risk in order to manage and follow-up.

6 sessions

Risk assessment team meetings in 2021

57 attendees

Attendees of the risk assessment team meetings in 2021

8 departments

Inter-departmental participation from Procurement, Supply Chain, QA, QC, Injection plant, Factory Affairs, Manufacturing, and R&D, etc.

5 subsidiaries

Participated by Taiwan headquarters and subsidiaries including the U.S., Japan, Korean, Beijing, and Panco Healthcare

Product Quality Assessment and Continuous Improvement

PEC inspects the validity of the quality management system and GMP compliance through routine internal audits and external audits. PEC has formulated the "Product Quality Review Procedures" and regularly performs product quality evaluation to ensure that the existing manufacturing process and the materials used can consistently produce products that meet our quality requirements. We convene quarterly product quality review meetings to improve quality incidents. Based on the severity of the incident, corrective and preventive actions (CAPA) will also be implemented to ensure the stability and consistency of product manufacturing process and product quality, which will be used as the basis for process improvement and optimization. Moreover, to provide sufficient drug supply to meet the demand in the U.S. Market, control points have also been added to the process and certain specifications of microorganisms have been tightened accordingly.

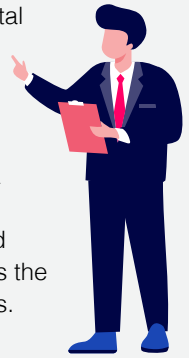
All departments within the Taichung plant will receive at least 1 internal quality audit each year. A total of 12 internal audits were carried out in 2021, and 43 minor deficiencies were found. No critical or major deficiency was found, and improvement and preventive plans have been drawn up for all 43 minor deficiencies within the deadline. In addition, the logistics center of subsidiary Panco Healthcare is also compliant with Taiwan's Good Distribution Practice (GDP) standard and its quality operations have been included in the Group's quality management system. A total of 11 minor quality system deviations were found during the internal quality audit in 2021, and all deficiencies have been properly handled.

Internal audits

- Conducting internal audits at least once every month
- Each department undergo internal audits at least once a year
- For non-conformities in the audit, a CAPA plan must be proposed and related tasks completed within the corresponding prescribed date according to the level of deficiencies.

External audits

- Undergoing governmental GMP inspection every 2-3 years.
- The first protein biopharmaceutical factory in Taiwan to obtain EMA certification.
- The short-, medium- and long-term goal is to pass the regular GMP inspections.



2021 Quality Audit / Factory Inspection / Relevant Verification Records

Audit/Inspection/ Verification Date	Audit/Inspection/ Verification Department	Audit/Inspection/Verification Process, Key Observation Items	Audit/Inspection/ Verification Results
2021/04/07~ 2021/04/09	TFDA	Routine GMP/GDP Inspection for active pharmaceutical ingredients (APIs) and Biological medical product (injection fluids)	Extended GMP certification
2021/09/20~ 2021/09/28	U.S. FDA	Pre-License Inspection for active pharmaceutical ingredients (APIs)	Obtained GMP certification
2021/1~ 2021/12	Internal audits	A total of 12 internal audits were carried out in 2021	Completed all

GMP/GDP Quality Training at the Production Plant

Through providing annual training courses, we instill the philosophy of quality management into the day-to-day operations of all relevant personnel. In addition to internal training, PharmaEssentia also appoints colleagues to participate in external trainings sponsored by related domestic and foreign academics/associations, and hires senior foreign consultants to visit the factory every year to update the knowledge of GMP or laws and regulations.

Statistics on Good Manufacturing Practice for Medicinal Products (GMP) Training in 2021

Training topic	Sessions	Participants	Training hours
GMP training in 2021	10	789	7,890
Regulation, manufacturing or new employee quality-related GMP training	28	503	14,084
Prevention and correction training	68	928	31,552
External training	13	14	1,092
Total	119	2,234	54,618

3-4 Excellent Manufacturing and Production

Advanced and High Standard Plant Equipment

The three main facilities of PharmaEssentia Taichung Plant: Polyethylene Glycol (PEG) production factory, Drug Substance (DS) manufacturing plant, and sterile agent filling plant. Our Taichung Plant is the first biopharmaceutical plant in Taiwan to pass the EU's EMA inspection and obtain Good Manufacturing Practice (GMP) certification. The sterile agent filling plant also obtained GMP and GDP certification from TFDA in April 2020, and passed MFDS GMP audit in January 2021 and U.S. FDA plant audit in September 2021. In addition to external inspections, PharmaEssentia's Taichung Plant also completed 12 internal audits in 2021, with investment of approximately NT$20 million toward repair and maintenance as well as acquisition of new equipment to ensure the high quality of drug manufacturing process.

The U.S. FDA conducted on-site audit at Taichung Plant in 2021

Three Main Facilities of PharmaEssentia

PEG Production Factory

Sterile Agent Filling Plant

DS Manufacturing Plant

Passed EU EMA plant inspection

(certification extended)

Passed MFDS audit

(new)

Sterile Preparation Filling Plant passed TFDA plant audit

(certification extended)

Passed the U.S. FDA onsite audit

(new)

Manufacturing Process with International Standards

Our product, Ropeginterferon alfa-2b (P1101), is manufactured in four major steps. API is manufactured first, followed by the filling and packaging process. All steps strictly comply with GMP regulations and international standards of quality management and standard operating procedures.

1 Fermentation process and cellular treatme

- Manufacture interferon

Fermentation tank

2 Extraction and purification of Pro-IFN alfa-2b (P1040)

- Remove impurities through purification process

Purification system

3 PEG chemical modification

- Chemical reaction between PEG and interferon creates the intermediate product of Ropeginterferon alfa-2b (P1101)

PEG & PEGylation system

4 Purification of Ropeginterferon alfa-2b(P1101)

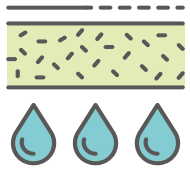
- Produce Ropeginterferon alfa-2b(P1101) API and enter into injection preparation and packaging process

Protein purification process

The Taichung plant's emergency response mechanism is implemented in accordance with the "Emergency Response Management Standards for Plant Facilities." When incidents that may cause harm to the factory due to natural disasters and equipment abnormalities occur, they can be handled correctly and effectively to ensure the normal operation of the equipment and all personnel can operate in a safe and secure working environment.

The Highest Quality Aseptic Filling and Packaging Process

After Ropeginterferon alfa-2b (P1101) goes through the aforementioned 4 steps, the filling and packaging operations are carried out based on market demand. The Company's injection filling and packaging operations can be divided into 3 stages: dispensing and sterile filtration, sterile filling, and labeling and packaging. As products that have not been fully sterilized could cause serious harm to patient health, we rigorously implement aseptic operations in our drug production processes.



1. Dispensing and aseptic filtration

The high-concentration API Ropeginterferon alfa-2b (P1101) is adjusted and diluted, and the sterile is filtered before filling

2. Aseptic filling

Filling with fully automatic prefilled syringe. Filled products are put into storage after performing 100% appearance inspections.

3. Labeling and packaging

Placing the label on the pre-filled syringe, and placing the relevant package inserts, plungers, finger flanges, and needles together into the box.

Improvement of the Next Generation Manufacturing Process

In addition to maintaining the process and product quality with high-quality equipment, professional personnel, internal and external inspections, and other mechanisms, we also continuously optimize and improve the process to reduce manufacturing process risks and improve its success rate.

Manufacturing Processes	Improvement Objectives	Results and Benefits
Fermentation	Increase yield of E. coli production.	Feeding into the fermentation tank after pre-cultivation increase the time efficiency by 23% and yield by around 5.2%.
Purification	Reduce the risk of process contamination.	Changed the process from "open operation" to "closed operation" to improve process stability and increase process success rate.

Outsourcing Manufacturing Management

PharmaEssentia's US injection filling CMO

Passed FDA inspection

Due to different market needs, on top of undertaking filling and packaging operations at our Taichung Aseptic Preparation Filling Plant, we also outsource the filling and packaging procedures to American and German CMO plants in order to supply to the local patients. To ensure that the operations performed at the outsourced production sites comply with the GMP specifications and PEC's standards, all CMO plants are verified by our suppliers. And they may only begin the outsourced filling and packaging operation after they have been determined to be qualified vendors by our QA department. Regarding CMO supplier management, in addition to the initial supplier evaluation mechanism, we also regularly monitor the service quality of such suppliers to maintain conformity to the highest quality requirements. Pyramid Laboratories Inc., a US injection filling CMO, has successfully passed the FDA inspection in early 2021 with no critical or major deficiency.

3-5 Safe and Stable Transnational Logistics and Transportation

Inventory Shipping and Sales Operation System

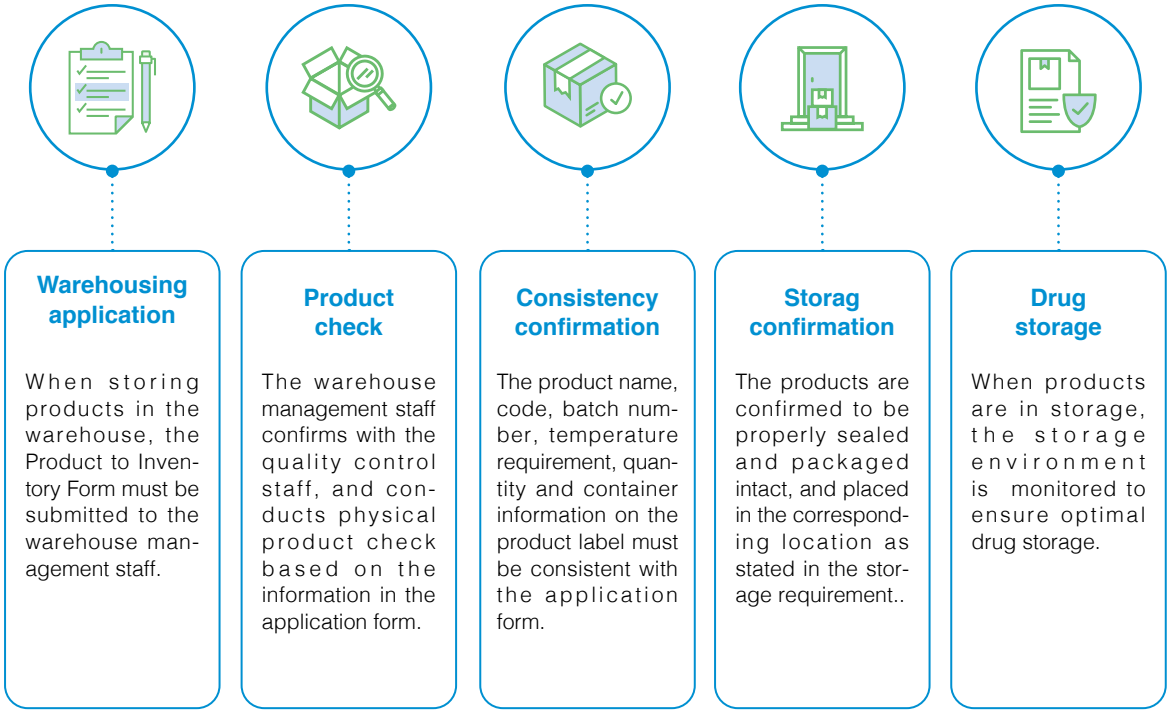
PEC has formulated an internal "Storage and Transportation Policy" to establish storage and transportation procedures to ensure that all raw materials, intermediate products, and products are stored in a good storage environment and management. In addition, we have established the "Product Distribution Management Procedures" to establish the distribution procedures and tracking mechanism in compliance with PIC/S Good Distribution Practice (GDP) requirements. The aforesaid procedures also specify that the product-receiving units, including the outsourced filling and packaging suppliers, medical institutions or distributors, are required to pass our evaluation processes. Furthermore, we have established the "Import, Export and Transportation Management Procedures" to establish the procedures for import, export and transportation so that the goods can be delivered to the designated destinations in a compliant, fast and safe manner to protect the drug use safety of the patients.

The logistics center of subsidiary Panco Healthcare also meets the Good Distribution Practice (GDP) requirements, and is mostly involved in facilitating the Group's product launch and clinical drug supply. To ensure the management over drug distribution chain in order to maintain the quality and completeness of drugs when the users receive them, more than 60 standards have been formulated to regulate various processes from logistics management, warehousing management, processing and labeling, to the quality management of each operating process. A wireless centralized temperature and humidity monitoring system has been established in 2021 to enhance the environmental quality of product storage. Meanwhile, we also upgraded our information management hardware and software and built a machine room. Additionally, the documents and information are not only stored locally, but offsite backup has also been established to ensure the safety and completeness of the information.

Warehousing Management

Regarding the storage management of intermediate products, API and drugs, the "Standard Operating Procedure for Warehousing and Storage Management" has been formulated to ensure product quality will not be affected by environment. From Taichung Plant, the storage facilities and equipment within the plant, to the suppliers and equipment used for transportation, as well as outsourced suppliers, all must be verified by our QA department to ensure that the quality of their services meet the current GMP regulations.

Product inbound and storage operation flow



Quality Control of Shipment and Transportation

For the shipment of API products and pharmaceutical products, we have established the "Product Shipment Standard." The scope of its application includes the operation of shipment from the Taichung plant of PharmaEssentia, or the packaging before transportation from the Taichung plant to the contracted manufacturing factories / storage factories.

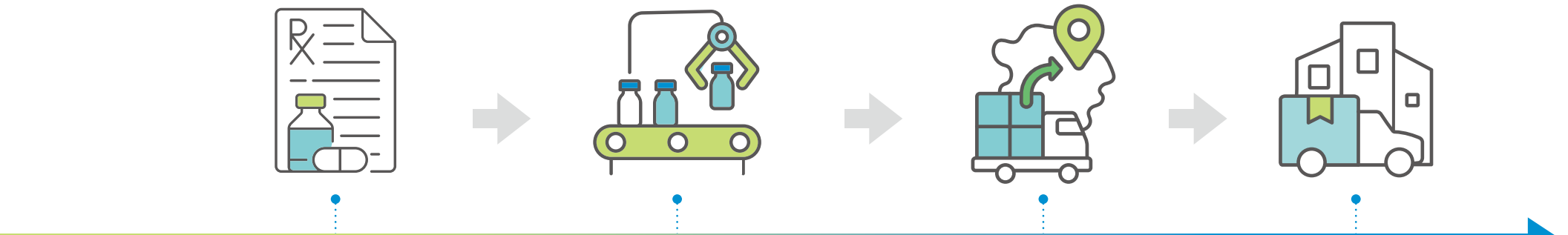
Quality monitoring during packaging procedure

- Warehousing management personnel will confirm the cleanliness and temperature within the transportation box meet the product storage criteria, and to place a thermograph within the transportation box to monitor its temperature.
- In the case of Ropeginterferon alfa-2b(P1101), the product needs to be stored within a temperature range of 2° C~8° C

Quality monitoring during transportations

- Product distribution is regulated through “Storage and Distribution Policy”, which aims to formulate proper storage and distribution procedures.
- Simulation analysis will be conducted prior to actual transportation to confirm refrigeration conditions and the necessary equipment.
- Implement regular audits to ensure that all raw materials, intermediate products, and products are stored in good distribution environments.

Stable and Safe Distribution at the U.S. Market



3-6 Effective Pharmacovigilance and Recall Mechanism

Persisting in our rigorous requirements on drug quality, we commit to constantly maintaining thorough and comprehensive pharmacovigilance system. A "pharmacovigilance mechanism" has been enacted in 2021 to continuously conduct safety monitoring and risk control over the new drugs after product launch. We also jointly coordinate the pharmacovigilance tasks of various countries or regions with our subsidiaries and local physicians and pharmacovigilance personnel to ensure that pharmacovigilance and reporting are implemented in line with the local laws and regulations. PEC will continue to establish a comprehensive pharmacovigilance system and continuously optimize drug safety-related policies and internal standard operating procedures to safeguard patient health and safety. Please refer to Chapter 3, Section 3.3 on the material topic management over "Drug Quality and Safety Management" for relevant management measures and policies.

Global Pharmacovigilance System and Reporting Process

SASB | HC-BP-250a.1~a.5

The scope of PEC's pharmacovigilance includes the collection of adverse reaction events and the evaluation of such events, safety signal detections and problem analysis. Subsequently, hazardous factor analysis, risk assessment, and initiation of preventive measures and management will be executed. To understand whether drug safety problems have occurred during post-marketing large-scale clinical patients' use, besides complying with the Regulations for Reporting Severe Adverse Reactions of Medicaments in Taiwan, PEC has also commissioned CROs to establish a pharmacovigilance mechanism, and formulate standard operating procedures that shall be practiced when concerns regarding drug safety arise. We also commit to complying with international pharmacovigilance standards and the Pharmaceutical Affairs Act, Regulations for Drug Safety Monitoring, and Regulations for Reporting Serious Adverse Reactions of Medicaments of Taiwan.

Organizing a Pharmacovigilance Funtion team

The headquarter collects information regarding drug safety and compiled it into the "Periodic Safety Update Report (PSUR)," and report relevant issues.

Building a cross-country Safety Database

Collecting various post-marketing safety information through CROs to establish a multinational integrated Safety Database.

Formulating drug safety notification procedure

If we receive any problems related to the safety or drug use from the hospital, CROs and subsidiaries around the world are required to report to the Pharmacovigilance team at the headquarter and take the initiative to notify the health authorities in accordance with local regulations. The goal is to provide prompt follow-up treatment within the shortest possible time.

Set up an adverse reaction notification mailbox

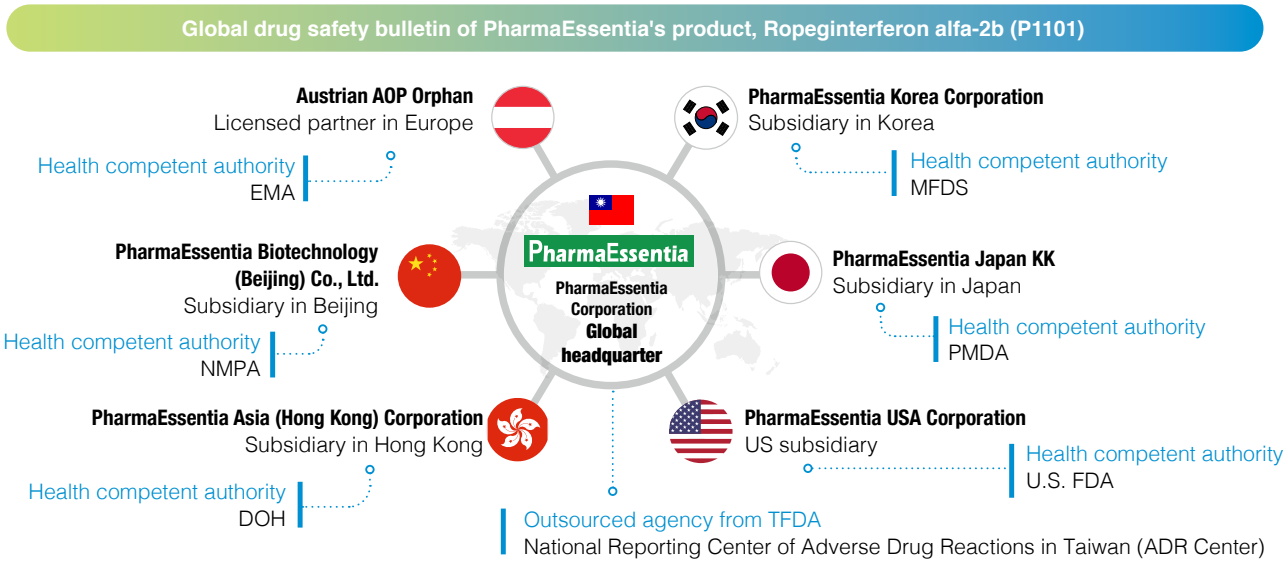
Taiwan headquarter has set up an adverse reaction notification mailbox: Safety@pharmaessentia.com

CRO sets up global adverse drug reaction notification mailbox: PharmaEssentia.drugsafety@labcorp.com

Mechanism for Reporting Adverse Reactions in Taiwan

In a case a severe adverse reaction has occurred from general use of post-marketed drugs, the event could be reported using the following methods:

1. A medical personnel (medical institution or pharmacy) and a member of the public will jointly fill "Form of Reporting Post-marketing Adverse Response to Medicament" and report the form by registering for an online account or emailing it to adr@tdrf.org.tw
2. A drug distributor will fill a "Statement of Medicament License-holding Supplier or Contracted Agency Application Procedures and Liability Management" and report the form by registering for an online account on reporting center.
3. After PEC receives a reported incident, generally, we will report it online via the online reporting system (https://adr.fda.gov.tw) in line with the "Guidelines to Filling the Post-marketing Adverse Response Reporting Form", or email a completed form to the mailbox of ADR Center (adr@tdrf.org.tw).
4. Panco Healthcare did not have any reported adverse response incident to the Ropeginterferon alfa-2b (P1101) that was launched in Taiwan in 2021 or any other medicament.



Drug Safety Reporting Training

In accordance with drug safety regulations, PharmaEssentia entrusts its CROs to develop and implement drug safety management and regulatory unit reporting programs, and holds regular employee drug safety reporting training and maintains all training records. In 2021 we held the company-wide annual employee drug safety reporting training, and all new employees underwent the employee drug safety reporting training within one month after onboarding. 2022 goal is to reach 100% completion rate of pharmacovigilance training for new employees.

Internal/external training	Type	Description
Expatriate training	Domestic training	The department prepares the budget for education and training, and employees can choose to attend drug safety training courses/seminars organized by domestic organizations.
	Foreign training	In order to absorb foreign drug safety knowledge, skills and training talents, the company will, depending on practical needs, assign personnel to participate in education and training courses organized by foreign institutions.
Internal training	Pre-employment training	Conduct training related to drug safety reporting and record training hours and course information when new employees are on board.
	Other trainings	To enhance employees' professional knowledge and skills in drug safety, we conduct annual training on drug safety reporting.

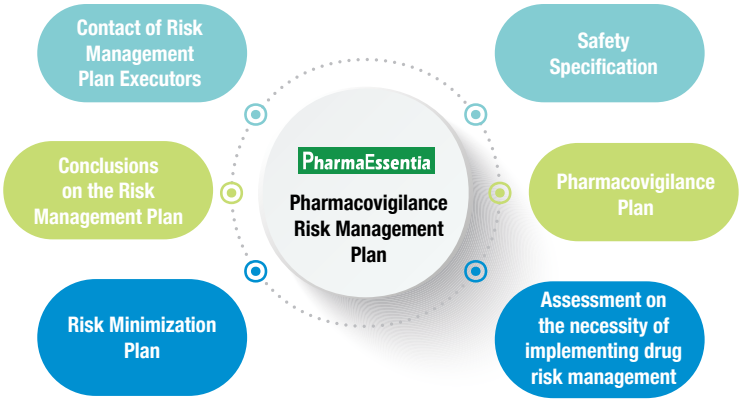
Pharmacovigilance System

In 2021, PEC's Taiwan headquarters has established the pharmacovigilance team, which directly reports to the Medical Research department. The team coordinates with other relevant departments and engages in relevant procedures in line with the "Pharmacovigilance Policy", "Standard Operating Procedures for Drug Safety, Functions, and Training", and "Standard Operating Procedures for Post-market Safety Data Collection".

To meet the relevant laws and regulations on pharmacovigilance and reporting from marketed countries or regions, PEC has set up dedicated physicians or pharmacovigilance personnel to be in charge of relevant tasks at our Taiwan headquarters and subsidiaries in the U.S., China, Japan, Korea, Hong Kong, and Singapore to ensure the thorough executions of global pharmacovigilance data collection and reporting tasks. In addition, we have also commissioned international contract research institutions (CROs) to report relevant incidents in line with regulations from the competent authorities at respective country. Our safety information database has been completed in 2020 and continues to operate and receive safety reports from countries around the world where we market our products. Responsible personnel from the headquarters and subsidiaries also convene routine meetings with the CROs either weekly or bi-weekly to ensure that the CROs are submitting routine safety reports in line with relevant laws and regulations in practice. In 2021, 32 meetings were convened to monitor and manage the pharmacovigilance system. We submitted the second Periodic Safety Update Report (PSUR) of BESREMi® to TFDA in May 2021, and will continue to provide PSUR to TFDA in accordance with regulations until the surveillance period expires in 2026.

Pharmacovigilance Risk Management Plan

We actively take the initiative to identify known risks, detect potential risks, and continue to track major deficiencies in the safety of marketed drugs, ensuring the safety of drug users and formulating comprehensive drug risk management. At this stage, in terms of the safety risk evaluations of marketed drugs, PEC will adopt the drug safety risk SOPs formulated by CROs, and commission the CROs to draft risk management plans accordingly. In terms of the Taiwanese market, PEC will formulate the "Drug Risk Management Plan" in line with requirements from the competent authority, and we will also formulate relevant plans in line with the requirements from competent authorities at countries or regions that we market to. After the drugs are marketed, we will collect actual clinical data to evaluate whether chronic side effects will develop after long-term use of the drug, and such data will serve as the basis for the "Drug Risk and Benefit Evaluation." Results from the Periodic Safety Update Report (PSUR) in 2021 indicated that no new safety information that may affect the safety of BESREMi® has been found. We will continue to collect safety information of BESREMi® at countries where it is marketed, and such information will be used to update the PSUR and to evaluate the risk and benefits of BESREMi®.



Product Traceability Mechanism

SASB | HC-BP-260a.1

In order to ensure the traceability of pharmaceutical products, PharmaEssentia has established a product traceability mechanism for the global supply chain, and has formulated the "Product Code and Batch Number Coding Procedures" and "Batch Record Review and Product Release Procedures," which detail the material number, lot number and factory activity records of each batch of pharmaceutical products to ensure the basic principles of product batch number coding such as lot flow and traceability, as well as the operational procedures for product lot release. We also actively deploy drug serialization mechanisms, and the internal "Product Secondary Packaging and Serialization Batch Record" has been formulated to regulate the operation process of commercial packaging and serialization of products by overseas OEM plants, so that the flow and usage records of individual products can be fully traced even for large quantities of products. Drug serialization has been completed in 2020 for the BESREMi® marketed in the U.S., in which Pyramid Laboratories Inc. will be responsible for the packaging and serialization of pharmaceutical products to comply with relevant regulations from the U.S. FDA's Drug Supply Chain Security Act (DSCSA).

Drug Recall Mechanism

SASB | HC-BP-260a.2

PharmaEssentia has established a comprehensive drug recall mechanism by incorporating a product traceability system. When concerns regarding product quality arises, the drug can be recalled quickly and effectively, thereby providing an extra layer of protection for patients' drug use safety. Drug recall simulations are also organized every year to ensure the accuracy and proficiency of recall operations. No adverse drug recalls have occurred in 2021.

When to start	When the product has known or possible manufacturing defects, deterioration, counterfeits or any other serious quality problems.
Recall procedure	QA department initiates the recall procedure in accordance with the Procedure for Return and Recall and proposes the "Recovery Plan Application Form" to initiate actions.
Report to competent authorities	According to the hazard level of drugs, we remove the drugs from the user-end within a certain period, properly dispose of the recovered product, and notify the local competent authority.

Chapter 4

Human Capital Management

Chapter 4: Summary of 2021

Highlights

High-performing human capital is the cornerstone to a company's sustainable management and the key to its pursuit of excellence. Founded on our human-centric philosophy, PEC provides well-rounded benefits system, enriched and diverse learning resources and training courses, as well as a competitive salary system to enhance our employees' core competencies and our corporate competitiveness, thereby attracting professional talents from the biotechnology industry to form a high-quality team at PEC. Over the past three years, we have successfully created a safe, healthy, and happy workplace environment for our employees through maintaining an excellent record of zero occupational accidents.

Relevant Material topics

Attraction and Retention

Human Rights

Relevant stakeholders

Employees

Shareholders and Investors

Suppliers and Business Partners

Local Community

Performance Highlights

91%

Average retention rate of PEC Taiwan

69%

Nearly 70% of our employees hold Master's and PhD degrees.

Gender-balanced

Equivalent number of male and female employees in Taiwan.

100%

Completion rate of employee performance assessment.

49%

Nearly 50% of PEC Taiwan employees have been working with us for more than 5 years.

100%

Employee reinstatement and retention rate after parental leave.

NT$2.52 million

Total employee benefit expense in Taiwan.

100%

Implementation rate of maternal health protection program in Taiwan.

0 occupational accident

58+ sessions
252 participants

Internal and external occupational safety and health staff training in Taiwan.

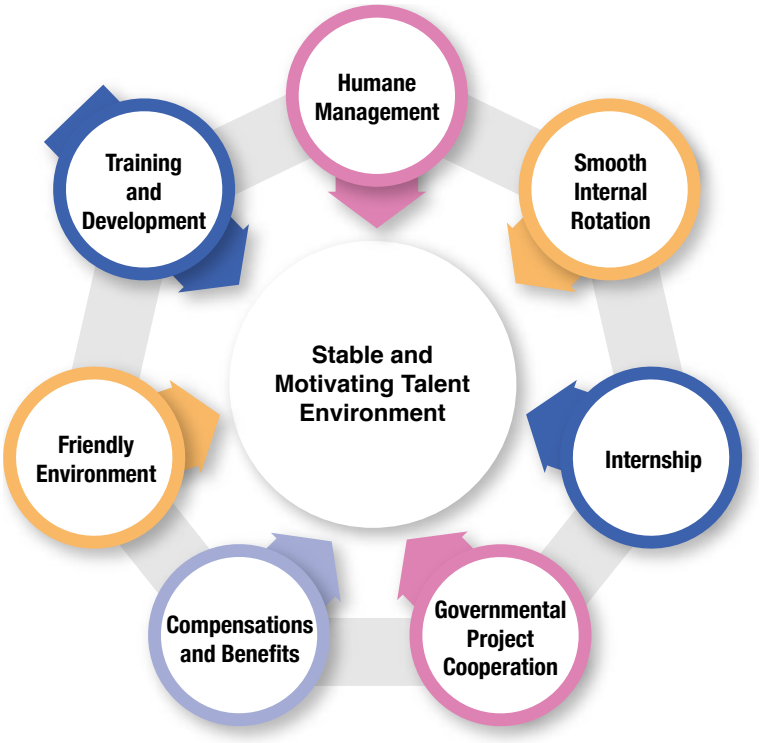
4-1 A Happy Workplace

Creating a Stable and Inspiring Environment for Employees

To formulate a work environment conducive to stable retention, we strive to inspire the developments of internal staff through various systems. We understand employees' expectations through referring to Global Culture Report and routine new employee feedback survey to strive for improvement. In addition, we systematically develop and attract external talents to join us through corporate internships, government projects, etc

.

We set up subsidiaries all over the world. The workforce structure in Taiwan and the U.S. also highlights the three main characteristics of our human resources: globalized operations, localization recruitment and promotion, gender equality and inclusion, and stable retention of talented people. Our U.S. Subsidiary currently has 75 employees engaged in various functions, ranging from marketing and product sales, medical research, clinical trials, administrative management, and business management.



91%

Average retention rate of PEC Taiwan is over 90%

Gender-balanced

Equivalent number of male and female employees in Taiwan.

High retention rate

Nearly 50% of senior employees with more than 5 years of experience in Taiwan headquarter

GRI | 102-8 GRI | 202-2 GRI | 405-1

Manpower Structure of Taiwan in 2021

Category	Sub-category	Male		Female		Total	
		Number of person(s)	As a percentage of sub-category	Number of person(s)	As a percentage of sub-category	Number of person(s)	As a percentage of total employees
By job type	R&D	31	48%	34	52%	65	30%
	Manufacture and production	61	54%	53	46%	114	53%
	Administrative	10	26%	28	74%	38	18%
By position (Note 1)	Operational management directors (Vice President and above)	3	75%	1	25%	4	2%
	Senior-level supervisors (department directors and above)	9	60%	6	40%	15	7%
	Middle-level supervisors (managers and above)	13	48%	14	52%	27	12%
	Junior-level supervisors (team leaders)	15	63%	9	38%	24	11%
	Staff level	62	42%	85	58%	147	68%
By age	< 30 (incl.)	10	37%	17	63%	27	12%
	30 - 50 (incl.)	78	48%	86	52%	164	76%
	> 51 (incl.)	14	54%	12	46%	26	12%
By educational background	PhD	21	64%	12	36%	33	15%
	Master's	56	46%	67	54%	123	57%
	Bachelor	22	42%	30	58%	52	24%
	Others	3	33%	6	67%	9	4%
By seniority	< 1 year	11	39%	17	61%	28	13%
	1 – 3 years	21	45%	26	55%	47	22%
	3 – 5 years	13	42%	18	58%	31	14%
	5 – 10 years	45	55%	37	45%	82	38%
	10 – 20 years	13	43%	17	57%	30	14%
Total (Note 2 -3)		102	47%	115	53%	217	100%

Note 1: Among the positions, middle-level managers and above refer to senior managers. The ratio of local recruitment has reached 89.5% (of the19 persons, 17 are local residents), and the data do not include Panco Healthcare or other PEC subsidiaries.
Note 2: All employees of PEC headquarters are full-time employees (indefinite contract employees) and full-time contract workers (work at PEC for at least 40 hours per week).
Note 3: As of December 31, 2021, PEC headquarters has 2 physically or mentally disabled employees, and the weighted number of disabled employees amounts to 3.

Manpower Structure of Panco Healthcare in 2021

Category	Sub-category	Male		Female		Total	
		Number of person(s)	As a percentage of sub-category	Number of per-son(s)	As a percentage of sub-category	Number of person(s)	s a percentage of total employees
By job type	Manufacture and production	6	55%	5	45%	11	69%
	Administrative	2	40%	3	60%	5	31%
By position (Note 1)	Operational management directors (Vice President and above)	0	0%	1	100%	1	6%
	Senior-level supervisors (department directors and above)	0	0%	0	0%	0	0%
	Middle-level supervisors (managers and above)	1	33%	2	67%	3	19%
	Junior-level supervisors (team leaders)	2	100%	0	0%	2	13%
	Staff level	5	50%	5	50%	10	63%
By age	< 30 (incl.)	1	33%	2	67%	3	19%
	30 - 50 (incl.)	7	64%	4	36%	11	69%
	> 51 (incl.)	0	0%	2	100%	2	13%
By educational background	PhD	1	100%	0	0%	1	6%
	Master's	2	50%	2	50%	4	25%
	Bachelor	5	46%	6	54%	11	69%
	Others	0	0%	0	0%	0	0%
By seniority	< 1 year	0	0%	2	100%	2	13%
	1-3 year	2	50%	2	50%	4	25%
	3-5 year	5	71%	2	29%	7	44%
	5-10 year	1	50%	1	50%	2	13%
	10-20 year	0	0%	1	100%	1	6%
By contracts	Full-time job	8	57%	6	43%	14	88%
	Part-time job	0	0%	2	100%	2	13%
Total (Note 2)		8	50%	8	50%	16	100.00%

Note 1: Among the positions, middle-level managers and above are senior managers.
Note 2: All employees of Panco Healthcare are full-time contract workers (work at PEC for at least 40 hours per week).
Note 3: At the end of 2021, Panco Healthcare has not had current physically or mentally disabled employees.
Note 4: The complete HR capital data only includes PEC HQ and Panco Healthcare, and do not include other foreign subsidiaries. The total number of employees disclosed was 109 persons.

New Hires and Retentions SASB | HC-BP-330a.1~a.2

To meet the milestone of globalization and continuous development of innovative new drug research and development, PEC has been recruiting talents from biomedical, R&D, medical and clinical fields, and those with expertise in globalized management. We select employees based on their skills and core competence and we use diverse and openness recruitment channels in the spirit of non-discrimination and fair treatment to select suitable candidates. The amount of employees have steadily grown over the past three years. To stimulate organizational revitalization and cultivate a wide range of talents, when new business needs arise or important job vacancies arise, we will also give priority to staff rotation evaluation. For resigning employees, supervisors are required to interview with each resigning employee to understand the reasons and room for improvement. Building talent retention programs, reduce the turnover rate and stabilize the continuous retention of outstanding talents.

Growth rate of employee numbers of Taiwan headquarters in the recent 3 years

2019	2020	2021
9.04%	4.15%	7.96%

Note 1. Growth rate of employee number = (employee number at current year-end - that at prior year-end) ÷ employee number at prior year-end

New regular hires and employee turnover of Taiwan headquarters and Panco Healthcare in the most recent 3 years GRI | 401-1

Category	2019				2020				2021			
	New hires		Employee turnover		New hires		Employee turnover		New hires		Employee turnover	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
< 30 (incl.) of age	5	5	-	3	4	5	2	2	5	8	1	1
30 - 50 (incl.) of age	17	6	11	4	8	13	12	6	8	13	10	5
> 51 (incl.) of age	-	-	1	1	3	3	2	1	1	2	3	0
Total	22	11	12	8	15	21	16	9	14	23	14	6
Percentage of new hires to employee turnover	11.96%	5.98%	6.52%	4.35%	7.35%	10.29%	7.84%	4.41%	6.24%	10.24%	6.24%	2.67%

Note 1. The data from 2019 does not include the subsidiary Panco Healthcare.
Note 2. Percentage of new hires = 2021 accumulated new hires ÷ (employee number at the beginning of period + end of period) / 2.
Note 3. Percentage of resignees = 2021 accumulated resignees ÷ (employee number at the beginning of period + end of period) / 2.

Global Recruitment Strategies -

Recruitment in the United States

As an industry requiring extensive knowledge and experience, employees are our most valuable assets. Besides formulating a comprehensive talent system in Taiwan HQ, for our U.S. subsidiary, we have also formulated a specific employee system and benefits handbook which elaborates our commitment and protection of the employees.

Fair Employment and Recruitment

We provide equal opportunities to all and do not factor in a person's race, religion, skin color, gender (including pregnancy, sexual orientation, or gender identity), nationality, disability, age, hereditary information, or any other status protected by Federal, state, or local laws. We strictly abide by our commitment to equal employment principles and anti-discriminations policy. When recruiting new employees, besides factoring in abilities and experiences, we also encourage employees to file applications and to recruit new talents for us. We gladly provide referral bonuses to eligible employees.

Employees Performance Evaluation and Promotional System

PEC has formulated a systematic performance management system that conducts performance evaluation on an annual basis. The salary adjustments and promotions of employees are determined by their work performance, attendance, quality of work, ability to work independently, attitude, coordination skills, incentives/disincentives given, and the ratio of their overall performance improvements.

Employee Care Policy

Besides specifying the implementation of various employee care policies, including telephone communications, rules on smoking, realizing a workplace environment with no drug abuse, drug abuse management, and rules on safety and accident prevention, we have also formulated policies on workplace violence preventions and promise to thoroughly investigate any violent conduct against employees when employees are fulfilling their duties. We also adopt proper response measures, including accepting legal investigations at proper times to build a safe and reliable workplace environment.

Anti-discrimination and Anti-harassment

PEC commits to providing employees with a work environment that is fair, respectful, and dignified, and we respect all basic human rights of our employees. To honor this promise, PEC adopts a zero-tolerance policy against employee harassments. We clearly follow anti-discrimination, Pregnancy Discrimination Act, and the Americans with Disabilities Act to safeguard the provision of a quality work environment. We have formulated comprehensive handling procedures against workplace harassments, and we prudently handle sexual harassment reports. Internal grievance channels and comprehensive investigation mechanisms have been established and punitive measures are included to root out such conduct. In addition, we also provide remedies to employees to truly build a friendly work environment in practice.

Competitive Compensation and Benefits

PEC is very open about our compensations system such as salary levels, taxes and insurance deductions, and descriptions of salaries and benefits. Comprehensive benefits standards that specify general benefits, medical insurance, health insurance system, pension plan, employee relief system, labor insurance, and business travel system, have been formulated, so that all employees can clearly understand their rights and benefits. In terms of leaves, on top of the general personal leave, sick leave, and funeral leave, we have also formulated religious activity leave, annual leave, paid sick leave, paid leave, military leave, and civil duty leave (e.g., jury duty, serving as a witness, or elections) and flexible work hours for nursing mothers, to care for our employees' physical and mental well-being.

4-2 Competitive Compensation and Benefits

Competitive and Fair Salary System

PharmaEssentia is equal towards all employees, and the overall salary does not vary regarding differences in gender, religion, race, nationality, or party affiliation. To stay on top of the biotech job market and to both retain high-performing staff and attract external talents, we also commissioned external consulting companies to research about the average compensations and benefits standard in the industry. Each year, based on the achievement of the Company's annual management goals, the individual's annual performance appraisal and the external salary and benefit survey, performance pay adjustment, promotion pay adjustment and structured pay adjustment are conducted respectively to provide salaries that are better than the industry level. To encourage employees' long-term retention and boost employee cohesion, we also provide profit-sharing mechanisms such as employee stock options, issuance of new restricted employee shares treasury shares transfers or cash capital increase by issuance of new employee shares to motivate employees to co-create innovations and operating performance, as well as to create long-term value with PEC.

Ratio of remuneration and compensation of male employees compared to female employees in 2020 of Taiwan headquarters (Note)

GRI | 405-2

Type		Compensation	Remuneration
Management	Operational management directors (Vice President and above)	1	0.95
	Senior-level supervisors (de-partment directors and above)	0.98	0.94
	Middle-level supervisors (managers and above)	1.2	1.92
	Junior-level supervisors (team leaders)	1.33	1.38
Non-managerial employees	Staff level	1.04	1.18

Note : Compensation refers to monthly salary, while remuneration is compensation plus bonus.

Over the past three years, the total salary and average salary of our full-time employees who are not in supervisory positions (excluding managers) have increased significantly, which is an exemplary of our salary incentive for mid-tier and advanced talents and personnel who have received promotions, as well as our continuous salary increase for our junior staff.

Information on salary of 2019~ 2021 non-managerial full-time employees of Taiwan headquarters

Year	2019	2020	2021	Changing rate between 2021 and 2020
Amount of employee	168	181	198	+9.4%
Total Salary	175,752	196,378	228,391	+16.3%
Average Salary	1,046	1,085	1,153	+6.3%
Median	857	853	918	+7.6%

Note 1: The information in this table has been audited by Ernst & Young.
Note 2: The denominator of “Average Salary” is the number of non-managerial employees, which is a weighted average of the proportion of monthly salary.

Information on salary of 2021 non-managerial full-time employees of Panco Healthcare(Unit: NT$ thousands)

Total Salary	17,486
Average Salary	1,142
Median	700

Diversified Benefit System GRI | 201-3 GRI | 401-2

PEC established the Employee Welfare Committee in 2013. The committee regularly convenes 4 times in each year, and PEC joins the committee in planning many employee benefits and welfare activities. In 2021, the total expenses for employee benefits for Taiwan headquarter and the subsidiary, Panco Healthcare, amounted to NT$2.52 million, with a total of 473 claims for various types of benefits.

Competitive salary system

- Holiday bonuses
- Project bonuses
- Employee stock options

Comprehensive insurance plans

- Labor insurance
- Health insurance
- Group insurance
- Overseas business travel insurance

Marriage and childbirth care

- Kindergarten cooperation plans
- Leaves related to pregnancy and childbirth, and unpaid parental leaves
- Nursing room establishment
- NT$6,000 maternity allowance per child

Flexible vacation system

- Flexible working hours
- Comprehensive vacation system (partly better than the Labor Standards Act)

Retirement protection and benefits

- For the employees under the old pension system, 2% of their monthly salary is deposited into the old retirement reserve account of the Bank of Taiwan on a monthly basis.
- After the implementation of the new pension system, the Company allocates 6% of individuals' monthly salary to their pension accounts on a monthly basis according to the pension level of employees.
- Retirement farewell dinner party.

Overall employee care

- Health examination
- Weight loss activities
- Massage
- Unpaid leaves
- Health seminars
- Commendation to excellent employees
- Special store offer
- Free taxi rides for evening shifts

Diverse employee activities

- Department dinner
- Club Activities
- Sports activities
- Employee travel

Note: This table does not include the compensations and benefits for the U.S. Subsidiary. Please refer to Section 4.1 Recruitment in the United States for details on the benefits system in the U.S.

Table of employees applying for unpaid parental leave in the past 3 years GRI | 401-3

Year	2019			2020			2021		
Item	Male	Female	Total	Male	Female	Total	Male	Female	Total
Number of employees qualified to apply for unpaid paternity leave in the given year (A)	24	15	39	23	11	34	18	16	34
Actual number of employees applied for unpaid paternity leave in the given year (B)	1	6	7	-	5	5	0	5	5
Unpaid paternity leave appli-cation rate (B/A*100%)	4%	40%	18%	0%	45%	15%	0%	31%	15%
Number of employees antici-pated returning to work after unpaid paternity leave in the given year (C)	1	5	6	-	3	3	0	4	4
Actual number of employees that return to work after the unpaid paternity leave in the given year (D)	1	3	4	-	3	3	0	4	4
The rate of return to work after the unpaid paternity leave (D/ C*100%)	100%	60%	67%	-	100%	100%	0%	100%	100%
Number of employees that returned to work after unpaid paternity leave in the previous year (E)	-	2	2	1	3	4	0	3	3
Number of employees that returned to work who contin-ued to work for one year after the unpaid paternity leave in the previous year (F)	-	2	2	1	3	4	0	3	3
The retention rate for parental leave (F/E*100%)	-	100%	100%	100%	100%	100%	0%	100%	100%

Note: The data in this table cover Taiwan headquarters and subsidiary Panco Healthcare.

4-3 Human Rights Protection

Human Rights Management Approach

Materiality Topic

GRI | 103-2~3

Policies

Internal Policy

PEC's "Human Rights Policy"
"Corporate Social Responsibility Best Practice Principles"

External Guidelines

1. UN Global Compact, "Universal Declaration of Human Rights"
2. "Declaration on Fundamental Principles and Rights at Work"

Commitments

- We commit to protecting the fundamental human rights of all PEC employees. We formulate an environment that protects human rights and privacy and identify with and support various international human rights treaties including the Universal Declaration of Human Rights, UN Global Compact, and ILO Declaration of Fundamental Principles and Rights at Work. In addition, we request all vendors that we have business dealing with to prohibit any conduct that infringes or violates human rights throughout all operating activities, so that all internal and external members of PEC could receive fair and respectful treatment. Furthermore, relevant information and communications security maintenance and control measures have also been adopted.
- To protect human rights and privacy, we comprehensively control and manage information access, handling, transmission, storage, and personnel and equipment safety. And relevant safety and maintenance and control measures have also been deployed over the design and maintenance in the development of relevant application systems, databases, networks, personal computers, and storage and media devices.

Responsibilities

- The Board of Directors of PEC headquarters, senior managers, the legal compliance department, the legal affairs department, the human resources department and all functional departments, as well as the senior management team and the legal compliance team of all subsidiaries.
- Execution Center for Corporate Sustainability - Employee Care Taskforce, Corporate Governance Taskforce, IT department, and procurement department from Product Quality and Patient Safety Taskforce

Resources

Personnel/operational input

- Each functional department of the Group's headquarter, and subsidiary shall prepare the annual budgets related to various plans, which shall be reviewed by the finance department of the headquarter and submitted to the Board of Directors for approval.
- IT department will commission a qualified professional information management supplier for information security risk control.
- Procurement department will advocate our "Supplier Code of Conduct" externally to practice the human rights initiative in PEC's supply chain.

Goals & Targets

2022 Short-term Goals

- Human resources department to organize training related to human rights protection to all employees at Taiwan HQ. An online digital learning course will be concurrently formulated and become a part of mandatory new employee training.
- Build a friendly environment and practice human rights protection policy in PEC's day-to-day operations.
- IT department to organize relevant information security vulnerability scanning and social engineering training for all employees at Taiwan HQ and strengthen information security protection
- Procurement department will continue to advocate our "Supplier Code of Conduct" to suppliers and contractors
- Reinforce the channel on PEC's website designed to directly communicate or file grievances with the Independent Directors (Audit Committee)

GRI | 406-1 GRI | 412-2

To fulfill its corporate social responsibility and to protect the basic human rights of all employees, PEC strictly abides by the labor-related laws and regulations in the operating locations around the world to protect the legal rights and interests of employees. The Company also supports the human rights protections and basic principles outlined in international covenants such as "United Nation Global Compact", "Universal Declaration of Human Rights" and "Declaration on Fundamental Principles and Rights at Work" We take our corporate responsibility to respect and protect human rights and treat all paid employees, including contract employees and interns, with dignity and respect. There are no incidents of forced labor, child labor or discrimination in any form. For more details on the Company's "Human Right Policy," please refer to the official website.

Specific anti-discrimination and anti-harassment policy have also been formulated by our U.S. subsidiary, and we also comply with relevant Federal laws and those from the state of Massachusetts to protect the equal opportunity to employment and to protect their rights. Please refer to Section 4.1 "Recruitment in the United States" for details.

Goals & Targets

2023~2025 Mid-term Goals

- Adopt ISO 27001 Information Security Management System.
- Complete key IT equipment retirement and replacement management, expand scope of annual system disaster drills, and building of virtual private cloud
- Procurement department will continue to draft and amend the "Supplier Code of Conduct" to strengthen the suppliers' and contractors' enforcement of human rights protection
- Plan to build human rights risk management plan to systematically identify, evaluate, reduce, and fully manage risks related to human rights infringements

2026 Long-term Goals

- Ensure the safety of suppliers' work environment, protect employees' rights and respectful treatment, practice environmental protection in business operations and comply with ethical and moral principles
- Protect PEC's business secrets and competitiveness in the development of new drugs by continuing to improve the intensity of its confidential information management policy.
- Comply with relevant policies and regulatory requirements, ensure the privacy and security over the personal information of patients and employees, and maintain the rights and interests of stakeholders.

Evaluation of Management Approach

Mechanism of Evaluation

- "Employee Handbook" and "Management Procedures of Human Resources Processes" have been formulated in Taiwan headquarter.
- "PEC US Employee Handbook" has been formulated by the U.S. subsidiary
- Internal control system is regulated through "Control Operations over R&D Information and Documents" at Taiwan HQ.
- Management of protection of personal information
- Internal audit feedback
- Implement system validity project with the goal of obtaining FDA certification.

2021 Assessment Result

- No grievance incident on infringement of human rights.
- No deficiencies reported in internal audit feedback.
- No complaints regarding customer privacy impairment.
- IT department has organized 2 sessions of social engineering and information security training with cumulative participants reaching 200 persons and total hours of training reaching 600 hours.
- Procurement department carried out PEC CSR Report advocacy to 177 suppliers
- Commissioned external practicing attorney to give 1 training session on legal risks from workplace unlawful infringement, with participants reaching 198 persons and total hours of training reaching 297 hours.

Transparent Internal Communication and Grievance Channels GRI 406-1

To build a harmonious workplace environment, we actively create diverse and bilateral communication channels for our employees and regularly organize labor-management meetings to listen to their voices. We expect internal communication to be seamless and transparent in order to protect the legitimate rights of each employee. The issues and results of each case are kept by the Audit Office to ensure reasonable compliance. There were no cases in the various communication and grievance channels in 2021.

Regular staff meetings and department meetings

PEC has not set up a union and we regularly engage in bilateral communication with our staff through internal meetings. In addition to announce important corporate issues and operational goals, it also allows senior managers to directly discuss PEC's visions and culture with executives and employees, and to build consensus and goals. All employees can respond to comments or suggestions through this channel.

Internal announcement

The Company's internal system or important information will also be announced in different categories according to the content, so that employees can grasp the information content immediately and achieve zero error in information.

Labor management meetings

At PharmaEssentia, we hold regular labor-management meetings to explain to employee representatives about various issues such as employee health, environmental safety, and welfare, and we announce the minutes of these meetings to our employees. The Taipei headquarter and Taichung branch held 4 meetings each in 2021.

Prevention of workplace sexual harassment

- To ensure a gender-friendly workplace, we strictly prohibit any tangible or intangible sexual harassment in the workplace, and have clearly established relevant measures, such as: "Codes of Ethical Conduct", and we also set up a sexual harassment prevention and punishment complaint hotline and an e-mail box to protect the information of complainants and to protect the rights of fellow employees.
- The Company does not have any sexual harassment complaints in 2021.
- In 2021, we commissioned external practicing attorney to strengthen the corporate human rights policy required for listed companies, and to provide training on legal risks from workplace unlawful infringement, with participants reaching 198 persons, or an attendance rate of 85.71% and total hours of training reaching 297 hours.

Complaint channel

- Diverse channels of communication including the employee mailbox, labor-management meetings, and Employee Welfare Committee meetings have been set up internally to welcome employee feedback.
- Employees mailbox: voice@pharmaessentia.com
- Grievance channel for reporting violations of Code of Ethics from stakeholders or employees have been set up at PEC's website, allowing external entities to report or file grievances.
- Unlawful infringement at workplace: hr@pharmaessentia.com
- All grievance cases received are submitted to the responsible units from the receiving department, and will be communicated to the employees based on the contents of the incident.
- The issues and results of each case are kept by the Audit Office to ensure reasonable compliance.

4-4 Talent Training and Career Development

Management Policies of Talent Training

Materiality Topic

We are committed to employee development and training, and closely align the individual characteristics and qualities of our employees with the strategic development objectives of the organization by focusing on core functionalities. This would allow us to enhance our human capital, so that human resources can be effectively used to achieve our business objectives, and alternatively, it also allows us to help employees to acquire expertise in their professional fields or refine their management skills, so that they can continue to grow in their career path and achieve synergistic growth with PEC.

GRI | 103-2~3

Policies

Internal Policy

It is now implemented in accordance with the "Procedures on Training Management" and "Procedures for Incentives from Talent Referral"

External Guidelines

Ethical Corporate Management Best Practice Principles for TWSE/GTSM Listed Companies

Sustainable Development Best Practice Principles for TWSE/TPEx Listed Companies

Commitments

As the responsibility and commitment of PEC to its employees, we will continue to train and develop talents in order to retain them.

Responsibilities

- Talent cultivation and development policy: human resources and management ex-ecu-tives
- Responsible unit for talent cultivation: heads of departments
- Execution Center for Corporate Sustainability - Employee Care Taskforce

Resources

Personnel/operational input

- Organize internal and external education training, and regularly invite experts from leading academic and research institutions to exchange and share innovative new drug development expertise with all colleagues for their learning and development.
- We continue to collaborate with academia and Academia Sinica on projects to refine the expertise and project integration capabilities of our R&D personnel. Each project is a function of On-the-Job Training and Project Leadership Training for R&D personnel.
- Each department uses a mentor system to help pass on experience, reduce the turnover rate of new recruits, and train senior colleagues in the function of cultivating talents.
- Commission expert consultants to optimize and to integrate the methodology of performance evaluation with talent management development mechanisms
- Diversify the methodology of training for key talent development and to integrate the training with personal characteristics and career development goals; undertake employee rotation training both at home and abroad in line with the Company's long-term development objectives
- Launch digital learning platform to digitize internal training courses and to prepare in-house digital courses, make learning more accessible to employees by uploading relevant contents on digital platform

Expense input

- We expect to invest over NT$100 million toward talent training and development

Goals & Targets

2022 Short-term Goals

- The training program starts with new recruits, and new recruits are given training courses to convey the company culture and introduce the company's development history, systems, and procedures, so that new recruits can be familiar with the working environment and bring their strengths into play as soon as possible.
- Continuous staff skills training by the department head to implement 1-2 skills for staff duties.
- Inventory the status of existing talent professional functions and complete the definition of professional functions in each department as a basis for talent development.

Goals & Targets

2022 Short-term Goals

- Provide department heads with 2 professional function training courses, linked to the performance management system, to enhance various professional abilities and improve management performance.
- Establish the professional function system of each department to ensure the professional capabilities required for each position. Provide the standards and learning indicators of the employees, and at the same time establish the talent hiring standards.
- Integrate the department's professional functions with performance evaluation and project execution, and implement performance and function evaluation for all staff, and implement the learning and establishment of professional functions through performance evaluation.
- Establish succession system.

2023~2025 Mid-term Goals

- Develop and implement a duty rotation system to improve the efficiency of talent transfer by by 2%-3%.
- Establish and implement an internal lecturer system and train 5 to 7 internal lecturers to cultivate talents and establish a knowledge management system to pass on professional knowledge
- Conduct employee satisfaction survey for the first time and strengthen key issues.
- Implement six executive leadership-related programs from 2023 to 2025, supplemented by a leadership assessment mechanism, to develop succession leadership and increase retention rates.
- Complete succession talent assessment and plan for 3-year succession development plan and leadership training
- Construct a 5-year long-term talent development plan and to incorporate it into annual KPI for all departmental supervisors.
- Establishing a talent management and talent development system, prioritizing the development of key talents and successors and providing talent evaluation report to the management team.
- Translate corporate culture and core values into feasible core functions for employees (4-5 items) and to build a learning organization and refine PEC's core functions.
- Optimize the organizational developments through the results of the employee satisfaction survey to continuously improve employee retention rate and employee satisfaction, aiming to reach the market average.

2026 Long-term Goals

- Establish a succession system and conduct annual talent leadership evaluations to establish a succession pool and continuously cultivate key talent in line with the Company's long-term goals for sustainable development.

Evaluation of Management Approach

Mechanism of Evaluation

- Promotion rate for supervisory positions from internal staff
- Manager retention rate

2021 Assessment Result

- Promotion rate for supervisory positions from internal staff: 29.79% in 2021
- Manager retention rate: 89.36% in 2021

On-the-job Training and Key Talent Development Objectives

Through intensive on-the-job training, multiple learning channels, and overseas training for quality personnel, PEC strives to develop professional talents in the biomedical field. In the future, we will hire expert consultants with the goal of optimizing performance evaluation and developing a talent management system, and we expect to invest millions of NTD toward talent training and development. Through this process, we will identify key quality personnel and focus on training them. This is complemented by a corporate succession system that allows us to upgrade the efficiency of our human resources management and reserve leadership for long-term sustainable management.

Graph of 2019~ 2021 training hours

2021 average training hours by position and gender (Unit: Hour) GRI | 404-1

Category	Taiwan Headquarters		Panco Healthcare	
	Male	Female	Male	Female
Average training hours - Operational man-agement directors (Vice President and above)	16.25	10.50	NA	31
Average training hours - Senior-level super-visors (department directors and above)	11.34	17.43	NA	NA
Average training hours - Middle-level su-pervisors (managers and above)	11.39	16.39	31	16.50
Average training hours - Junior-level super-visors (team leaders)	10.10	11.35	34.50	NA
Average training hours – Staff level	10.10	7.40	23.30	9

Note: "NA" in the table indicates we currently do not have this type of employee.

Performance Evaluation and Promotion System GRI | 404-3

PEC has established a fair and objective performance appraisal system that is integrated with our strategic development and implemented it in a performance-based compensation system as a reference for employees' work-related objectives and personal growth and development. 100% of full-time employees from PEC Headquarter and Panco Healthcare underwent performance and career development inspections in 2021 (deducting factors such as probationary periods, leave without pay, etc., the completion rate of each job category, regardless of male or female.) Employees and supervisors can jointly confirm performance output and status of target achievement through the annual mid-year interview and the end-of-year appraisal, which are both conducted once per year. Supervisors will actively explore the reasons for employees with relatively low performance output or those who are falling behind on targets through adequate communications, individual instructions and making proper adjustments or offering support and jointly formulate improvement plans and estimated completion times. At the same time, the human resources department will arrange for proper courses so employees can improve accordingly. As for those with excellent performance and potential, they will have better promotional opportunities in the annual employee promotion nomination and evaluation. We also plan relevant rotational mechanisms for employees; When internal vacancies are available, internal suitable candidates will be recommended first. By developing talents with multiple professional capabilities, we can promote the continuous retention of internal talents, and play the ability of cross-departmental communication and coordination capabilities.

4-5 Occupational Health and Safety

Implementation of Occupational Health and Safety

We have been even more focused on our employees' prevention against infectious diseases since the outbreak of the COVID-19 pandemic in 2020. In line with PEC's "Occupational Safety and Health Policy", we have reinforced employees' health management and health promotions, and implement the ISO 45001 occupational safety and health management system in 2023 as well as to launch comprehensive, company-wide hazard identification, risk assessment, accident investigation and other related measures to build a safe and healthy workplace environment with zero hazards.

Complying with government

Implementing government regulations and promote safety and harmony

Valuing hazards prevention

Seeking zero disasters and providing a safe environment

Implementing continuous improvement

Creating a safe, hygienic and good corporate image

Promoting full participation from employees

Encouraging employee participation and enhancing safety awareness

Workplace Health Promotion GRI | 403-3

Providing a safe and friendly workplace to our employees is our commitment and the basic guarantee for them. We are committed to reducing the risk of occupational injuries and creating a work environment that allows employees to enjoy a balanced, healthy, and happy environment. Following the footsteps of our Taichung Plant, which again received the " Workplace Health Certification/Health Promotion Label" in 2020, our Taipei HQ also received the 2021 Workplace Health Certification" with a three-year validity, which confirms our achievement in implementing health protection for our employees. PEC provides free routine physical examination to all employees once a year. The examination items are more superior than what is required by the law. This allows employees to understand their health status and key improvements, thereby reducing and preventing from diseases. Moreover, we also invited professional doctors to serve as lecturers in our "Getting to know Cardiovascular System and Preventions" health promotional seminar in October 2021, which was attended by 82 persons, which in 73.87% attendance rate .

Employees participating in "Getting to know Cardiovascular System and Preventions" health promotional seminar.

Healthy workplace certification/health promotion label at Taipei Headquater

Healthy workplace certification/health promotion label at Taichung Plant

Health examination

Routine safety health examination and special operational health examination

- We assist employees in health management by providing one health examination per year. Health examination was given to 208 employees
- Special operational health examination is provided to personnel engaged in hazardous operations. Special health examination was given to 47 employees. Among them, the employees who are classified as requiring tier 2 management were deemed as having no relevance to the work by professional specialists, and PEC will subsequently arrange nurses or doctors to provide healthcare education.

Medical and nursing staff clinical health education services

Contracted nurses to provide health education services

- And arrange employees to engage in interviews and to receive healthcare instructions. In 2021, we invited nurses, doctors, physiotherapists and psychologists to visit our plants for health education and promotion. A total of 80 sessions were held.

Protection of mother's health

Evaluate hazardous factors to ensure the safety of female employees in the workplace

- For pregnant staff or female staff who gave birth for less than one year and are engaged in work that may affect the health of the fetus, mother and baby during pregnancy or lactation, Health protection measures such as changing their work conditions, adjusting working hours, or switching their duties and tasks may be implemented based on the identification, evaluation, and control of workplace or operational hazards, as well as the classification of hazardous chemicals in line with professional physician's assessment and recommendations. The implementation rate of the maternal health protection program for the past three years has been 100%.

Human factors hazard prevention plan

Identify hazards and research and evaluate injuries and diseases

- Based on the statistical results of the 2021 ergonomic hazard prevention survey, employees who are suspected to have risks of ergonomic hazards are arranged to be interviewed by doctors and nurses and their subsequent health status is monitored and tracked.

Prevention against diseases from overwork

Implement integrated health promotion services to evaluate employees' health-related risks

- Risk classification is identified and evaluated based on annual health examination reports, attendance forms, and personal and workload assessments. Those with moderate risk after assessment in 2021 will be interviewed by a specialist and followed up with a health care provider.

Contractor Safety Management

Regarding the safety of contractors entering the Company's factory, management mechanisms and management measures are established for the pre-construction, pre-entry, and construction period to ensure the safety of the Company's colleagues and contractors. In 2021 PEC and Panco Healthcare did not have any occupational injury accidents by contractors in the Company's workplace, nor did they have any recordable number of occupational disease cases. In the future, we will continue to ensure the safety of our contractors, protect their rights, and promote a safe and secure working environment.

Before construction

- The “Contractor’s Safety, Health and Environmental Protection Letter of Commitment” and the “Contractor In-plant Letter of Declaration” must be signed by the contractors and sent back to the Company.
- Submit 6 hours of safety and health education training certificate.
- Retained by the Company’s environmental safety unit.

Before entering the factory

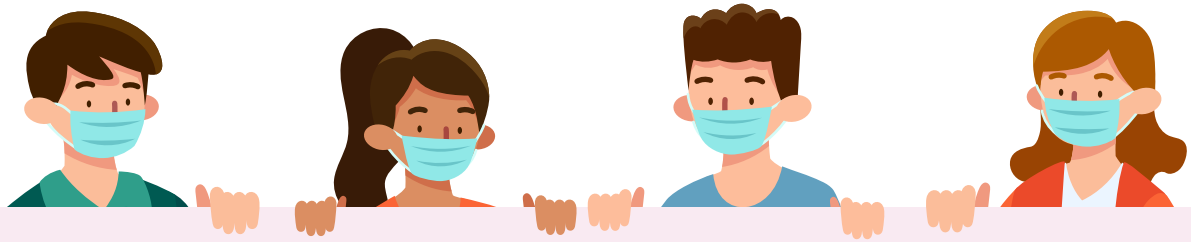
- Arrange for the contractor to receive pre-production safety and health training.
- The contracts must sign the “Notification of Workplace Environment and Hazardous Factors”.

During construction

- The engineering unit must ensure the contractors comply with the requirements stated in the “Regulations for Contractor Environmental, Safety and Health Management.”
- In case of special operations, a training certificate must be attached.
- Environmental safety unit conducts spot checks. In case of safety concerns, construction work should be suspended immediately.

Workplace safety maintenance in response to the COVID-19 pandemic

In the face of the continuing epidemic in 2021, which saw a nation-wide level three alert from May to October, PEC has established an epidemic response team consisting of the Chairman, CEO, President, Chief Operating Officer, Head of Production and Manufacturing Division, Human Resources and Environmental Safety units, etc. Meetings will be held in any time, depending on the development of the pandemic, to protect the health and safety of employees. Going forward, we will also respond immediately to the announcement of the pandemic threat level and the latest regulations, formulate a system platform that allows employees to work remotely from home, and prepare for the resumption of normal operations in case we were severely affected by the pandemic.



Our Response Measures to COVID-19 at PEC's Headquarters

For internal personnel

1. Strengthen the promotion of prevention policies.
2. Diverse staff traffic
3. Keep social distancing in the working area.
4. Strictly requiring employees to take temperature, wear masks, and disinfect hands alcohol when entering the office.
5. Remote office to avoid cross-infection.
6. Prohibit all cross-site traffic
7. Employees who were at "hot zones" are required to file an application to enter the plant and to use rapid test kits to screen for the virus to reduce the risk of workplace infections.
8. Suspend large-scale educational training (except the ones required by applicable laws and regulations).
9. Suspend all travels that are not necessary and adopt online/video conferences
10. Reduce persons involved in offline meetings and add partitions to meeting rooms
11. Regularly clean and disinfect the environment
12. Disinfection

For external personnel

- Reduce non-essential visit, and essential visitors are required to file an application to enter the plant and to use rapid test kits to screen for the virus
- In addition, subsidiary Panco Healthcare continued to regulate on-site operations from contractors, and personnel requiring access to the plant are required to use a rapid test kit
- PEC will apply for a special visa from the government by proposing an epidemic prevention plan and traffic route and protective gears before plant inspection from foreign governmental bodies could ensue; a written request shall be submitted to the local competent authority and all employees are required to undertake PCR test, practice self-healthy management measures, environmental and personal sanitation procedures, wear masks, and to use the real-name registration system

Note: From left to right: taking body temperature, recording body temperature, disinfecting both hands with sanitizing alcohol, and environmental disinfections

Workplace Safety and Accident Prevention Mechanism GRI 403-5 GRI 403-7 GRI 403-9~10

33 sessions
189 participants

Internal and external occupationalsafety and health staff training at PEC HQ

25+ sessions
63 participants

Internal and external occupational safety and health staff training at Panco Healthcare

0
occupational accident

*Excludes traffic accident while commuting to/from work

To respond to various emergencies and for the prevention of industrial safety incidents, the Company has formulated the "Labor Safety and Health Work Rules" and "Procedures for Emergency Responses" to ensure environmental safety and employees' health. Our employees receive regular safety and health on-the-job education and trainings. Regarding the operation items or operation supervisors as stipulated by laws and regulations, personnel shall be delegated according to law, and non-operators shall not be allowed to operate these operation items. The Lost-Time Injury Frequency Rate (LTIFR) for all employees in 2021 are 0.

To prevent injuries related to occupational health and safety, the "Industrial Hygiene and Safety Management Rules" and precautions regarding material transportation have been formulated by the logistics center of Panco Healthcare. In case of emergency, the logistics center manager will be immediately notified, and the emergency response team will immediately commence relief and personnel evacuation or reporting and hospitalization process in case of injury. In 2021, more than 25 rounds of internal occupational safety and health training were organized, and the total number of employees trained reached 63 people.

Statistics on Occupational Safety and Health Employee Training at PEC HQ in 2021

Training topic		Sessions	Number of participants
Internal	On-the-job safety and health training (includes current employees and new employees)	6	102
	Annual self-defense firefighting team training	1	61
External	On-the-job safety and health training (includes operators of hazardous equipment, emergency relief personnel, and fur-nace/boiler operators)	14	14
	On-job safety and health education and training for hazardous work supervisors	1	1
	General training for professional responders of poisonous disasters in Central Taiwan Science Park	3	3
	Environmental protection seminars and briefings on legal compliance	8	8
Total		33	189

Statistics on Occupational Safety and Health Employee Training at Panco Healthcare in 2021

Training topic	Number of par-ticipants
Rules and procedures on health management and attire of operators	23
Emergency response operating procedures	6
Operating procedures on cleaning the processing and labeling assembly line	29
Access management system procedures	5
Total	63

Occupational injury data from PEC headquarters, Panco Healthcare, and U.S, subsidiary indicated that the disabling injury frequency rate (FR), disabling injury severity rate (SR) and frequency-severity indicator (FSI) were all 0 in 2021. The company does not have any occupational injuries caused by the number of deaths, serious occupational injuries, and occupational diseases. When an occupational disaster occurs, we will investigate and follow-up improvement measures in accordance with the "Accident Investigation and Handling Measures." In 2021, Taiwan HQ held 2 emergency response drills. The topics of the drills included self-defense fire drill and biosafety emergency response drills. The total number of participants was 72. We implement the ISO 45001 Occupational Health and Safety Management System in 2023 to conduct systematic safety risk assessment in production processes and experimental operations.

Case Introduction

Real Case of Biosafety Response Drill

Setting the drill scenario:
Microorganism specimen has overturned in the biosafety cabinet (BSC)

Participants:
A total of 9 colleagues from related units of the Taichung manufacturing plant.

1 Remove the outer glove and to toss them in the BSC sterilized bag.

2 Maintain continuous operation of the BSC and the doors at proper heights, and to inform a lab supervisor.

3 Put on a new layer of gloves, take a wipe clothe and 1% bleach. Absorb any spillover with the wipe clothe, and pour the 1% bleach over all surfaces using an inward motion.

4 Remove outer layer of gloves inside the BSC and to toss them in the BSC sterilized bag. Leave BSC, shut BSC door and maintain its operation, and turn on the UV lamp for at least 30 minutes.

5 Put on a second layer of gloves and enter the BSC, use a clamp to grip all wipe clothes and to place them inside the BSC sterilized bag.

6 Wipe all BSC interior surface and all objects with a clothe filled with disinfectant, and the clothe will also be placed inside the BSC sterilized bag, and the bag will be sealed.

7 Shut BSC door and maintain its operation, and turn on the UV lamp for at least 30 minutes, then either resume work or turn off the BSC.

8 After personnel leaves D zone, sterilize the gloves as one would with infected waste, and wash hands with soap before leaving the lab.

Case Introduction

Response Measure to Sudden Blackout at Panco Healthcare

Emergency response scenario:
Notice for blackout

Emergency response situation:
On March 26, 2021, Panco Healthcare received a notice from Taiwan Power Company that a 5-hour power outage would occur from 00:00 to 05:00 on April 3, 2021. Since various equipment at the company require uninterrupted 24-hour power supply, the plant had reported the situation to prevent any discrepancies in power supply.

1 Confirm the diesel level in the emergency generator; the current level was at 840 liters, which would allow the generator to run continuously for 65 hours or more

2 Schedule a 30-minute blackout in the morning of March 31 to check that the generator and the automatic transfer switch (ATS) were functioning normally. The simulation was completed between 11:30 to 12:00

3 Arrange a warehousing personnel to Stay on site between 23:00 on April 2nd to 05:00 On April 3rd (6 hours total) and another warehousing personnel to be on call. The generator supplier was also notified to be on call at the same time to handle any abnormalities related to the generator during the blackout.

4 Currently, 5 areas at the plant are used to store medicament inventory, and all areas are equipped with 2 thermographs, which are set up to record the changes in temperature within the warehouse in case the generator fails to initiate or fails to operate.

Chapter 5

Environmental Impacts

Chapter 5: Summary of 2021

Highlights

To achieve sustainable development, the impacts of commercial activities on the environment is significant. PEC comprehensively examines all management activities related to environmental impacts and influences, from the climate governance management approach, water resource and waste management, to the toxic and priority substances of concern. We further took the strategies to mitigate the effects of climate change in response to the climate emergency faced by all humankind. The greenhouse gas (GHG) taskforce has been formulated at the Taichung Plant, which pioneers our efforts toward climate governance, have formulated the "Greenhouse Gas Management Procedures" currently, as well as the GHG inventories for 2019 had been completed and was verified by a third-party for ISO 14064-1 in October 2021. In 2022, we expect to continue the GHG inventories of Taichung Plant for 2020 and 2021. We also plan to deploy ISO 45001: 2015 Environmental Management System in 2023. By building an environmental management system, enterprises can find potential environmental problems during the entire product life cycle, including production, sales, consumption, and waste disposal, and to improve accordingly, thereby reducing environmental impacts and energy consumption, as well as the waste of raw material. This would enhance the enterprise's productivity and increase its operating revenues, and furthermore, to ensure that the goal of being friendly to the environment during operating processes could be met.

Relevant Material Topics

Relevant Stakeholders

Performance Highlights

Zero penalty

No incidents of violation of environmental laws and regulations

Zero leakage

Toxic substances are properly managed without accidental leakage

Zero emission

No Ozone Depleting Substances (ODS) were emitted during production process

Introduction of the Management System

It is expected to implement ISO 45001:2015 Occupational Safety and Health Management System by 2023

Greenhouse Gas Management

Completed ISO 14064-1:2018 Greenhouse Gas Inventories In 2019, and received third-party certifications

7.779 million liters of process water is recycled and reused

Effectively utilize water resources throughout the production process

Air pollutant emissions are lower than the legal value

Monitor air pollutant emission data actively

Reduce CO_2e intensity per unit output by 40.5%

Mitigate the impacts of GHGs on the globe

Reduce waste intensity per unit output by 21.3%

Improve productivity and reduce the impacts on the environment

5-1 Climate Governance

Management Approach to Climate Governance

Materiality Topic

GRI | 103-2~3

Climate change has become an ongoing issue in the environment. To respond to the United Nations' Sustainable Development Goals (SDGs) 13 - Climate Action, PEC has introduced the training course for Task Force on Climate- related Financial Disclosures (TCFD) framework for the first time. By actively addressing the challenges and opportunities from climate change and providing relevant and reliable financial information to stakeholders, we aim to jointly preserve the sustainable development of the environment.

Policies

Internal Policy

Comply with the "Greenhouse Gas Management Procedures"

External Guidelines

"ISO 14064-1:2018 Greenhouse Gas Inventories", Taiwan's Greenhouse Gas Reduction and Management Act, Task Force on Climate- related Financial Disclosures (TCFD) framework, and Corporate Governance 3.0 - Sustainable Development Blueprint, and the Regulations Governing Information to be Published in Annual Reports of Public Companies.

Commitments

In line with SDG 13 - Climate Action, PEC has introduced the training course for TCFD framework for the first time. The four core elements of TCFD will be formally introduced in 2023, including Governance, Strategy, Risk Management, Metrics and Targets. By actively addressing the challenges and opportunities from drastic climate change and providing relevant and reliable financial information to stakeholders, we aim to jointly preserve the sustainable development of the environment.

Responsibilities

- The Board of Directors, Auditing Office, Corporate Governance Officer
- Execution Center for Corporate Sustainability - Environmental Friendliness Taskforce
- Greenhouse Gas Inventories Promotional Taskforce at Taichung Plant

Resources

- GHG Taskforce at Taichung Plant is comprised of the following departments: 15 persons from administrations department, factory affairs department, biopharmaceutical manufacturing department, injection preparations department, materials management, and quality analysis department
- Task Force on Climate-related Financial Disclosures (TCFD) training was attended by 40 members from the ESG functional groups
- Expense for setting up the GHG inventories project at Taichung Plant: Approximately NT$300,000 for external consultants and verification fees

Goals & Targets

Short-term Goals for 2022

- GHG inventory improvement plan at Taichung Plant - systematic procedural improvements or optimizations
- Continuing the ISO 14064-1: 2018 GHG inventory at Taichung Plant, we expect to take inventories of GHG emissions in 2020 and 2021 by 2022 to meet the criteria for Corporate Governance 3.0
- In line with regulatory requirements and the criteria for Corporate Governance 3.0, information on climate governance is disclosed in the Annual Report and Sustainability Report

Mid-term Goals for 2023~2025

- Implement ISO 14001 Environmental Management System to strengthen the environmental, safety, and health management system
- Continue to implement ISO 14064-1: 2018 GHG Inventories
- Continue to strengthen the TCFD organizational risk management identification system training.

Long-term Goals for 2026

- Continue to implement ISO 14064-1: 2018 GHG inventories
- Continue to implement ISO 14001 Environmental Management System
- Continue to evaluate potential impacts from climate change in PEC's strategic planning, analysis, and risk management in line with the TCFD framework

Evaluation of Management Approach

Mechanism of Evaluation

- Internal audit mechanisms: Carry out internal training, data collection, internal audit, and external verifications in line with "Greenhouse Gas Procedures"
- External audit mechanisms: Corporate governance 3.0 evaluation indicators
- TCFD framework

2021 Assessment Result

- Taichung Plant was the first in PEC to form a GHG Taskforce, the plant has already completed the 2019 GHG inventories in October 2021 and received ISO 14064-1 third-party external assurance certification.
- Introduced TCFD educational training course for the first time; total number of participants from the ESG functional groups was 40, reaching a 76.92% attendance rate. Expected benefits from current training: By understanding the climate-related risks and opportunities in our corporation and value chain, we hope to use such awareness as important information in internal decision-making to help PEC to effectively communicate with the competent authority, investors, and other stakeholders.
- Replaced 36 T5 lights with LED lights at the office, each can conserve 26 watts of electricity per hour.

CPDC GHG Emission Statistics

Total CO_2 emissions have been reduced by 11.9%.

Mitigate the impacts of GHG on the globe

CO_2 equivalent emission intensity per unit output has been reduced by 40.6%

In 2021, PEC's Taichung Plant completed ISO 14064:2018 GHG inventories for 2019 and third-party assurance has been received. In 2019, PEC cumulatively emitted 4,585.027 tons CO2e of greenhouse gases, and we expect to take inventories by 2022 for the emission in 2020 and 2021. We hope that we can use the TCFD framework to disclose our risks and opportunities related to climate change gradually.

PEC's energy consumption mostly consists of two major categories, namely purchased electricity and natural gas. As a pharmaceutical industry, we are required to comply with Good Manufacturing Practice (GMP) regulations and have to maintain a certain level of cleanliness and quality control even during non-production periods, which made it difficult to reduce the total amount of basic electricity consumption and carbon emissions. But we are still devoted in several energy-saving actions, and regularly reviewing the results of the implementation of purchasing and replacing the equipment and appliances, saving electricity and water, and formulating of improvement measures through tracking mechanisms and difference analysis. We will continue to work towards the goal of reducing the intensity of energy consumption and reducing the impact of our operations on the environment.

2019 Statement on GHG Inventories

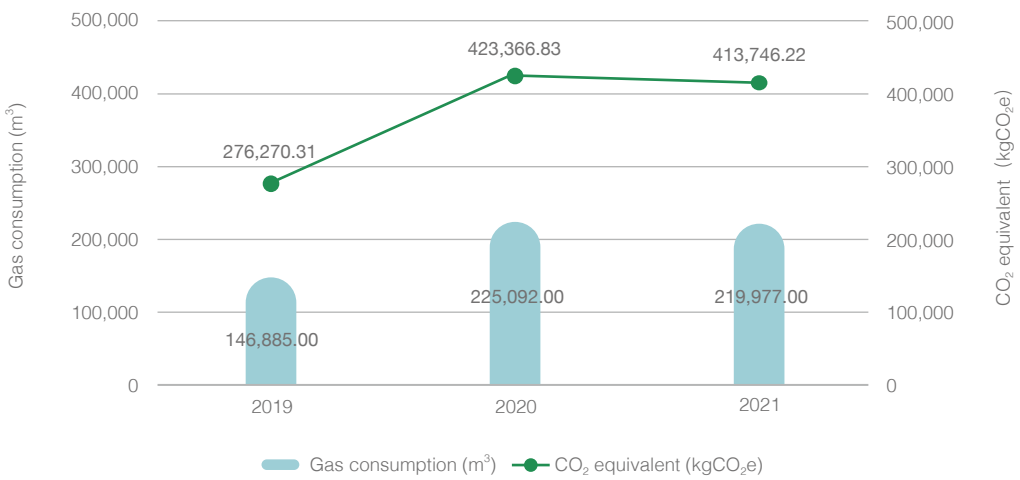
Energy consumption and greenhouse gas emission statistics of PharmaEssentia headquarters and Panco Healthcare for the past 3 years

GRI 302-1 GRI 302-3

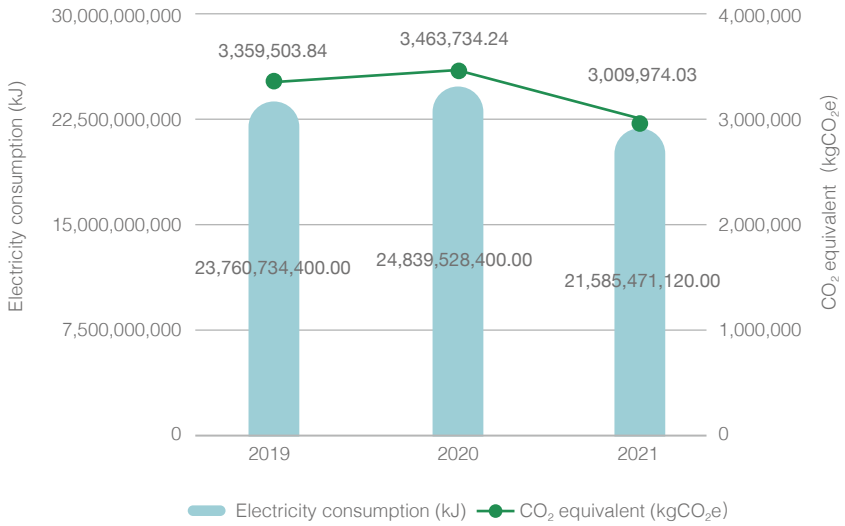
Type	Electricity				Natural Gas			Total	Emission intensity per unit product
Year	Electricity from renewable energy (kJ)	Electricity from non -renewable energy (kJ)	Total electricity intensity (kJ/g)	CO_2 equivalent ($kgCO_2e$)	m^3	Natural gas intensity (kJ/g)	CO_2 equivalent ($kgCO_2e$)	CO_2 equivalent ($kgCO_2e$)	$kgCO_2e/g$
2019	0	23,760,734,400.00	387,613,938.01	3,359,503.84	146,885.00	2,396.17	276,270.31	3,635,774.15	59,311.16
2020	0	24,839,528,400.00	577,394,895.40	3,463,734.24	225,092.00	5,232.26	423,366.83	3,887,101.07	90,355.67
2021	2,789,564,400.00	21,585,471,120.00	382,894,054.67	3,009,974.03	219,977.00	3,455.50	413,746.22	3,423,720.25	53,781.34

Note 1: The data of electricity, natural gas and GHG emissions in 2019 do not include Panco Healthcare.
Note 2: The GHG statistics method uses the "emission coefficient method," i.e., "activity data" is multiplied with the corresponding "emission coefficients," and then the various GHGs global warming potential (GWP) is converted into CO2 emission equivalents.
Note 3: Electricity emissions are calculated according to Article 28 of the Electricity Law (110.11.03), and the carbon dioxide equivalent coefficients announced by the Bureau of Energy, Ministry of Economic Affairs, are used to convert the carbon dioxide equivalent coefficients of electricity. The coefficients used for 2019 and 2020 are 0.509 and 0.502 kilograms of carbon dioxide equivalent ($kgCO_2e$) for 1 kWh of electricity. The latest known coefficient for 2021 is 0.502.
Note 4: The greenhouse gas emission coefficient required for greenhouse gas emissions is based on the "Greenhouse Gas Emission Coefficient Management Table 6.0.4 Edition" announced by the Environmental Protection Administration, Executive Yuan, and use the GWP of various GHGs in the IPCC AR5 (2014) report as the basis for calculation.
Note 5: Emissions intensity is measured using total annual production. Since we mostly adjusted total production output based on clinical trial requirements from 2019 to 2020, and since we have not yet entered into mass production and stable productivity, there still remains some fluctuations in our CO_2 emission intensity per unit output production.

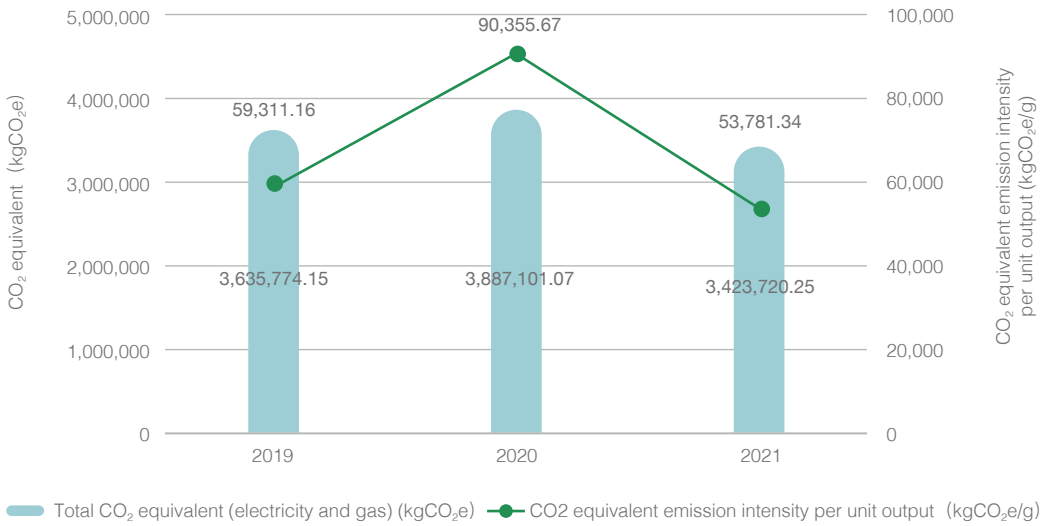
Gas consumption and greenhouse gas emissions in the past three years



Electricity use and greenhouse gas emissions in the past three years



Statistics of carbon dioxide equivalent emission intensity per unit output in the past three years



Statistics of Air Pollution GRI | 305-6~7

Regarding the emission of air pollutants, as PEC uses boilers in the manufacturing process, the main emission source is the nitrogen oxides from combustion of the boilers. PEC prudently treats our emissions, and does not use or emit ozone depleting substances (ODS), which are regulated by the Montreal Protocol, nor do we emit any Persistent Organic Pollutants (POPs). Additionally, we also regularly test and report fixed air pollution sources in line with the regulations from the Environmental Protection Administration, which is outsourced once a year to EPA-certified testing agency Ji Chuan Environmental Technology Co., Ltd. The testing results indicated that air pollutant emissions are lower than the statutory levels, and there were no incidents of violation of environmental laws and regulations, thereby fulfilling our responsibilities to environmental friendliness in all production processes.

PharmaEssentia Headquarter - Information on major gas emissions affecting the environment for the past 3 years (Unit: kg)

Air pollutants	Nitrogen oxides (NO_x)	Sulfur oxides (SO_x)	Volatile Organic Compounds (VOCs)	Hazardous Air Pollutants (HAP)	Particulate Matter (PM)
2019	649.00	102.00	10.00	8.00	8.00
2020	415.70	29.60	13.30	Lack of Data	7.00
2021	352.41	0	734.31	168.54	14.77

Note: Panco Healthcare does not emit any air pollutant included in these items.

5-2 Waste Management

Waste Management Approach Materiality Topic

In order to manage our waste effectively, we review the detailed processes of waste generation, removal, treatment and recycling from a life-cycle perspective. Through a systematic waste management policy, we avoid the risk of improper treatment that may lead to illegal concerns or pollution of the environment. We also actively assign our business executives to participate in external environmental seminars and regulatory presentations. In 2021, we sent our staff to eight external training sessions to keep abreast of various environmental regulations and the latest trends. By doing so, we can effectively follow the changes in regulations and keep up with the trends when we promote the actions to reduce emissions at source, adjust our process design, or improve the utilization of consumables. With that, we can reduce the waste of resources, minimize the environmental pollution, and achieve the specific practice of friendly environment. For our environmental protection expenditure, please see our 2021 Annual Report for relevant disclosures.

GRI | 103-2~3 GRI | 306-1~2

Policies

Internal Policy
Follow the "Environmental Safety and Health Policy" and "Waste Management Procedures."

External Guidelines
Regulations for the Review of Business Waste Cleaning Plans

Commitments

In addition to complying with environmental protection laws and regulations, the manufacturers are also required to implement waste flow control together to fulfill the commitment of being friendly to the environment.

Responsibilities

- The environment friendly team is responsible for developing, planning and promoting waste management issues, and collaborating with R&D, environmental safety and production units to implement waste management responsibilities.
- Execution Center for Corporate Sustainability- Environmental Friendliness Taskforce

Resources

In 2021, the cost of business waste removal and disposal amounted to approximately NT$608,000, consisted of NT$223,000 for non-hazardous waste and NT$385,000 for hazardous waste, and have set up dedicated personnel to such tasks.

Goals & Targets

Short-term Goals for 2022

- Following the efforts in 2021, we will continue to check the output of waste chemicals (including toxic substances) and follow-up treatment procedures; besides, we will submit the amendment of the "Industrial Waste Cleanup Plan" and apply the approval of the disposal of toxic substances to the environmental protection authority. And we will keep the treatment of waste chemicals (including toxic substances) legally to avoid violating environmental protection laws and regulations.

Mid-term Goals for 2023~2025

- To reduce the burden and impact on the environment and implement environmental protection obligations, we will introduce the ISO14001 environmental management system through PDCA to strengthen the environmental management in the factory and incorporate the concept of life cycle assessment.
- Reinforce the waste management responsibilities of each unit.
- Seek alternative solutions for green products based on waste materials, increase the frequency of reuse, promote resource recycling, and reduce the total generated amount of waste.
- Strengthen the auditing of waste manufacturers and use compliance performance as the evaluation criterion for the selection of future manufacturers.

Long-term Goals for 2026

- Implement the ISO14001 environmental management system, and follow the environmental assessment results and recommendations for improvement.

Evaluation of Management Approach

Mechanism of Evaluation

- Internal audits: Audit the waste management companies from time to time in each year and review our internal waste classification and storage management process, as well as evaluate the waste intensity per unit output routinely. The calculation method is based on an evaluation standard of “Waste output (unit: ton)/production output (unit: per gram)”.
- External verifications: Competent authorities including the Central Taiwan Science Park Administration and Environmental Protection Bureau of Taichung City Government will conduct routine legal compliance audits on the "Business Waste Cleanup Plan," waste removal and disposal procedures, and waste storage sites.

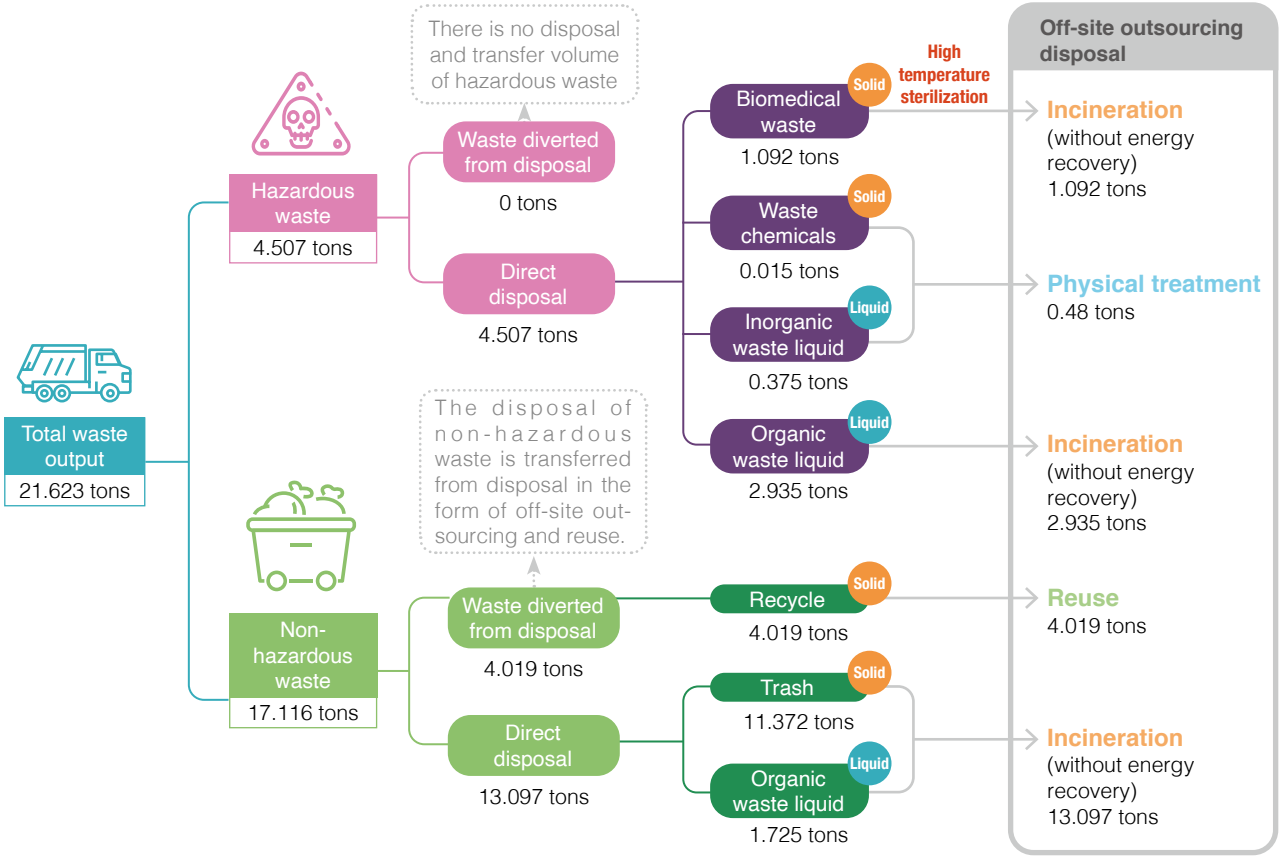
2021 Assessment Result

- In 2021, every 1 gram of product produced generates 0.3397 tons of waste, showing a 21.3% decrease from 2020.
- Auditing results: We audited 2 waste disposal vendors and conducted 4 audits over temporary waste storage areas, all complied with regulations.
- Improvements: We continue to implement the existing SOP and to review and amend the “Best Waste Cleanup Plan” on a timely basis to meet regulatory requirements. The Taichung plant commissioned a legal vendor to assist in the removal of waste chemicals (including toxic chemicals) in 2021, and after the environmental protection authority agreed to complete proper disposal of the waste, a copy was made available for inspection.

Waste Output and Disposal GRI | 306-2~5

The hazardous waste of PEC is specially classified and sealed in specific containers, and labeled with information including its name, weight, waste code and date, and then entrusted to qualified vendors for further processing. Hazardous liquid waste related to biopharmaceuticals, which may be infectious, are first sterilized using high temperature, then entrusted to qualified vendors for further processing. Moreover, the toxic liquid wastes are mostly chemical wastes, which are stored according to their flammability or acid-base value. When liquid wastes are collected, the handling personnel must pay attention to potential chemical reactions caused by the mixing of the liquid wastes, and at the same time, fill out the "Liquid waste mixture form" and affix it on the liquid wastes container to facilitate subsequent clearance and processing from contractors.

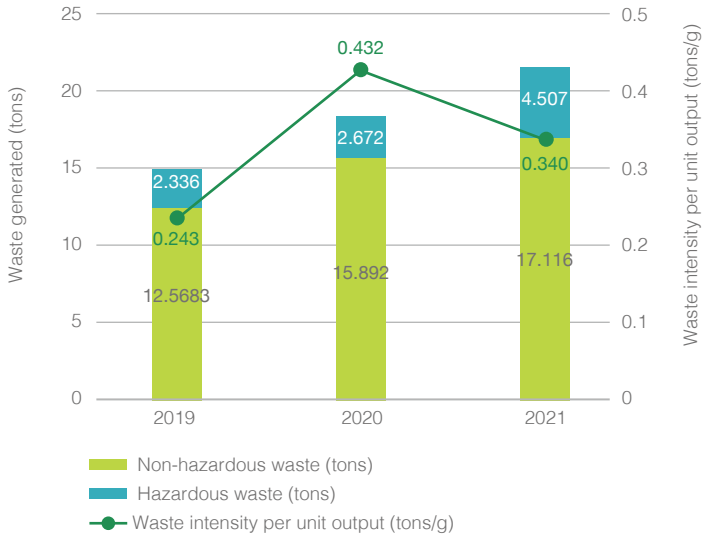
Non-hazardous waste is separately stored at temporary waste storage area based on its nature before further processing. Our waste disposal methods include: General trash and recyclable trash. In terms of waste disposal, we prioritize reuse, which is the friendliest to the environment, followed by recycling; if the wastes cannot be recycled and reused, they will undergo intermediate handling procedures, such as incineration or burial, or final disposal. The waste disposal companies contracted by the Company are legally registered class A licensed waste removal/processors regardless responsible for removal or final disposal. We also operate in a "tripartite checklist operation," which requires the completion of the process by the Company, the cleaning company, and the final treatment plant with a seal, and then finally reporting to the EPD official website to complete the process in order to control and manage the final flow of waste.



GRI | 306-3

Through capacity and efficiency enhancements in 2021, the waste intensity from PEC's headquarters and Taichung Plant have been reduced by 21.3% from the previous year. In the future, we will continue to reduce the amount of waste, improve the efficiency of unit output, and reduce the intensity of unit waste output as our goal, and follow short-, medium-, and long-term goals and action to refine management policies and implement management actions. Panco Healthcare did not generate any hazardous waste, and the only waste generated was domestic refuse, which is lower than the lowest 0.5 tons threshold set for businesses. The waste was entrusted to a qualified vendor for clearance and incineration.

Statistics of waste generated and waste intensity per unit output in the past three years



Note 1: The data for 2019 do not include Panco Healthcare.
Note 2: Emissions intensity is measured using total annual production. Since we mostly adjusted total production output based on clinical trial requirements from 2019 to 2020, and since we have not yet entered into mass production and stable productivity, there still remains some fluctuations in our waste emission intensity per unit output production.

5-3 Hazardous Substance Management

Hazardous Substance Management Approach

Materiality Topic

PEC production processes use certain toxic and concern chemical substances regulated by the EPA. Therefore, in terms of chemical toxicant management, PEC is focused on source management and its proper storage and usage. At the same time, we also stipulate written records of usage status to manage the flow of chemical toxicants and prevents toxicant pollution on the environment and human health.

GRI 103-2~3

Policies

Internal Policy
Adhere to the "Environmental Safety and Health Policy" and "Chemical Hazard Management Procedure."

External Guidelines
Toxic and Concerned Chemical Substances Control Act

Commitments

Comply with environmental laws and regulations, implement toxic chemical management to avoid disasters that cause environmental pollution or harm to human health.

Responsibilities

The actual use, maintenance, management and operation of toxic chemicals are the responsibility of the research and development or use unit, while the rest are the joint responsibility of environmental safety, use and storage units for the management of toxic chemicals.

Resources

- The cost of disposal of hazardous waste in 2021 amounted to approximately NT$385,000 and the dedicated personnel was set up to handle all issues related to waste management. The annual chemical toxicant hazard drill was postponed to January 11, 2022 due to the pandemic.
- The QC department has designated 2 persons to participate in the professional chemical and toxicant response - operator training organized by the Management Center of the Central Taiwan Science Park, and they passed the training and obtained professional licenses (fees were paid by the CTSP project plan).
- ESH department designated 1 person to participate in the professional chemical and toxicant response - general training, and passed the training and obtained professional license (the person will serve as a point of contact for the chemical and toxicant disaster response organization at the plant).

Goals & Targets

Short-term Goals for 2022

- Implement the concepts of toxic chemical hazards and emergency response for toxic chemical operators (and departments), assign personnel to participate in external training to obtain qualifications, and implement daily toxic chemical disaster response and drills.

Mid-term Goals for 2023~2025

- Strengthen the awareness of chemical hazards (including toxic chemicals), risk assessment, and disaster emergency response management in the plant to reduce the risk of chemical operation to personnel.

Long-term Goals for 2026

- Extend the use period of chemicals and reduce chemical waste by reducing 2~3% per year to achieve chemical waste reduction measures.

Evaluation of Management Approach

Mechanism of Evaluation

Taichung Environmental Protection Bureau visits the plant to check the implementation of toxic chemical operations.

2021 Assessment Result

No major violations

Classification and Control of Toxic and Chemical Substances

PharmaEssentia classifies toxic chemicals according to the definition of the Toxic and Concerned Chemical Substances Control Act, and stores the listed toxic chemicals in explosion-proof fume hood in the laboratory according to different categories. The Company's classification and control measures are as follows.

Category

Type 1 chemicals

Difficult to decompose material, meaning that it is not easy to decompose in the environment or due to bioaccumulation, bioconcentration, biotransformation and other effects, resulting in pollution of the environment or harmful to human health.

Type 2 chemicals

Chronic toxic substances, which have the effect of causing tumors, impaired fertility, malformations, mutations of genetic factors or other chronic diseases.

Type 3 chemicals

Acute toxic substance, the chemical substance will immediately endanger human health or biological life after exposure.

Type 4 chemicals

Endocrine disruptors or those who pollute the environment and endanger human health.

Fume hood for toxic chemical operations.

Explosion-proof fume hood for storage of toxic substances in tubes.

Management procedures

Access control

Personnel access control

Chemical cabinet control

The chemical cabinets are locked and the key is managed by a delegated person.

Usage control

The user must fill in the usage form, and the environmental safety unit collects and reports the monthly operation amount on a monthly basis.

Toxic Chemical Disaster Response

To protect the safety of employees, we have formulated emergency response procedures for toxicant leakage and subsequent containment, and we can quickly and effectively complete response procedures by following the four major steps: report, special dressing, leakage treatment, and decontamination. Emergency response equipment are also prepared in the laboratories and are available for employees to use in emergencies. The status of the equipment and their safety inventory levels are also checked on a monthly basis. In addition, we also conduct toxic and chemical spill management disaster drills and biosafety drills from time to time in each year to ensure that employees can respond immediately and quickly to reduce the impact of disasters and maintain workplace safety in the event of an emergency.

Future, in accordance with the Toxic and Concerned Chemical Substances Control Act, we will also set up professional response personnel for toxic and chemical substances in plants to take necessary protective, response and cleanup measures in the event of an accident, and to implement toxic and chemical disaster response operations and education and training for toxic and chemical substance operators in plants.

Case Study

Emergency Response Exercise for Toxic and Chemical Leakage

Setting the drill scenario:
Type 1 toxic chemical accidentally leaked during operation

Participants:
A total of 16 colleagues from departments related to manufacturing processes from Taichung Plant.

Drill response procedures

1 Report

1. Initiate toxic chemical spill reporting procedure
2. Alert the ESH personnel and ESH supervisor at the plant
3. Notify toxic chemical emergency response personnel to prepare for response materials and to support in response measures
4. Personnel evacuation and access control outside the parameters of the disaster site

2 Special dressing

Before entering the site, emergency personnel should wear Class C protective clothing, filter canister type gas mask, chemical protective gloves, chemical protective boots and other equipment.

3 Leakage treatment

1. After the emergency personnel enter the site they should check and confirm that the operator has completed the decontamination and ask the enforcement personnel to retreat and leave.
2. Emergency personnel perform disaster control operations.
3. After the spilled solution is cleaned, put it into the chemical waste bin together with the collection bag and the cleaning and absorbing cotton, and confirm whether the cleaning of the site is completed.

4 Response personnel to remove pollutants

1. Before evacuating the site, the emergency personnel should enter the emergency shower room to decontaminate and put the protective clothing into the chemical waste bin before evacuating.
2. The emergency personnel shall inform the environmental safety personnel that the disaster site has been decontaminated, and then the environmental safety personnel shall report to the plant supervisor that the disaster condition has been lifted.
3. Follow-up disposal of waste in accordance with hazardous waste treatment procedures.

5-4 Water Resources Management

Although the nature of our main pharmaceutical research and development business and the manufacturing process do not consume a large amount of water resources, we do take measures to conserve water resources. In terms of Taichung Plant, which accounts for the largest water withdrawal, discharge and consumption throughout PEC, according to the statistics in 2021, the annual water consumption of the Taichung Plant, approximately 5.6 million liters, only accounts for 0.014% of the Taichung Park of the Central Science Park. Moreover, Panco Healthcare's water intake was 0.115 million liters, and a rainwater collection tower has been established. To conserve water use, tap water is only used when the rainwater is insufficient.

Statistics of water withdrawal, discharge and consumption of the Taichung plant for the past 3 years (unit: million liters)

	2019	2020	2021
Water withdrawal	15.91	15.64	16.1
Water discharge	9.08	9.46	10.5
Water consumption	6.83	6.18	5.6

Note: The Company's water sources are fresh water from third-party. Wastewater is also discharged through a third-party, the Sewage Treatment Plant of the Central Taiwan Science Park.

The water quality monitoring of the discharge water of Taichung Plant is carried out in line with regulations from the EPA in each year. The relevant testing is conducted by EPA-approved testing agency every six months to meet the water discharge and effluents standard. The discharged water is properly treated at the wastewater treatment plant in the Taichung Science Park of the Central Taiwan Science and Technology Administration (CSTA) and discharged in accordance with the standards for the pharmaceutical manufacturing industry under the CSTA Taichung Science Park wastewater treatment system. We rigorously control all processes to ensure that we do not raise any concerns regarding major environmental impacts. In terms of recycling and reusing water resources, Taichung Plant recycles the reverse osmosis brine and wastewater from the manufacturing process to the cooling water tower in the air conditioning system, thus enhancing the efficiency of water recycling and reuse. In 2021, the cumulative volume of recycled water reached 7.779 million liters. More information about water discharge treatment procedure, please refer to page 139 in PharmaEssentia Corporation 2020 Sustainability Report.

Chapter 6

Access to Healthcare and Medicine Pricing

Chapter 6: Summary of 2021

Highlights

The mission of PEC is to provide comprehensive, R&D, innovative and groundbreaking medication to patients to improve their well-being and health. We are always committed to the research and development of new drugs and continue to promote the accessibility of new drugs to patients around the world through our Access to Medicine Strategies: enhance the accessibility of medication, facilitate its affordability and increase the drugs' availability. We also propose the strategic objectives through the Access to Medicine Index framework. By bridging the gap between the accessibility to medicine, patients in need can obtain the drugs in a reasonable, affordable, correct, and easy way. We aim to become a sustainable enterprise and make social influence so that patients can trust and count on. And through the Access to Medicine Management Policy which is closely consistent with the business development strategy, we strive to create shared values with patients. We also expect to achieve the UN SDG Goal 3 "Good Health and Well-Being" by 2030 with our corporate efforts.

Relevant Material Topics

- Access to Medicine
- Patient Relation and Community Engagement

Relevant Stakeholders

- Patients
- Medical Personnel
- Shareholders and Investors
- Local Community
- NPOs / NGOs

Performance Highlights

Ropeginterferon alfa-2b (P1101) is used by more than 1,500 PV patients

BESREMi® is now available in 37 countries worldwide.
Treating more than 1,500 patients cumulatively as of December 31, 2021.

Accumulated certification of orphan drugs for PV in 2 countries.

Ropeginterferon alfa-2b (P1101) has received orphan drug approval for the treatment of PV in the U.S. and South Korea.

Reliable and stable drug supply chain

PEC has built a comprehensive global supply chain and did not receive any incident reports related to product quality in 2021.

Strengthening the medical system and increasing shared value

Sponsored MPN Asia, an international seminar for MPN for 5 consecutive years

Patient support actions

Established "MPNiCare" platform, commenced SOURCE Program in the U.S., and formulated the first MPN center in Taiwan

Engaging in global patient welfare promotional organizations

Supported activities by foundations and patient organizations including ASH Foundation, The Hematology Society of Taiwan, and MPN Research Foundation

6-1 Governance on Access to Medicine

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Materiality Topic

Corporate philosophy and strategy

Based on the 3 principles of Access to Medicine Index, including Accessibility, Affordability, and Availability.

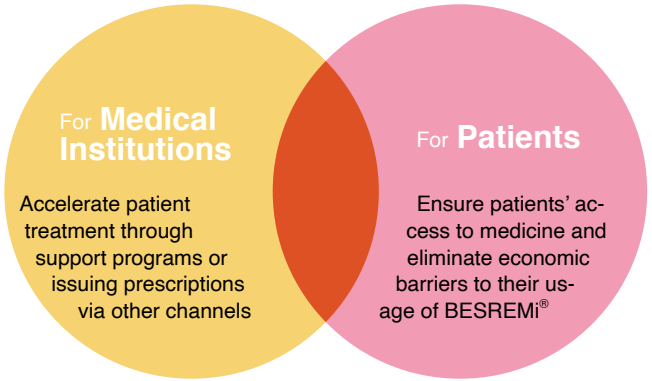
Core concept and commitment

Eliminate the pain of patients and promote the health and well-being of all mankind with our new pharmaceutical products

Strategic Objectives and Access to Medicine Plans

Close-use management of access to medicine closely integrated with business strategies

- Combined with business development strategies, the Board of Directors and senior-level management of subsidiaries in various regions to promote the access to medicine.
- Strictly following the relevant laws and ethical regulations involved in each stage of the product life cycle (please refer to Chapter 2).



Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
R&D of new drugs	Early-stage R&D	Continue to develop innovative drugs	• Modifying existing drugs to reduce the risks of new drug development • Utilizing technology platform to effectively develop diverse products • 4 pre-clinical trials are being carried out successfully (please refer to Section 1.3 "R&D of Innovative Biopharmaceuticals" • Total R&D expense reached NT$1.27 billion; 83 R&D personnel (accounting for 23.3% of total employees) throughout the world are committed to satisfying the unmet medical needs
	IP Management	Active Industry-Academia Partnership and Research	• Engaged in multinational industry-academic partnership with Athenex and Axis Therapeutics • Commits to take into consideration the **access to medicine of patients in low income countries and least developed countries** when utilizing and applying for patents • Clinical trials and post-marketing sales of new drugs worldwide through licensing in and licensing out
Clinical Development	Clinical Trial	Clinical trials at medical institutions throughout the world	• Launching multi-country and multi-center clinical trials with procedures that comply with relevant laws, regulations, and ethical standards • Commits to assist patients who meet criteria to obtain legal access to proper treatment • Simultaneously promoted more than **20 clinical trials**; trial data can also be used as a basis for regulatory marketing approval approval and the drug application from physicians
	Compassionate Use	Support patients with critical conditions	• Provide compassionate use to patients with severe or life-threatening diseases who did not participate in clinical trials; such patients may apply to use experimental new drugs that have passed scientific research but have not yet been launched to begin urgent treatment. • In 2021, **number of patients around the world who benefited from compassionate use reached 40 patients**

Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
Production and Manufacturing	Product Quality	Rigorous product manufacturing that meet regulatory compliance	• Manufacturing process has been approved and tested, and obtained GMP certifications from US FDA, EU EMA, and TFDA
	Logistics and Supply	Timely and Stable Medicine Supply	• Built safe and stable drug supply chain in Taiwan and worldwide
Regulatory Marketing Approval Application	Regulatory Marketing Approval Application	Actively obtained licenses from multiple countries	• Short- and mid-term drug license application plans around the world. • **Currently, BESREMi® has been granted regulatory marketing approval in 37 countries** and the number of regulatory marketing approvals continue to increase, thereby improving the rights to medical access to patients throughout the world.
Market Access	Reasonable Pricing	Proving the economic values of products	• Fair, reasonable and affordable drug pricing. • Analyze product value using **Pharmacoeconomics and Health Technology Assessment (HTA)**, evaluate benefits and risks of the products in medical and economic systems of various countries and realize **appropriateness and sustainability of pricing strategy in the U.S. & Europe**
	Patient Support	Provide resources to accelerate treatment	• **PharmaEssentia SOURCE** (online portal) is the source for patient support and education in US market . – SOURCE offers personalized support services designed to help US patients or caregivers successfully start and stay on BESREMi®. – SOURCE supports the U.S. Healthcare professional your Patients' Access to BESREMi®, can guide your patients through the access and reimbursement process and offer personalized support through their treatment . • Established the **first MPN center** in Taiwan

Value Chain Stages	Access to Medicine Strategies		2021 Action Plans and Performance
Marketing and Sales	Academic Exchange	Demonstrating the medical value of products through academic exchange	• Sponsoring **the conference on Myeloproliferative Neoplasms Asia (MPN Asia)**. • Cooperate with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry. • Promote initiatives and support organizational activities on issues related to access to medicine
	Medical Contribution	Reduce gap in medical access	• As of December 31, 2021, **more than 1,500 patients have used BESREMi® in treatment** • Accumulated hundreds of activities with PV Organization and supported patient organizations in the U.S.
Patient Safety	Immediate Reporting	Established an immediate reporting system	• PEC headquarters' **adverse reaction reporting mailbox**: Safety@pharmaessentia.com • CRO set up **global adverse reaction reporting mailbox**: PharmaEssentia.drug-safety@labcorp.com • A **dedicated reporting management center PEC U.S. Call Center (800) 999-2449** that caters to the U.S. Market and is in charge of handling drug quality and safety demand and reporting information was set up in November 2021
	Serialized Products	High-tech Serialized Products	• **Drug serialization** has been completed in 2020, in which injection preparations OEM Pyramid Laboratories Inc. will be responsible for the packaging and serialization of pharmaceutical products to comply with relevant regulations from the U.S.'s Drug Supply Chain Security (DSCSA)
	Product Recall	Product Recall Management Mechanism	• A comprehensive product traceability mechanism was set up, and **no adverse drug recalls have occurred** in 2021

Management Approach on Access to Medicine

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Policies

Internal Policy

- Draft on Clinical Study Policy
- Draft on Compassionate Use Policy
- Standardized operating procedures related to clinical trials
- Standardized operating procedures related to Compassionate Use Policy

External Guidelines

- International laws and standards
- ICH E6 Good Clinical Practice
- Local laws and standards (take Taiwan for example)
  - Pharmaceutical Affairs Act
  - Medical Care Act
  - Human Subjects Research Act
  - Personal Data Protection Act
  - Regulations on Human Trials
  - Good Clinical Practice, GCP
  - Regulations on Management of Medical Samples and Gifts

Commitments

PEC commits to adherence with relevant international and local laws and standards, and uses our strengths to implement the three approaches of access to medicine strategies from the Access to Medicine Index: Governance on Access to Medicine, Research & Development, and Product Delivery. We expect to contribute to the improvement of global health with our technology and expertise, and committed to following the 5 major aspects of access to medicine strategies:

1. Enhance the management strategies of drug accessibility.
2. Innovative medicine – addressing unmet medical needs
3. Responsible and transparent intellectual property right management
4. Provide stable and safe medicines.
5. Leading the industry development to enhance the local capabilities.

Responsibilities

- Currently, the Board of Directors and the senior management team of each subsidiary act as issue managers and implement governance on access to medicine in conjunction with the business strategies within the current system
- Execution Center for Corporate Sustainability - Access to Medicine Taskforce

Resources

- The Company's investment in promoting access to medicine is closely linked to all stages of our value chain, as described in the management approach to each material topic in each section. Most of these expenses are related to R&D expenses, which amounted to approximately NT$1.27 billion in 2021, while marketing expenses amounted to NT$956 million.

Goals & Targets

2022 Short-term Goals

- Obtain regulatory marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in Macao.
- Obtain regulatory marketing approval for Tirbanibulin (KX01) for the treatment of actinic keratosis (AK) in Taiwan.
- Complete a reasonable and fair internal management policy for drug pricing to achieve global operational goals.
- Establish access to medicine policy.
- Implement health education programs to raise awareness of MPN disease and provide medical education to help patients understand the disease or obtain proper diagnosis and treatment, such as sponsoring the creation of the International Symposium on Myeloproliferative Neoplasms in Asia (MPN Asia) and sponsoring the American Society of Hematology (ASH).
- Strive to provide patients, families, physicians, caregivers, and other stakeholders in many different regulatory settings with appropriate information and opportunities to properly understand disease and the proper use of medicines.
- Establish a global logistics supply chain management system to provide stable, safe and high-quality pharmaceutical products through reliable manufacturing, and to effectively and responsibly manage the transportation and retrieval of pharmaceutical products to ensure that high quality products reach patients in a timely manner.
- Address unmet disease needs through innovative medicines such as value creation through innovation, access to medicine programs that integrate global R&D, initiation of multi-country, multi-center clinical trials, planning of short- to mid-term worldwide regulatory marketing approval programs, and transnational industry collaborations.

Goals & Targets

2023~2025 Mid-term Goals

- Obtain marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in other Asian countries (to expand and develop the use of the drug in Southeast Asia), and Central and South American countries.
- Obtain marketing approval for ET in each participating country after completion of Phase 3 clinical trials of Ropeginterferon alfa-2b (P1101) in the U.S., Taiwan, China, Japan and South Korea.
- Establish the medicine life cycle management plan.
- Leading the industry development
- Cooperate with value chain partners to strengthen social influence on the local biotechnology and pharmaceutical industry.
- Promote initiatives on issues related to access to medicine.

2026 Long-term Goals

1. The goal is to accelerate regulatory marketing approval in all countries by 2026 and to integrate the Company's ability to support patients in developing or low- and middle-income countries with additional drug indications.
   - Promote Ropeginterferon alfa-2b (P1101) to enter Eastern Europe, Central Asia, and some African markets, and apply for regulatory marketing approval for PV to provide early access to patients in need.
   - Enter Southeast Asia, Central and South America, Eastern Europe, Central Asia, and some African markets to apply for regulatory marketing approval to market ET.
2. Responsible and transparent intellectual property right management
   - PEC commits to take into consideration the access to medicine of patients in low-income countries and least developed countries when utilizing and applying for patents to ensure the treatment needs of patients.
   - Conduct clinical trials and post-marketing sales of new drugs worldwide through licensing-in and licensing-out.

Evaluation of Management Approach

Mechanism of Evaluation

- Strictly follow the laws and external regulations involved in all phases of the product cycle from R&D to sales.
- Establish internal policies for ethical and responsible pharmaceutical supply, fair pricing, and international marketing compliance.
- PEC's Board of Directors and the senior management team of each subsidiary act as issue managers, and governance on access to medicine is consistent with business strategies within the current system.

2021 Evaluation Results

- BESREMi® has been granted regulatory marketing approval in 37 countries and the number of regulatory marketing approvals are still increasing, thereby improving the rights to medical access to patients throughout the world.
- BESREMi® was granted regulatory marketing approval as a first-line treatment for PV patients by the U.S. FDA in November 2021.
- Completed the formulation of the global supply chain for commercial use.
- Compassionate use has cumulatively benefited 40 patients worldwide, including 39 MPN patients in Taiwan, and 1 rare EDC disease in South Korea.
- Approved the implementation of a project for the importation of MPN-related diseases in Hong Kong.

6-2 Innovative Medicine - Solving Unmet Medical Needs

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Creating Value Through Innovation

During the long development process of biopharmaceutical R&D, a drug developer not only invests heavily in R&D and recruits science experts, but it must also have the patience and perseverance to keep trying and pursuing breakthroughs as well as bear the potential risks associated with the failure of new drug development, competitive risks, or various risks associated with intellectual property rights. In addition, it must also meet the expectations for the new drug from patients and their families, relevant insurance companies, and medical personnel. In view of this, we have developed our own "PEGylation Technology Platform" that builds on our platform of existing drugs and have also successfully developed a new generation of PEG-based long-acting alpha interferon drugs. Moreover, this drug may have therapeutic potential across multiple indications, which is a competitive advantage compared with other competitors. It is being studied not only for the treatment of indications related to blood diseases, but also for tumor diseases and viral infections. It is exactly where PEC creates the value of access to medicine for patients.

Value of the PEGylation technology platform

Improve on existing drugs Reduce the risk of new drug development

We have successfully developed a new generation of PEG-based long-acting alpha interferon drugs based on our PEGylation Technology Platform, an original protein-based drug development, which has significantly reduced the risk of new drug development. For patients, they can enjoy fewer side effects, physicians can provide better treatment, and the insurance industry can potentially reduce hospital and clinic costs, creating shared value with stakeholders.

Utilizing technology platform Effectively develop multi-products

Through the PEGylation Technology Platform, we are innovating drugs that can be used not only for indications related to hematologic diseases, but also for oncologic diseases and viral infections, making it possible to use one drug for multiple indications. If the indication is a rare disease, the time to market can be improved.

Improvement of Existing Drugs to Reduce the Risks of New Drug Development

Ropeginterferon alfa-2b (P1101) 7 years clinical trial research data results

7.5 Years of Safety and Efficacy Data

The safety and efficacy of BESREMi® has been studied through a 7.5–year, multi–center single–arm clinical trial, and 61% of the patients showed complete hematologic response (CHR).

Myeloproliferative neoplasm (MPN) is a chronic hematologic cancer, which is recognized as a rare disease in certain countries, that has been a serious and unmet medical need. As for the treatment of polycythemia vera (PV), a type of MPN, we have developed a new generation of PEG long-acting α interferon, Ropeginterferon alfa-2b (P1101), utilizing our PEGylation technical platform. Our partner AOP Orphan used our Ropeginterferon alfa-2b (P1101) for the treatment of PV in a 7.5-year clinical study and found that 60% of the patients achieved complete hematologic response (CHR), demonstrating its potential to benefit the patient community. Currently, Ropeginterferon alfa-2b (P1101) has obtained regulatory marketing approval for the treatment of PV, and Phase III pivotal trial for essential thrombocythemia (ET) has been carried out. As the next step, we seek to expand the indications of Ropeginterferon alfa-2b (P1101) to Pre-fibrotic primary myelofibrosis (Pre-PMF), thus expanding its reach across the MPN field and for more patients worldwide.

Effectively Develop Diverse Products Through Technical Platform

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After receiving the orphan drug approval from the U.S. Competent authority for Ropeginterferon alfa-2b (P1101), an orphan drug designation was also obtained from the Korean MFDS in 2020. PEC also passed the Good Manufacturing Practice (GMP) audit by the Korean MFDS competent authority in early 2021, allowing us to bring our products to the Korean rare disease market, and becoming the first approved treatment for PV in Korea's clinical medicine. The drug is expected to bring better treatment plans to approximately 5,000 local disease patients. Additionally, we were also granted the U.S. regulatory marketing approval by the U.S. FDA in November 2021, which provides7 years of exclusive marketing rights in the local market.

Ropeginterferon alfa-2b (P1101) is being studied not only for indications related to hematologic diseases, but for indications in neoplastic diseases and hepatitis viral infection diseases. If these studies prove successful, these potential uses across multiple indications can create efficiencies across R&D expenses and company resources, increase the likelihood of regulatory marketing approvals, and allow us to serve and benefit a broader group of patients. We have also initiated multi-country and multi-center clinical trials globally. At present, PEC has simultaneously promoted more than 20 clinical trials for cumulatively more than 1,500 patients. Going forward, such trial data can also be used as a basis for regulatory marketing approval and the drug application from physicians.

In addition, through the cooperation between Taiwan and Japan, we have a deeper understanding of the disease needs of the public health system in various regions. Based on the long-accumulated knowledge and insights of related diseases of external academic institutions, as well as our ability in the latest and most cutting-edge technology and skills, we can jointly implement the medicine access plans required by different diseases in various regions. In the future, we will also continue to accelerate access to medicine for patients around the world to fulfill our commitment.

Designation of orphan drug for Polycythemia Vera (PV) and regulatory marketing approval in the US and South Korea

One drug for multiple indications

In 2021, the number of subjects who used the drug in clinical trials have grown 18% from the previous year

Collaborations with foreign universities - Enhancing local R&D and clinical trial capability

2018 2019 2020 2021

Ongoing joint research studies with universities in Taiwan since 2018. Mostly for development and applications of new kidney drugs. Project was completed in Q2 2020, cumulative investment toward this industry-academic project reached nearly NT$2.7 million.

Sponsored Taiwan's medical centers and Japanese academic institutions to conduct related viral hepatitis research programs since 2019. The project was completed by the end of 2020, with a total investment of over NT$1 million in research expenditures.

Partnered with university in Taiwan to research Hepatitis and anti-PD-1 immunotherapy since 2019. Total investment neared NT$3 million but the project was postponed and completed in the end of July 2021 due to the COVID-19 pandemic.

Using Ropeginterferon alfa-2b (P1101) in Compassionate Use to Benefit the Patients

40 patients

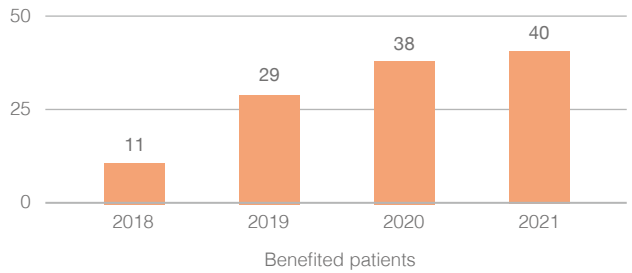
Number of patients around the world who benefited from compassionate use in 2021

Benefits Korean patient

First compassionate use in patient overseas

Certain patients with severe or life-threatening diseases are neither qualified for enrollment in clinical trials nor have other alternative medical choices; "Compassionate Use" addresses the access to medicine needs of these patients. After passing the filter criteria from PEC's internal standardized operating procedures, internal reviews, and meeting both statutory requirements and standards from the ethics committee, patients may apply to use new experimental drugs that have passed scientific research but are not yet approved for marketing and sales throughout the world for their urgent treatments. As of December 31, 2021, a total of 39 cases were approved in Taiwan, and the first overseas application was also approved in South Korea. PEC will continue to provide measures related to compassionate drug use to satisfy unmet medical needs.

Chart of Compassionate Use patients



6-3 Insights of Intellectual Property Rights

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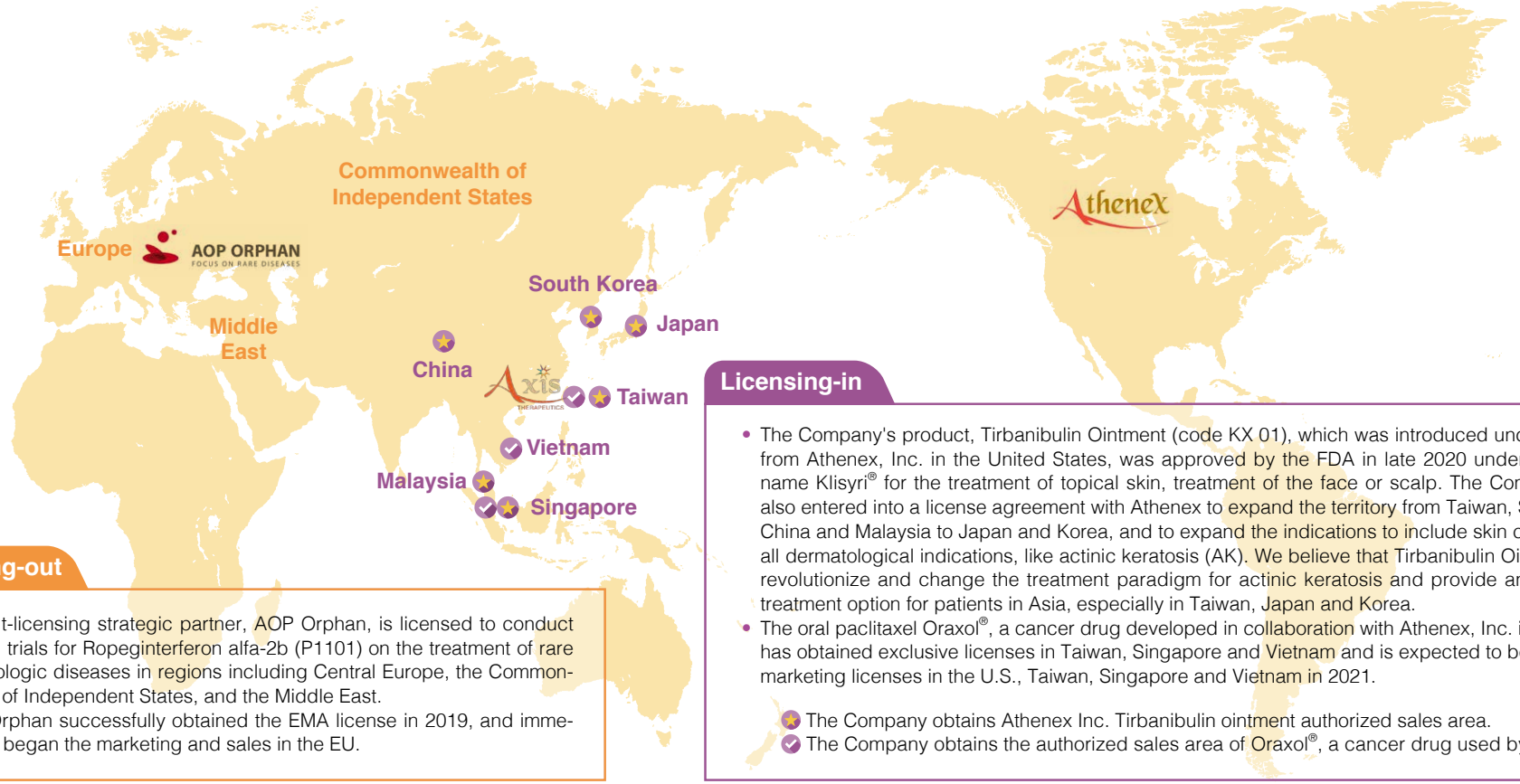
Maximizing the Value of IP Rights via Technology Licensing

PEC attaches great importance to the transparency and sharing of intellectual property rights. Applying for a global patent is the most effective way for us to spread our exclusive knowledge and to promote technology progress. Based on our patent rights, we license-out the patents and technologies to our partners based on our business development strategies. We also collaborate with major foreign pharmaceutical companies to obtain licensing-in patents and technologies for development and subsequent commercialization. Since our founding, PEC has benefited more than 80 countries/sovereign states by filing patent applications for patented brand drugs. In the future, we will establish a systematic management mechanism for out-licensing and in-licensing management based on our own patents and technologies, to maximize the management efficiency and social value of intellectual property rights, and we also hope to benefit more than 10,000 patients after 3 years of marketing our patented drugs, and to continue to improve the accessibility of medicine.



Licensing-out

- Our out-licensing strategic partner, AOP Orphan, is licensed to conduct clinical trials for Ropeginterferon alfa-2b (P1101) on the treatment of rare hematologic diseases in regions including Central Europe, the Commonwealth of Independent States, and the Middle East.
- AOP Orphan successfully obtained the EMA license in 2019, and immediately began the marketing and sales in the EU.

Licensing-in

- The Company's product, Tirbanibulin Ointment (code KX 01), which was introduced under license from Athenex, Inc. in the United States, was approved by the FDA in late 2020 under the trade name Klisyri® for the treatment of topical skin, treatment of the face or scalp. The Company has also entered into a license agreement with Athenex to expand the territory from Taiwan, Singapore, China and Malaysia to Japan and Korea, and to expand the indications to include skin cancer and all dermatological indications, like actinic keratosis (AK). We believe that Tirbanibulin Ointment will revolutionize and change the treatment paradigm for actinic keratosis and provide an excellent treatment option for patients in Asia, especially in Taiwan, Japan and Korea.
- The oral paclitaxel Oraxol®, a cancer drug developed in collaboration with Athenex, Inc. in the U.S., has obtained exclusive licenses in Taiwan, Singapore and Vietnam and is expected to be ready for marketing licenses in the U.S., Taiwan, Singapore and Vietnam in 2021.

The Company obtains Athenex Inc. Tirbanibulin ointment authorized sales area.
The Company obtains the authorized sales area of Oraxol®, a cancer drug used by Athenex.

The IP Rights of the Access to Medicine Commitment

Commitment

To ensure the drug accessibility of patients, PEC promises to take into consideration the patients in low-income countries and least developed countries in addition to the countries with the most market opportunities when applying for patents and drug applications.

New drug development companies must bear the costs and risks of R&D over a long period of time. Therefore, proper patent protection and management can provide them with sufficient time to recover their R&D expenses, and it is also an important incentive for new drug development companies to invest in R&D of new drugs. After obtaining patent protection in various countries, PEC can allocate resources more effectively and implement strategic plans to enter the local markets. In addition, we can also better educate local medical staff and patients based on the medicine access gap and the demand from local markets, local supply chains, and public health infrastructure.

The least developed countries may restrict the public's right to access to medicine due to intellectual property protections. While applying for important new drug patents, PEC is committed towards giving special consideration for developing countries with relatively low income, and low income as well as the least developed countries in addition to the global prevalence of the indications of the new drugs, thereby satisfying the drug accessibility from the patients in these areas. When it comes to making a choice between the patent rights of a new drug and humanitarian aid, PEC will first prioritize the medical needs of the patients and provide patients with our patented new drug in an affordable and convenient manner.

As of 2021, PEC's drugs have obtained 72 patents in 51 developed countries as defined by the International Monetary Fund (IMF), which accounts for 43.9% of all patents owned by PEC. In addition, we own 92 patents in 23 developing countries as defined by the IMF, accounting for 56.1% of all PEC patents. In terms of global strategic layout and allocations of patented new drugs, PEC is generally more committed to the patients' demand for the new drugs than our revenues and profit. Going forward, this strategy will continue to be adopted in PEC's product life cycle management, so that in terms of access to medicine, those in-need will always be prioritized over the high-income individuals.

We will continue to take inventories of our intellectual properties in the future in order to understand the positioning of PEC's new drug technologies in terms of the world technological standard, expand our global IP strategic layout, and to direct more attention to low-income countries and countries with high numbers of patients and market demand for our patented drugs. Concurrently, we will also regularly update our intellectual property management plans and disclose our patent policies, applications, and implementation status.

6-4 Stable and Safe High-Quality Drugs

Ensure Safe, Stable and Timely Delivery of Medicines to Meet Patients' Needs

To ensure that patients can obtain safe and high-quality drugs on a timely basis, we inspect and consider all factors that may affect patients' accessibility to drugs in all management actions related to the right to the access of medicine, and draft solutions accordingly. By enforcing quality management before, during, and post- production and post-marketing, we provide a safe, stable, and timely delivery of drugs to patients so that the patients' needs can be met. As BESREMi® has obtained regulatory marketing approval from the U.S. FDA in November 2021, action plans that specifically address the U.S. market will also be described to provide American patients with access to medicine as well as to widen our impact to the overall medical and healthcare system and the external society. For a complete description of our quality and safety assurance at each stage of the product life cycle, please refer to Chapter 3.

Early stage
Comprehensive demand integration and planning

Interdepartmental production and sales coordination meetings from time to time to integrate clinical and commercial requirements and to establish secure inventory and secondary sources of materials.

Mid-term
High-quality manufacture and production

Passed tests and meet GMP requirements from the U.S. FDA, EU EMA, and TFDA, and implement strict quality and safety and product release standards monitored by quality control units

Late stage
Safe product delivery

The warehouse management unit arranges the shipping operations according to the shipping instructions, and coordinates and arranges the transportation operations according to the demand temperature of medicines and GDP regulations.

Ensure stable supply chain and enable to deliver safe and high-quality drug on time.

Perfectly integrate customer needs and ensure safe and stable product delivery.

U.S.-based Logistics of BESREMi®

After Pyramid Laboratories Inc., an US injection preparations foundry, completes filling,
The product is transported to a qualified third-party logistics vendor with stable quality for warehousing and batching and transported to specialty distributors and specialty pharmacies.

Please refer to Section 3.4 in Chapter 3 "Outsourcing manufacturing management" for information on the injection preparations foundry, Pyramid Laboratories Inc.

Key Supply Chain Activities in the U.S. For BESREMi® Post-marketing

- Printing of Medication Instructions and Packaging
- Assembly, Serialization, Release
- Deliver the products to third-party logistics
- Deliver products to specialized pharmacy/distributors

6-5 Patient Relation and Community Engagement

Management Approaches for Patient Relation and Community Engagement

Materiality Topic

Patients are the most important stakeholders to PEC. We uphold our patient-centered approach in planning various access to medicine action plans to meet various needs related to patient health and well-being. To provide an integrated package of both medical support and healthcare education to the patients, we aim to enhance patient education, promote research on relevant diseases and to raise the public's awareness by organizing healthcare education, medical and academic seminars and activities related to BESREMi® around the world. This would help to reduce the patients' out-of-pocket medical expenses and barriers to medical access, and we also flexibly and rapidly match the patients' medical needs with various medical and healthcare assistance organizations, thereby allowing appropriate patients to receive the medicines they need and to actively begin relevant treatments. PEC collaborated with Chiayi Chang Gung Memorial Hospital to establish Taiwan's first MPN center to enhance and to align the MPN medical research in Taiwan with international standards. These efforts have helped to expand PEC's external influence in the medical and healthcare system and the community.

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Policies

Internal Policy

- HCP& HCO Interaction Policy》
- 《Promotional Material Policy》

External Guideline

- World Health Organization (WHO)
- International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- National Council for Prescription Drug Programs (NCPDP)
- International Research-Based Pharmaceutical Manufacturers Association (IRPMA)

Commitments

Execute action plans related to patient health.

- Help all patients who use drugs from PEC to clearly understand the characteristics of diseases, mechanism of drug action, and medication.
- Promote knowledge related to the diseases and provide treatment consultation and referral service.
- Care for patients' health and continue to follow-up during the treatment process.
- Promote local medical and healthcare and social engagement to expand PEC's external social influence.

Responsibilities

- Marketing Department and Medical Affairs teams from the Taiwan HQ and all subsidiaries
- Execution Center for Corporate Sustainability - Access to Medicine Taskforce

Resources

Personnel / operational input

- Participated in healthcare education and support programs for patients in Taiwan, sponsored the hosting of MPN Asia for 5 consecutive years, and promoted interactions and sharing of the latest treatment perspectives between Asian experts/scholars and clinical physicians.
- Interactive platform for patient health education, "MPN iCare", is used to provide health care information to patients and their families.
- Launched "PharmaEssentia Can Help" project to provide BESREMi® to medical institutions that participated in the clinical trials
- Launched SOURCE patient support program in the United States

Expense input

- Please refer to Management Approach to Access to Medicine.

Goals & Targets

2022 Short-term Goals

- Promote BESREMi® and related healthcare education activities across the world to strengthen the relationship with local patient organizations.
- Engage in local medical, healthcare education, and academic seminar activities to foster increased understanding of therapeutic information in the MPN area.
- Launched SOURCE patient support program in the United States as a resource for patient support and education.
- Sponsored the establishment of MPN Center at Chiayi Chang Gung Memorial Hospital in Taiwan.

2023~2025 Mid-term Goals

- Continue to provide the patient support program to assist appropriate BESREMi patients to start therapy.
- Continue to promote BESREMi® and related healthcare education activities across the world to strengthen the relationship with local patient organizations.
- Continue to strengthen various diverse activities and stakeholder engagements, and to reach more local medical institutions and organizations.
- Promote patient support plans in other countries where BESREMi® has been marketed to enhance global coverage.
- Accelerate the research and development of using BESREMi® toward other MPN diseases and expand its indications toward treatment of other diseases.
- Monitor relevant international initiatives and review the resources that can be allocated as well as the benefits to be created.

2026 Long-term Goals

- Increase the number of countries where BESREMi® is marketed, build comprehensive rare disease patient support and community engagement in each of these countries, and enhance PEC's positive contribution and influence over the global rare disease medical and healthcare system as well as the whole society and industry.

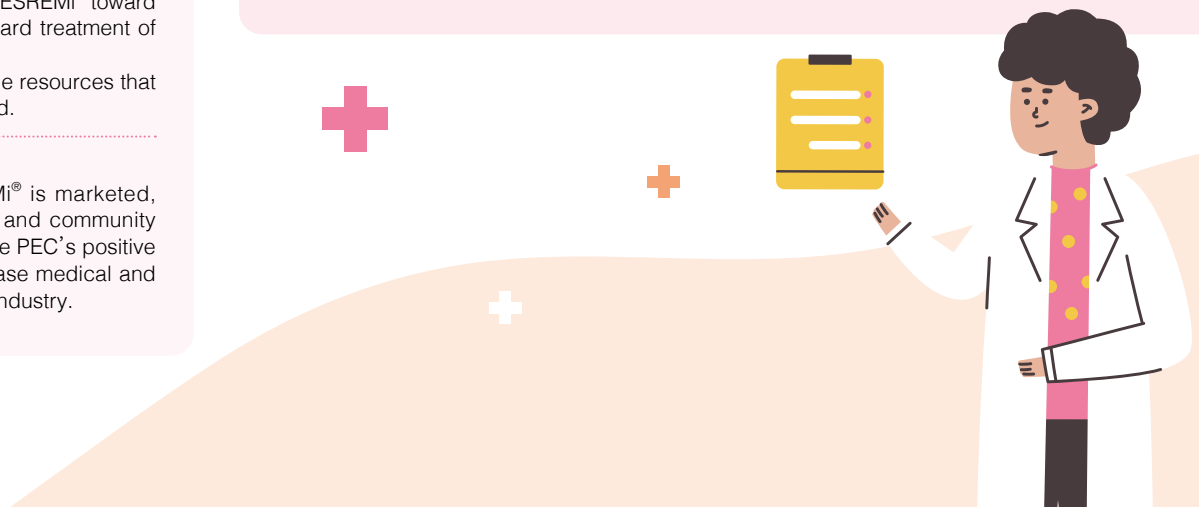
Evaluation of Management Approach

Mechanism of Evaluation

- Budgets for marketing and seminar activities from Marketing Department and Medical Affairs teams from the Taiwan HQ and all subsidiaries.
- Budget Management Procedures

2021 evaluation results

- Collaborated with Chiayi Chang Gung Memorial Hospital to establish Taiwan's first MPN center to reinforce Taiwan's medical research in terms of myeloproliferative neoplasm (MPN) and to be more aligned with international trends.
- Continued to operate the interactive "MPN iCare" to provide health care information to patients in Taiwan.
- Organized rare hematology education programs at local hospitals, which are cumulatively participated by 70 persons.
- Organized MPN Nurse Seminar in Taiwan, which was participated by 30 medical staff from 14 hospitals.
- Co-organized the 2021 Taiwan MPN workshop, which was participated by 167 persons (including online participants); Supported the MPN, MDS, and AML seminars in the United States, as well as MPN Research Foundation, Physicians Education Resource, PV Reporter, and MPN Asia, among other relevant activities.
- Provided BESREMi® through the "PharmaEssentia Can Help" project.
- Commenced patient support program "SOURCE" to assist the patients in the United States.



Short- and mid-term drug license application plans

Accelerate regulatory marketing approval, being able to provide medical healthcare to local markets..

Promote the short- and mid-term regulatory marketing approval

We have successfully developed the product Ropeginterferon alfa-2b (P1101) for the treatment of rare blood disorders and have successfully obtained regulatory marketing approval for the treatment of PV in 37 countries including the European Union, Switzerland, Liechtenstein, Israel, Taiwan, South Korea, and the United States. We continue to apply for PV regulatory marketing approval applications for PV to competent authorities of other countries, and to realize the equal right to medical equality for the patients worldwide step by step. Subsequently, we are planning to apply for the regulatory marketing approval for the treatment of a rare hematologic disease, essential thrombocythemia (ET). We hope to bring the drug into all corners of the world for the treatment of patients with rare diseases, bringing new hope to their lives.

2022

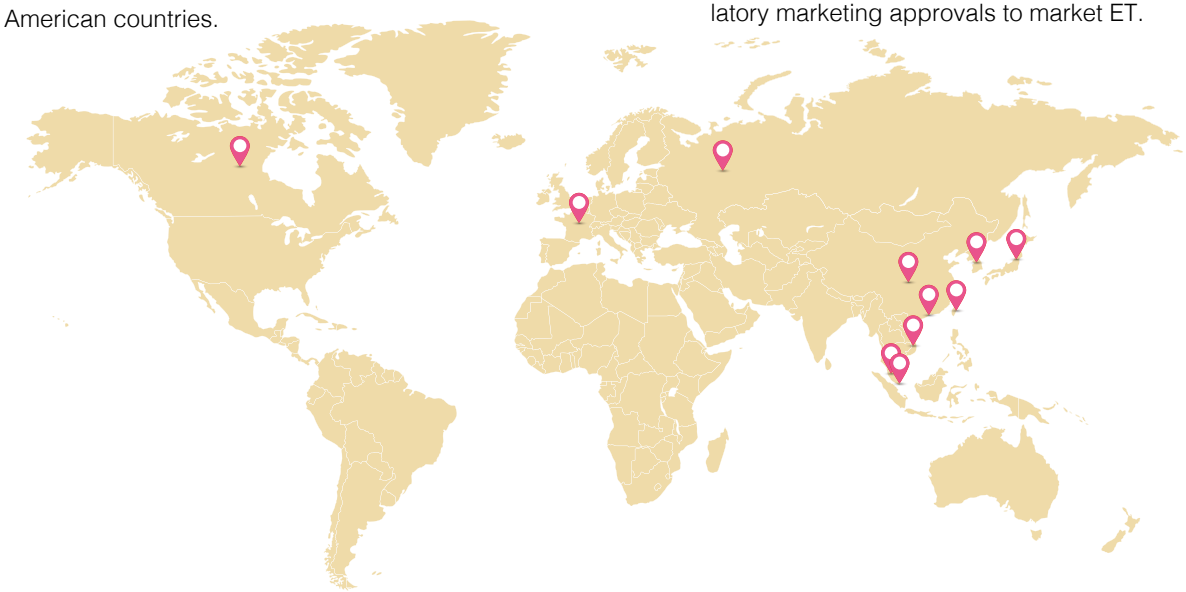
- Obtain regulatory marketing approval for Ropeginterferon alfa-2b (P1101) for the treatment of PV in Hong Kong and Macao.
- Receive marketing approval of Ropeginterferon alfa-2b (P1101) for the treatment of ET from participating countries after completion of Phase 3 clinical trials in the U.S., Taiwan, China, Japan and South Korea.

2023~2025

- Obtain regulatory marketing approvals for the use of Ropeginterferon alfa-2b (P1101) for the treatment of PV in other Asian countries, and Central and South American countries.

After 2026

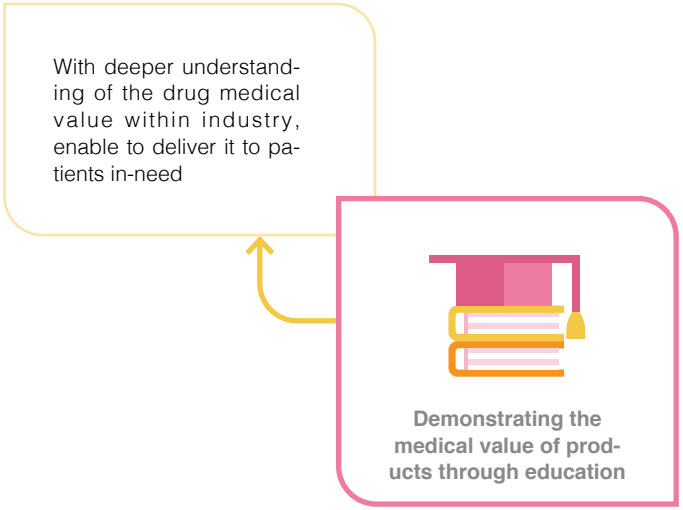
- Enter Eastern Europe, Central Asia, and even some African markets, and apply for a marketing license for PV.
- Enter Southeast Asia, Central and South America, Eastern Europe, Central Asia, and even some African markets to apply for regulatory marketing approvals to market ET.



Demonstrating the Medical Value of Products Through Academic Exchange

SASB | HC-BP-240a.1

"Remember the original intention" is the belief that PharmaEssentia upholds. As a new drug company, its "original intention" is to develop new drugs to treat patients and to become a global benchmark of new biopharmaceutical company. By relying on our core capabilities, we actively participate in experience sharing activities with Taiwan's local companies in the same industry, government units, and value chain partners. Moreover, we assisted our contract research organization partner, Agricultural Technology Research Institute, to obtain the EU certification for Good Manufacturing Practice (GMP) laboratory through our own experiences in building a comprehensive quality system. It has successfully obtained the certification and become the first biosafety testing laboratory in Taiwan. In the future, we hope that with our profound influence in the industry, we aim to enhance our and Taiwan's overall contribution to the use of drugs in the global disease market.



Sponsor to hold MPN Asia

Since the first seminar held in 2016, PEC has been sponsoring MPN Asia for five consecutive years. The conference brings together experts and clinicians from many countries for in-depth interaction and academic exchange on the research and treatment of blood diseases. As the COVID-19 pandemic raged on in 2021, the conference was held online, allowing physicians and scholars around the world who are concerned about MPN disease to continue to exchange experiences with the latest research and treatment modalities during pandemic. For more information about the MPN Asia 2021, please visit its website.

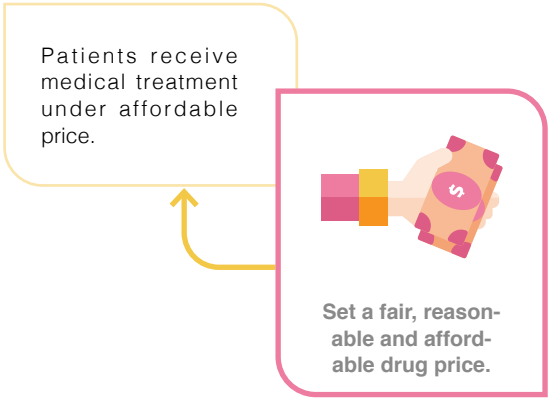
MPN Asia 2021 Sat. April 3 Virtual

Results of MPN Asia sponsorship in the past years

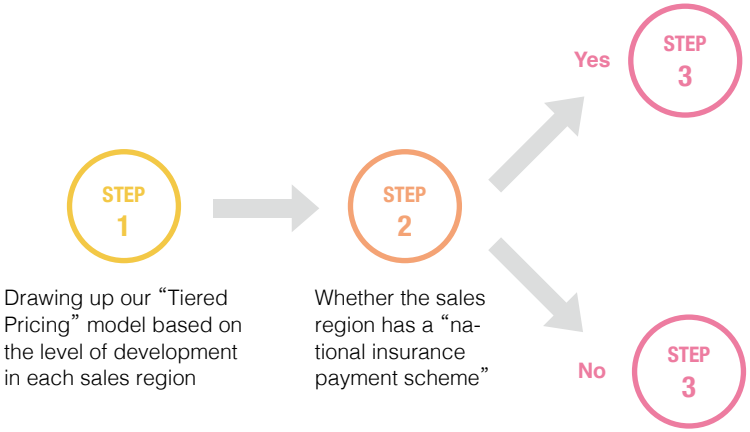
Year	Result description
2016	The first MPN Asia, organized by the Society of Hematology of the Republic of China, was held for the first time in Taipei, Taiwan. It facilitates the gathering of world-class experts and scholars, gains the attention of international hematology oncologists and scholars, and becomes one of the landmark international seminars
2017	The second MPN Asia was in Tokyo, Japan, and was broadcast live simultaneously in Taipei, Taiwan. Invited important medical doctors from Europe, the United States, Japan, and Taiwan to publish the latest MPN drug development and disease treatment methods. Ko-Chung Lin, CEO of PharmaEssentia, expressed that through this international medical conference, he hopes to improve Taiwan's research status in the field of blood diseases, and promote exchanges with doctors of blood diseases in Europe, the United States, and Japan, and promote everyone's attention to the treatment of blood diseases.
2018	The 3rd MPN Asia was held in Hangzhou, China. Key opinion leaders (KOLs) from Europe, the United States, Japan, China and Taiwan were invited to present the latest drug development and disease treatment approaches, and the agenda was divided into basic science and focus topics of MPN. Discussed clinical trial data of our next generation interferon in the treatment of blood diseases.
2019	The 4th MPN Asia was held in Seoul, South Korea to exchange treatment and clinical data from around the world for the treatment of MPN. In addition, through the annual conferences, we can help increase the visibility of Taiwan's new drug R&D capability and win honor for Taiwan.
2020	The 5th MPN Asia which should originally hold in Taipei, Taiwan was canceled due to the pandemic.
2021	Physicians and scholars around the world specializing in MPN diseases were able to exchange experiences with the latest research and treatment modalities during pandemic through the online forum.

Proving the Economic Values of Products Through Fair & Reasonable Pricing

SASB | HC-BP-240b.3



The patients' rights are the first and foremost concern in setting the prices for PEC's drugs. We believe that we can only care for all patients in need through setting fair, reasonable and affordable prices. When setting drug prices, we take into consideration the overall factors covering the R&D costs invested, as well as reimbursement landscape in various countries. We formulate reasonable and fair prices based on the affordability of medical expenses, economic development, and drug preparation costs in various countries, also with reference to the "WHO Guideline on Country Pharmaceutical Pricing Policies" announced by the WHO.



Taiwan

Besremi® is a medicine that requires a doctor's prescription in Taiwan. Taiwan's prescription drugs are mostly paid for by the National Health Insurance, and the government determines drug prices in accordance with the national budget and regulations on health insurance drugs. Pricing will be based on the principles of drug price setting for National Health Insurance, taking into account clinical opinions, proof of efficacy, current treatment costs, recent national benefit budget guidelines, etc., and proposing benefit specifications, drug price planning, 5-year budget and in order to successfully obtain national insurance coverage.

Europe

Marketing and excusive market rights of BESREMi® is licensed to AOP Orphan. AOP Orphan has set the price of BESREMi® based on value-based pricing. Prices of BESREMi® in Germany and Austria are within the tiered pricing of developed countries, the prices are equivalent to the prices of other drugs for the same disease, and the drug prices are within a reasonable range for the patients.

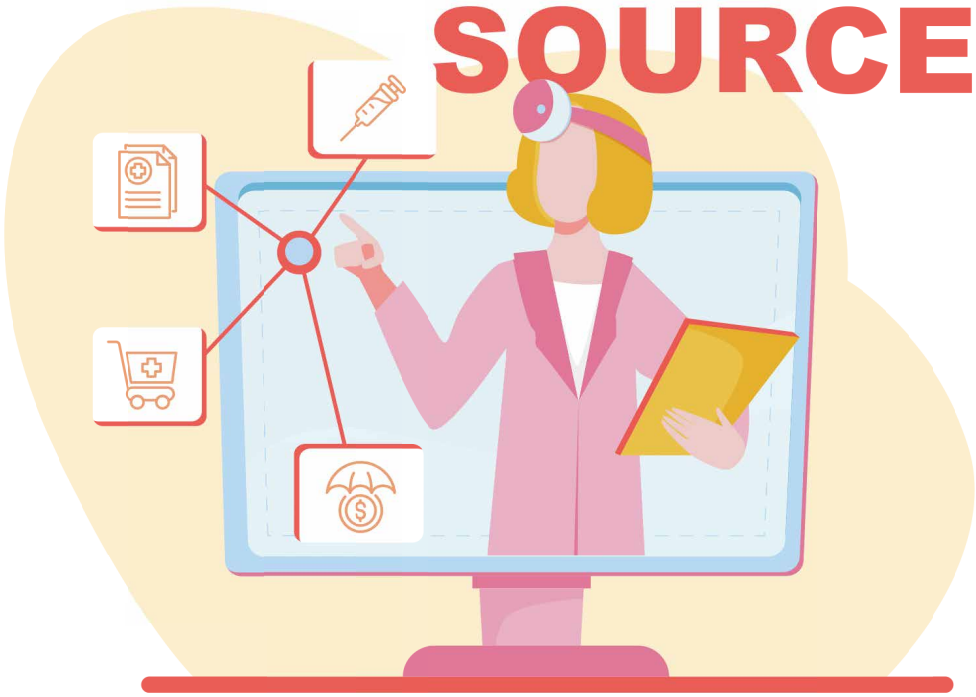
Participation in Activities from the Local Community

PEC is also committed to promoting and engaging in activities to bring us closer to the local community. We participated in 3 sessions of industry-academia exchanges in 2021, including the "MPNs and R&D of New Drugs Practices" in May at National Central University; PEC was invited to shared our experiences in "CMC & Clinical in successfully launching a biopharmaceutical drug" at Nangang Biotech Incubation Center by the Biopharmaceutical Committee of the Taiwan Pharmaceutical Manufacturer's Association in October, and conducted a speech on "A Fully Integrated Operating Global Biopharmaceutical Company in Taiwan" at Bio-Asia in November. We also co-organized investors conference and recruitment fair with Academia Sinica and businesses from the Nangang Biotech Incubation Center to contribute toward the biotechnology industry in Taiwan as well as to increase our external social influence.

An Integrated Platform Providing Medical Support and Healthcare Education

Initiating the PEC SOURCE Patient Support Program

After obtaining FDA approval of BESREMi® in the U.S. for polycythemia vera, PEC initiated a patient service program (SOURCE) for American patients in November 2021 to provide both patient support and education to the patients. The SOURCE program is available for patients prescribed BESREMi® and offers a full suite of services designed to help patients start and stay on therapy. Services include insurance navigation support, titration and injection training, and ongoing adherence guidance. The program also includes physician resources, including guides to help patients get started on treatment and ordering processes. As part of this program, PharmaEssentia will help patients with financial barriers to starting therapy. The company is offering co-pay and co-insurance programs to assist eligible patients who experience financial need. Programs include a $0 copay card for commercially insured patients, temporary product supply in case of insurance delays and/or gaps in coverage, free drug for the uninsured and under-insured as well as assistance identifying additional support as needed. For more information, please refer to the official website of the U.S. Subsidiary and SOURCE program.



Patient Healthcare Education and Medical Contributions

After obtaining approval from the TFDA for Ropeginterferon alfa-2b (P1101) for the treatment of PV in 2020, we have also actively begun our patient healthcare support program. The interactive healthcare education platform, "MPNiCare" provides knowledge regarding myeloproliferative neoplasm (MPN) disease and the latest medical information, through which we hope to integrate medical resources for the patients and their families and help them to deal with the disease courageously and to work toward a healthy and happy life. In addition, we will plan to provide self-funded projects and produce a variety of health education materials and tools. For offline physical patient health education and assistance activities, we organize patient activities and support programs through external third-party entities. In 2021, we held 3 separate sessions of rare hematology educational seminars at hospitals in Taiwan, 2 sessions at the Hematology Society of Taiwan, and 2 at nurses' seminars; cumulatively these activities were participated by more than 500 persons. To ensure that our employees interact with healthcare professionals in a reasonable manner and in accordance with relevant drug and medical regulations, PEC conducts internal training and legal awareness advocacies, and strictly adheres to the ethical guidelines for pharmaceutical marketing from International Research-Based Pharmaceutical Manufacturers Association (IRPMA).

With sufficient knowledge, medical personnel is capable of supporting our patient treatment.

Provide patients and medical personnel with correct health education knowledge.

Construction of a Website in the U.S.

Set up a website (besremi.com) to serve the patients and medical institutions in the U.S.

Accumulated Hundreds of Activities with PV Organization

Provided relevant information for marketing and labeling of BESREMi® to ensure patients' drug use safety.

6-6 Patient Safety Management

PEC complies with GVP standards, and the Pharmacovigilance function team oversees the integration of drug safety information in various countries. Internal related management procedures include product serial number management system and drug recall allow us to recall the drugs promptly and quickly with safety concerns.

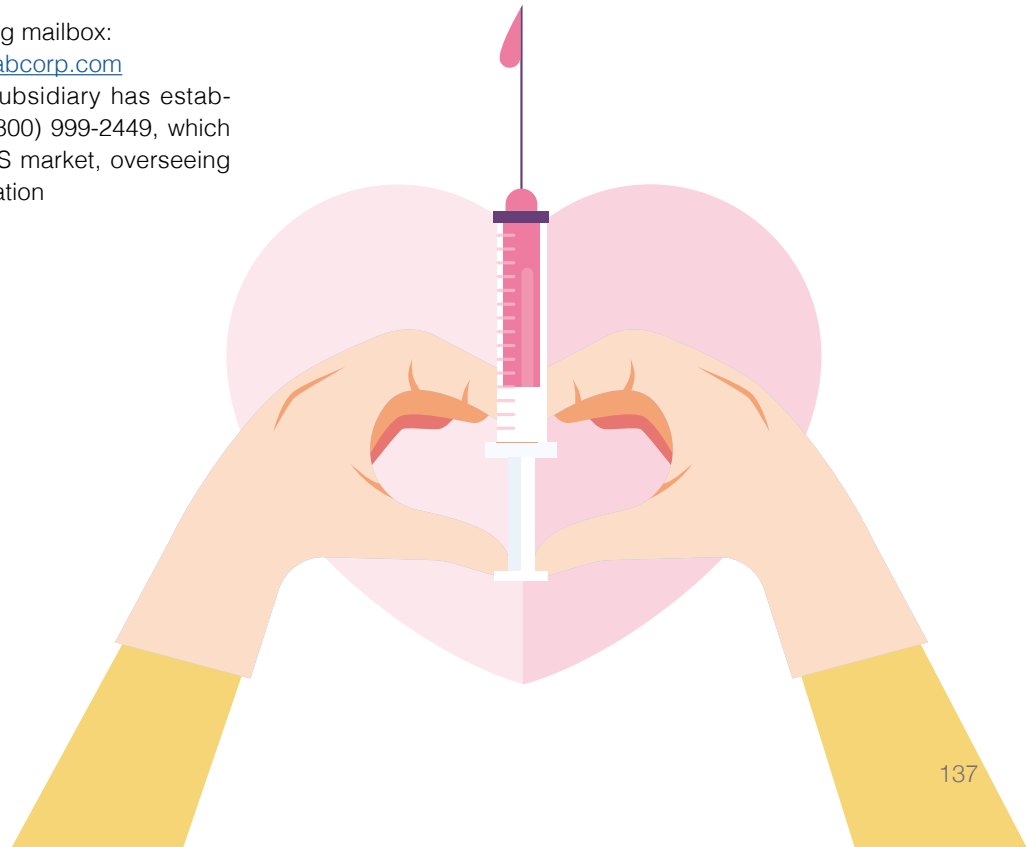
Building A Real-Time Reporting System

Contract research organizations (CROs) are asked to formulate a pharmacovigilance system, and PEC's Taiwan HQ has also established a pharmacovigilance function team responsible for coordinating the information of ongoing clinical trial information from all subsidiaries.

- The headquarters of PEC has set up an adverse reaction reporting mailbox: Safety@pharmaessentia.com
- Pharmacovigilance Call Center in Taiwan: 0800-818-886
- CRO adverse reaction reporting mailbox: PharmaEssentia.drugsafety@labcorp.com
- In November 2021, the US subsidiary has established PEC U.S. Call Center (800) 999-2449, which is dedicated to serving the US market, overseeing drug quality and safety information

High-tech Serialized Products

Drug serialization has been completed in 2020, in which our U.S.-based injection preparations OEM Pyramid Laboratories Inc. will be responsible for the packaging and serialization of pharmaceutical products. Through submitting transaction history (TH) records, transaction information (TI), and transaction sheets (TS) for verification, PEC fully comply with relevant regulations from the U.S. FDA's Drug Supply Chain Security Act (DSCSA). Please refer to Section 3.6 in Chapter 3 for detailed descriptions.



Product Recall Management Mechanism

When concerns regarding product quality arise, we can effectively and quickly recall the product through comprehensive product traceability mechanisms. Please refer to Section 3.6 in Chapter 3 for detailed descriptions on the implementation procedures of the recall mechanism. No adverse drug recalls have occurred during 2021.

Appendix 1 GRI Standards Comparison Table GRI | 102-55

GRI 102: General Disclosures 2016				
Disclosure indicator		Description	Reference section	Page number
Organization profile	102-1	Name of the organization	1.1 A fully integrated innovative biopharmaceutical company	32
	102-2	Activities, brands, product, and services		32
	102-3	Location of headquarters		32
	102-4	Location of operations		32
	102-5	Ownership and legal form		32
	102-6	Markets served		32
	102-7	Scale of the organization		32
	102-8	Information on employees and other workers	4.1 A happy workplace	88
	102-9	Supply chain	3.2 Accountable Supplier Management	67
	102-10	Significant changes to the organization and its supply chain	(There are no major changes in the supply chain in 2021.)	
	102-11	Precautionary Principle or approach	Preamble 6 Risk Management	20
	102-12	External initiatives	(The Company is not a signatory of any external initiatives.)	
	102-13	Membership of associations	(The Company is a member of 14 associations, societies and organizations related to the biotechnology and pharmaceutical industry, including the Taiwan Pharmaceutical Manufacturer's Association, the Taiwan Research-based Biopharmaceutical Manufacturers Association, and the Hematology Society of Taiwan.)	
Strategy	102-14	Statement from senior decision-maker	Preamble 3. Messages from the management team 1.2 Two Major Strategies for Global Markets	9 34
Strategy	102-15	Key impacts, risks, and opportunities	Preamble 6 Risk Management	20

GRI 102: General Disclosures 2016				
Disclosure indicator		Description	Reference section	Page number
Ethics and integrity	102-16	Values, principles, standards, and norms of behavior	Preamble 2 PharmaEssentia's Missions and Sustainability Performances	5
	102-17	Mechanisms for advice and concerns about ethics	2.2 Compliance and business ethics (There is a reporting and appeal channel for violation of integrity management at hr@pharmaessentia.com and a staff suggestion box voice@pharmaessentia.com)	53
Governance	102-18	Governance structure	2.1 Corporate ESG Governance and Management Performance	46
	102-19	Delegating authority		46
	102-20	Executive-level responsibility for economic, environmental, and social topics		
	102-23	Chair of the highest governance body	(The Chairman of the highest governance unit of the Company is not a member of the management team.)	
	102-31	Review of economic, environmental, and social topics	2.1 Corporate ESG Governance and Management Performance	46
	102-32	Highest governance body's role in sustainability reporting	Preamble 1 About our Sustainability Report	3
	102-33	Communicating critical concerns	2.1 Corporate ESG Governance and Management Performance	46
Stakeholder engagement	102-40	List of stakeholder groups	Preamble 4. Stakeholder Engagement	11
	102-41	Collective bargaining agreements	(The Company has not established a labor union, and thus there is no collective agreement. However, the Company holds labor relation meetings on a regular basis as one of the communication channels for employees.)	

GRI 102: General Disclosures 2016				
Disclosure indicator		Description	Reference section	Page number
Stakeholder engagement	102-42	Identifying and selecting stakeholders	Preamble 4 Stakeholder Engagement	11
	102-43	Approach to stakeholder engagement		11
	102-44	Key topics and concerns raised		11
Reporting practice	102-45	Entities included in the consolidated financial statements	Preamble 1 About our Sustainability Report	3
	102-46	Defining report content and topic Boundaries	Preamble 5 Identifying Material Topics	15
			Preamble 1 About our Sustainability Report	3
	102-47	List of material topics	Preamble 5 Identifying Material Topics	15
	102-48	Restatements of information		
	102-49	Changes in reporting	Preamble 1. About our Sustainability Report (We re-identified the material topics by the end of 2021.)	3
	102-50	Reporting period	Preamble 1 About our Sustainability Report	3
	102-51	Date of most recent report		3
	102-52	Reporting cycle		3
	102-53	Contact point for questions regarding the report		3
	102-54	Claims of reporting in accordance with the GRI Standards		3
	102-55	GRI content index	Appendix 1 GRI Standards Comparison Table	139
	102-56	External assurance	Preamble 1 About our Sustainability Report Appendix 5 Statement of Independent Assurance Opinion	3 151

GRI 103: Management Approach 2016				
Disclosure indicator		Description	Reference section	Page number
Management Approach	103-1	Explanation of the material topic and its Boundary	Preamble 5 Identifying Material Topics	15

GRI 200: Topic-Specific Standards Economic Topics 2016				
Disclosure indicator		Description	Reference section	Page number
Economic Performance	201-1	Direct economic value generated and distributed	2.1 Corporate ESG Governance and Management Performance	46
	201-3	Defined benefit plan obligations and other retirement plans	4.2 Competitive compensation and benefits (The Company guarantees the retirement benefits of all employees pursuant to the provisions of the pension system of the Labor Standards Act of Taiwan.)	93
	201-4	Financial assistance received from government	(The total amount of financial assistance from the government in 2021 is approximately NT$14.23 million.)	
Market Presence	202-2	Proportion of senior management hired form the local community	4.1 A happy workplace	88
Materiality: Access to Medicine				
Management Approach	103-2	The management approach and its components	6.1. Governance on Access to Medicine	121
	103-3	Evaluation of the management approach		121
Indirect Economic Impacts	203-1	Infrastructure investments and services supported		121
Procurement Practices	204-1	Proportion of spending on local suppliers	3.2 Accountable Supplier Management	67
Anti-corruption	205-3	Confirmed incidents of corruption and actions taken	(There were no incidents of corruption in 2021 .)	

GRI 200: Topic-Specific Standards Economic Topics 2016				
Disclosure indicator		Description	Reference section	Page number
Anti-competitive Behavior	206-1	Legal actions for anticompetitive behavior, anti-trust, and monopoly practices	(In 2021, there were no legal actions for anti-competitive behavior.)	

GRI 300: Topic-Specific Standards Environmental Topics 2016				
Disclosure indicator		Description	Reference section	Page number
Materiality: Climate Governance				
Management Approach	103-2	The management approach and its components	5.1 Climate Governance	109
	103-3	Evaluation of the management approach		109
Energy	302-1	Energy consumption within the organization		110
	302-3	Energy intensity		110
Emissions	305-6	Emissions of ozone-depleting substances (ODS)	5.1 Climate Governance	111
	305-7	Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions		111
Materiality: Waste management				
Management Approach	103-2	The management approach and its components	5.2. Waste management	112
	103-3	Evaluation of the management approach		112
Waste (2020)	306-1	Waste generation and significant waste-related impacts		112
	306-2	Management of significant waste-related impacts		112
	306-3	Waste generated		112
	306-4	Waste diverted from disposal		112
	306-5	Waste directed to disposal		112

GRI 400: Topic-Specific Standards Social Topics 2016				
Disclosure indicator		Description	Reference section	Page number
Employment	401-1	New employee hires and employee turnover	4.1 A happy workplace	88
	401-2	Benefits provided to fulltime employees that are not provided to temporary or part-time employees	4.2 Competitive compensation and benefits	93
	401-3	Parental leave		93
Labor/ Management Relations	402-1	Minimum notice periods regarding operational changes	(All matters are handled in accordance with the relevant provisions of the Labor Standards Act.)	
Occupational Health and Safety (2018)	403-3	Occupational health services	4.5 Occupational health and safety	101
	403-5	Worker training on occupational health and safety		101
	403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships		101
	403-9	Work-related injuries		101
	403-10	Work-related ill health		101
Materiality: Talent Attraction and Retention				
Management Approach	103-2	The management approach and its components	4.4 Talent training and career development	99
	103-3	Evaluation of the management approach		99
Training and Education	404-1	Average hours of training per year per employee		99
	404-3	Percentage of employees receiving regular performance and career development reviews		99
Diversity and Equal Opportunity	405-1	Diversity of governance bodies and employees	2.1 Corporate ESG Governance and Management Performance	46
			4.1 A happy workplace	88
	405-2	Ratio of basic salary and remuneration of women to men	4.2 Competitive compensation and benefits	93

GRI 400: Topic-Specific Standards Social Topics 2016				
Disclosure indicator		Description	Reference section	Page number
Non-discrimination	406-1	Incidents of discrimination and corrective actions taken	(There were no incidents of discrimination in 2021.)	
Materiality: Human rights				
Management Approach	103-2	The management approach and its components	4.3 Human Rights Protection	96
	103-3	Evaluation of the management approach		96
Human rights assessment	412-2	Employee training on human rights policies or procedures		96
Customer health and safety	416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	(There were no incidents of violation of the rights of indigenous peoples in 2021.)	
Customer Privacy	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	(There were no relevant incidents in 2021.)	60

PharmaEssentia Corporation and Industry-exclusive topics				
Disclosure indicator		Description	Reference section	Page number
Materiality: Business Ethics and Compliance				
Management Approach	103-2	The management approach and its components	2.2 Compliance and business ethics	53
	103-3	Evaluation of the management approach		53
Materiality: R&D and Innovation of New Drugs				
Management Approach	103-2	The management approach and its components	1.3 R&D of innovative biopharmaceuticals	36
	103-3	Evaluation of the management approach		36

PharmaEssentia Corporation and Industry-exclusive topics				
Disclosure indicator		Description	Reference section	Page number
Materiality: Supply Chain Management				
Management Approach	103-2	The management approach and its components	3.1 Constructing a comprehensive supply chain system	64
	103-3	Evaluation of the management approach		64
Materiality: Drug Quality & Safety Management				
Management Approach	103-2	The management approach and its components	3.3 Ensuring the quality and safety of drugs	73
	103-3	Evaluation of the management approach		73
Materiality: Hazardous Substance Management				
Management Approach	103-2	The management approach and its components	5.3 Hazardous Substance Management	115
	103-3	Evaluation of the management approach		115
Materiality: Patient Relation and Community Engagement				
Management Approach	103-2	The management approach and its components	6.4 Stable and Safe High-Quality Drugs	129
	103-3	Evaluation of the management approach		129

Appendix 2 United Nation Global Compact Comparison Table

Category	Ten Principles	Referenced Chapter / Description
Human Rights	1. Businesses should support and respect the protection of internationally proclaimed human rights.	**4.3 Human rights protection** The Company abides by the UN Global Compact, Universal Declaration of Human Rights and "International Labour Convention" and other international human rights conventions.
	2. Make sure that they are not complicit in human rights abuses.	
Labor	3. Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining.	**4.3 Human rights protection** The Company holds regular labor relation meetings.
	4. The elimination of all forms of forced and compulsory labor	**4.3 Human rights protection** There were no incidents of forced labor, child labor, or discrimination in any form.
	5. The effective abolition of child labor.	
	6. The elimination of discrimination in respect of employment and occupation.	
Environment	7. Businesses should support a precautionary approach to environmental challenges.	**5.1 Climate Governance** For the aspect, Environment (E), the Company step-by-step introduces an ISO management system and the Task Force on Climate-related Financial Disclosures (TCFD) as the disclosure framework.
	8. Undertake initiatives to promote greater environmental responsibility.	**5.2. Waste management / 5.3 Hazardous Substance Management** Complying with laws and regulations, the Company manages well the waste control, and requiring suppliers to implement jointly the commitment to environmental friendliness and prevent leakage of chemical substances.
	9. Encourage the development and diffusion of environmentally friendly technologies.	
Anti-Corruption	10. Businesses should work against corruption in all its forms, including extortion and bribery	**2.2 Compliance and business ethics** The Company will formulate its Anticorruption Code with reference to the United Nations Convention against Corruption (UNCAC).

Appendix 3 SASB Index Table

Code	Accounting Metric	Referenced Chapter / Disclosure	Corresponding SDGs	Page number
Topic: Safety of Clinical Trial Participants				
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	**1.3 R&D of innovative biopharmaceuticals** The risk assessment for clinical trials is monitoring by a CRO, and the internal standard operating procedure "Vendor Selection and Management" is the main requirement for performing quality assurance and quality management activities in clinical trials. There are no cases of clinical trials discontinued with CROs due to GCP violations. At each stage of clinical development, we have an audit and inspection mechanism and comply with the "Declaration of Helsinki" and the "International Council for the Regulation of Pharmaceuticals Good Clinical Practice (ICH-GCP)." Written informed consent shall be obtained from the subjects before the clinical trials are officially launched, and strictly screening suitable subjects according to the inclusion and exclusion criteria of the investigational new drug (IND) application.		40
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	No such information is available currently.		
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	No such information is available currently.		
Topic: Access to Medicines				
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	**1.5 Global Commercialization Strategy** **Ch6 Access to Healthcare and Medicine Pricing** One of the Company's 4 focused disease areas is Hematologic diseases. As of the issuance of this report, the drug BESREMi® for the treatment of PV has been sold in 30 countries around the world. We are also sponsoring the MPN Asia for 5 consecutive years since 2016. Also the conference of MPN/MDS/AML, MPN Research Foundation, Physicians Education Resource, PV Reporter and other relative activies since 2021, that physicians and scholars around the world who are concerned about MPN disease can continue to have access to the latest research and treatment modalities. The subsections of Chapter 6 of this report, describe in detail of our Access to Medicine strategy, implementation plan and annual results, and future goals following the Access to Medicine Index.		42 121 125 127 133
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	No such drug is available since November 2021, when BESREMi® is launched in the U.S. market.		
Topic: Affordability & Pricing				
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	No such information is available since November 2021, when BESREMi® is launched in the U.S. market.		

Code	Accounting Metric	Referenced Chapter / Disclosure	Corresponding SDGs	Page number
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	No such information is available since November 2021, when BESREMi® is launched in the U.S. market.		
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	**6.4 Stable and Safe High-Quality Drugs** The Company's pricing strategy is to formulate reasonable and fair prices based on the affordability of medical expenses in various countries with reference to the "WHO Guideline on Country Pharmaceutical Pricing Policies" issued by the World Health Organization (WHO). The price in 2021 is the sam as 2020. In the future, we will continue to track the price of drugs around the world to ensure patient affordability.		134
Topic: Drug Safety				
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	**3.6 Effective pharmacovigilance and recall mechanism** The Company has completed the establishment of a pharmacovigilance mechanism at the headquarter, and the subsidiaries and other drug supplying countries or regions will complete the establishment in accordance with local regulations and drug marketing schedules. We will continue to monitor the safety and risk management of new drugs after they are launched. There are six serious adverse drug reaction (ADR) events since BESREMi® is released in the U.S. market. We collected the detials in the PSUR report and continuously tracked.	 	73 83
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System			73 83
HC-BP-250a.3	Number of recalls issued; total units recalled			73,83
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal			73,83
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practalsoices (cGMP), by type			73 83
Topic: Counterfeit Drugs				
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	**3.1 Constructing a comprehensive supply chain system** **3.6 Effective pharmacovigilance and recall mechanism** We have established records of serial number, batch number and factory activities for each batch of pharmaceutical products to ensure batch flow and traceabilityto managed and tracked them with standard operating procedures such as the "Product Code and Batch Number Coding Procedures." We have also formulated "Product Secondary Packaging and Serialization Batch Record" to regulate the operation process of commercial packaging and serialization of products by overseas outsourced processing plants. BESREMi®, which is expected to be launchedin the U.S. market, has also completed the introduction of drug serialization in 2020.		65 85
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	**3.6 Effective pharmacovigilance and recall mechanism** When a drug is reported to have a known or probable manufacturing defect, deterioration, counterfeit or any other serious quality problem, our QA department will initiate an investigation and initiate product recall procedures and recovery actions. Furthermore, according to the hazard level of drugs, we remove the drugs from the user-end within a certain period, properly dispose of the recovered product, and notify the local competent authority.		85
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	No such information is availablesince November 2021, when BESREMi® is launched in the U.S. market.		

Code	Accounting Metric	Referenced Chapter / Disclosure	Corresponding SDGs	Page number
Topic: Ethical Marketing				
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	No such information is available in the Company.		
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	**2.2 Compliance and Business Ethics** In terms of marketing and labeling, we strictly follow the ethical standards of the WHO and other countries in the pharmaceutical industry. To ensure that our pharmaceutical employees interact with healthcare professionals in a reasonable manner and in accordance with relevant pharmaceutical and medical regulations, employees have received internal training and legal education on the ethical standards of pharmaceutical marketing.		58
Topic: Employee Recruitment, Developing & Retention				
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	**4.1 A happy workplace** The Company creates a stable working environment for retaining talents through compensation and benefits, friendly environment, humane management, smooth internal rotation and training and development. We are recruiting biomedical and R&D talents in various professional fields, and actively recruiting clinical and global management professionals.		91
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	**4.1 A happy workplace** The retention rate for executive positions in 2021 was 89.36%, and the growth rate of all PEC's employees has continued to grow steadily over the past three years.		91
Topic: Supply Chain Management				
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	**3.2 Accountable Supplier Management** The Company has conducted external audits of our upstream supply chain. and stringent internal procedures to monitor the selection, evaluation, and approval of suppliers of raw materials, materials, and instruments/equipment. We also conduct supplier/contractor evaluations on a regular basis each year, using a combination of internal evaluation reviews and on-site audits. For 3 consecutive years, 100% of internal assessments and field audits were completed.		69 72
Topic: Business Ethics				
	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	No such information is available in PEC and no related fees or charges.		
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals			
Activity Metrics				
HC-BP-000.A	Number of patients treated	**1.5 Global Commercialization Strategy** As of Q42021, BESREMi® is sold in 30 countries around the world and used by clincal trials, "Compassionate Use" and marketing channels nearly 1500 patients.		42
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	**1.3 R&D of innovative biopharmaceuticals** **6.2 Innovative medicine - solving unmet medical needs** Please refer to the product pipeline and clinical trial information on the company's official website.		39 125

Appendix 4 Reviewing Goal Implementations in 2021

MaterialityTopics in 2020	2021 Q1 Short-term Goals	Implementation and Performance as of December 31, 2021
R&D of innovative biopharmaceuticals	1. Expand the clinical application of Ropeginterferon alfa-2b (P1101) to areas of MPN other than PV, such as ET and viral hepatitis disease (HBV/HDV).	Goal achieved.
	2. Sponsor Ropeginterferon alfa-2b (P1101) drug and a portion of the cost to support the Chronic Myeloid Leukemia (CML) Investigator-Initiated Trial (IIT) for the benefit of patients in South Korea.	Goal achieved.
	3. License development of KX 01 entered clinical trials in Japan in phase I/II.	Goal achieved.
	4. Promote Ropeginterferon alfa-2b (P1101) for Adult T-cell Leukemia/Lymphoma (ATL) IIT in Japan.	Goal achieved.
	5. Actively develop therapeutic antibodies (PD1) and antiviral drugs (HBV), continue to develop a vaccine, and initiate a clinical development program for a new vaccine.	Goal achieved.
Corporate governance and management	1. Establish a Head of Corporate Governance to strengthen the regulatory function of the independence of the governance culture.	Goal achieved.
	2. The Board of Directors and the management team are scheduled to attend at least two training courses per year.	The statutory required hours of continuing education training from the Board of Directors and the management team has been met.
	3. Introduce external professional organizations to evaluate the annual performance of the Board of Directors and board members.	Goal achieved.
	4. Expand the scope of the sustainability report to the U.S. subsidiary and the Taiwan subsidiary.	Goal achieved.
Compliance and business ethics	1. Establish an inter-compliance committee within the Group to coordinate organizational procedures.	A Compliance Committee has been formulated by the U.S. subsidiary, and a cross-subsidiary Compliance Committee is being proposed.
	2. Establish the Group headquarters' "Top Management Principles for Group Business Conduct and Ethics" and related detailed operational policy documents.	Code of Conduct and ethical standards have been formulated at the PEC headquarters, Panco Healthcare, and the U.S. Subsidiary.
	3. Advise senior executive team on establishing an international compliance committee to oversee the effectiveness of the global compliance program under the compliance committee and establish a reporting mechanism to manage the headquarters and subsidiary/Board of Directors.	A Compliance Committee has been formulated by the U.S. subsidiary, and a cross-subsidiary Compliance Committee is being proposed.
	4. Establish an integrity management supervisory unit under the legal compliance committee.	The Code of Ethical Management have been formulated by PEC headquarters and the US subsidiary.
Risk and crisis management	1. Promote a risk management committee or risk management team to develop risk management policies at the corporate level.	PEC has set up an Audit Committee to assist the Board of Directors in supervising the overall business management risks, and the formulation of a risk management team and its management structure will be implemented based on operational needs.

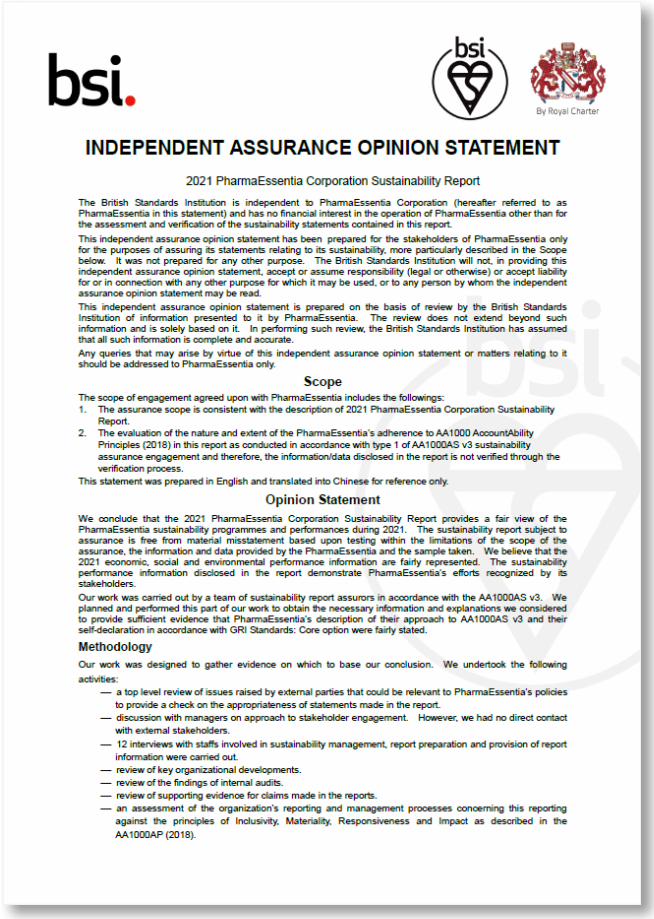
MaterialityTopics in 2020	2021 Q1 Short-term Goals	Implementation and Performance as of December 31, 2021
Risk and crisis management	2. Introduce a non-financial ESG risk management program.	Goal achieved.
	3. Introduce an external third-party validation unit for sustainability report audits.	Goal achieved.
Rigorous data privacy and cybersecurity	1. Formulate information team and Cybersecurity Management Committee.	Information security team is being formulated and the Company expects to set up an Information Security Committee in 2022.
	2. Complete internal cybersecurity and data privacy protection policies.	Information security management guidelines have completed a draft on the information security policy.
	3. Complete cybersecurity policy promotion, education and training, and audits and reviews. The Company regularly promotes, establishes the employees' cybersecurity awareness, and organizes training.	Goal achieved.
	4. Conduct regular cybersecurity external inspection annually.	Goal achieved.
	5. Conduct regular in-house cybersecurity social exercises annually.	Goal achieved.
	6. Complete the enhanced document management mechanism.	Goal achieved.
Comprehensive management of intellectual property rights	1. Complete the revision of the Intellectual Property Rights Management and Utilization Regulations to include a patent application for product life cycle management, risk control of intellectual property rights, and the new drug introduction policy of intellectual property rights.	Goal achieved.
	2. Implement a policy to promote more aggressive global patenting of new drugs. For example, in addition to applying for patents in significant economies worldwide, the need to include low and medium development countries must be evaluated on a case-by-case basis for ongoing applications and new inventions on a rolling basis.	Continue to implement a policy to promote patent application policy for new drugs worldwide.
	3. To extend the patent period, to swear the patent new drugs, and even to obtain better drug prices, the Company will consider applying for the corresponding patent registration system in each country immediately when obtaining the drug licenses in each country, to prevent the early infringement of generic drugs and counterfeit drugs by the pharmaceutical companies, and to achieve the purpose of supplying high-quality patented new medicines in the local area by the original factory only.	Continue to implement a policy to promote patent application policy for new drugs worldwide.
Constructing a comprehensive supply chain system	1. Meet the needs of drug users immediately.	Goal achieved.
	2. Global economic activity continues to be impacted by the COVID-19 pandemic in 2021. All business units covered by the supply chain have adopted feasible strategies to reduce the risk of supply chain disruptions, building on the experience gained in 2020.	Goal achieved.
Ensuring the quality and safety of drugs	1. Passed US FDA PLI (Pre-License Inspection) pre-approval inspection and obtained certification in 2021.	Goal achieved.
	2. Complete the import of electronic documents and quality systems (including document system, education, training system, QMS system, etc.).	Goal achieved.
	3. Continuously strengthen GMP-related training to implement quality operations and management, such as introducing a Training Management System to ensure 100% implementation of the training plan set at the beginning of each year.	Goal achieved.

MaterialityTopics in 2020	2021 Q1 Short-term Goals	Implementation and Performance as of December 31, 2021
Ensuring the quality and safety of drugs	4. Establish a Clinical Quality Assurance unit responsible for quality assurance and audit activities related to clinical trials and drug safety monitoring so that personnel can be familiar with and integrated into product safety practices.	Commissioned CRO to undertake quality assurance and audit activities related to clinical trials and pharmacovigilance.
Effective pharmacovigilance and recall mechanism	1. Complete the formulation and implementation of pharmacovigilance management regulations and standard operating procedures for pharmacovigilance at the headquarter in the first quarter of 2021.	Goal achieved.
	2. Complete the establishment of a post-marketing drug safety database in the first quarter of 2021. The implementation rate of drug safety information reporting reaches 100%, and the implementation rate of drug safety information reported by subsidiaries to headquarters in the required time frame to achieve 100%.	Goal achieved.
	3. Drug safety personnel will be designated at the Taiwan headquarters in the first quarter of 2021 to be responsible for pharmacovigilance and management.	Goal achieved.
	4. Complete the establishment of the drug safety mechanism at the headquarters in the first quarter of 2021. The establishment of the drug safety mechanism in the countries or regions where the subsidiaries and other pharmaceutical products are supplied will be completed according to local regulations and drug marketing schedules.	Goal achieved.
Talent training and career development	1. The training program starts with recruits. The recruits are given training courses to works to let them be familiar with the working environment and bring their strengths into play as soon as possible.	Goal achieved.
	2. Continuous staff skills training by the department head to implement 1-2 skills for staff duties.	Incorporate an on-the-job mentorship system within each department with department performance review report from managers to both instruct and pass on experiences to new employees.
Talent training and career development	3. Review the current status of existing talent professional competencies and complete the definition of professional competencies in each department as a basis for talent development.	Managers will use performance management charts to conduct functional assessment and define the key points in talent development.
	4. Provide department heads with 2 training courses of professional competency linked to the performance management system to enhance various professional abilities and improve management performance.	Each department will apply for external training in accordance with the training procedures based on their own needs; all managers at PEC headquarters received more than 100 hours of training in 2021.
	5. Establish the professional competency system of each department to ensure the professional capabilities required for each position. Provide the standards and learning indicators of the employees, and at the same time establish the talent hiring standards.	Managers will use performance management charts to conduct functional assessment and define the key points in talent development and compile a HR requirement chart during recruitment.
	6. Integrate the department's professional competencies with performance evaluation and project execution, implement performance and function evaluation for all staff, and implement the learning and establishment of professional functions through performance evaluation.	Goal achieved.
	7. Establish a succession system.	Incorporate an on-the-job mentorship system within each department with department performance review report from managers to both instruct and pass on experiences to new employees, thereby achieving successor capabilities training step by step.

MaterialityTopics in 2020	2021 Q1 Short-term Goals	Implementation and Performance as of December 31, 2021
Occupational health and safety	1. Establish Occupational Safety and Health Committee.	The Occupational Health and Safety Committee and dedicated personnel are being planned; the Occupational Health and Safety Policy has already been formulated, and Taichung Plant has obtained the "Badge of Accredited Healthy Workplace/Health Promotion", while the Taipei headquarters has passed the 2021 healthy workplace certification. PEC is gradually completing our occupational health and safety management.
	2. Taipei headquarter hires full-time occupational safety and health personnel.	Expected to increase occupational safety manpower in Taipei in 2022.
	3. Complete the risk assessment of the high-risk workplace of the Taichung manufacturing plant.	The production area is evaluated according to factors, such as the usage of raw materials used and the effectiveness of ventilation which to divided into dangerous areas.
Waste management	1. Continue to check the output of waste chemicals (including toxic substances) in 2020 and follow-up treatment procedures, submit to the environmental protection authority the amendment to the "Industrial Waste Cleanup Plan" and approval of the disposal of toxic substances, and the subsequent legal treatment of waste chemicals (including toxic substances) to avoid violating environmental protection laws and regulations.	Goal achieved.
	2. In 2021, we will check the types of waste output, improve reusability, and reduce waste output. The goal is to increase the recycling rate by 3 to 5% per year to reduce the impact on the environment.	
Toxic chemical substances management	Set up emergency response personnel for toxic chemicals, implement the concepts of toxic chemical hazards and emergency response for toxic chemical operators (including units), assign personnel to participate in external training to obtain qualifications, and implement daily toxic chemical disaster response and drills.	Set up concurrent personnel for emergency response drill for toxic chemical substances.
Access to medicine strategies	1. Obtain Koreans regulatory marketing approval marketing approval.	Goal achieved.
	2. Complete a reasonable and fair internal management policy for drug pricing to achieve global operational goals.	When setting drug prices, in addition to considering the financial ability of patients, we also take into consideration the overall factors covering the R&D costs invested, the number of patients during the patent term, competitive products and expected profits, third-party insurance companies, or the competent authorities of various countries. Reasonable and fair prices are formulated based on the affordability of medical expenses, economic development, and drug manufacturing costs in various countries with reference to the "WHO Guideline on Country Pharmaceutical Pricing Policies" issued by WHO.
	3. Establish access to medicine policy.	PEC commits to adherence with the Access to Medicine Index framework in drafting governance on access to medicine strategies and management approaches.

MaterialityTopics in 2020	2021 Q1 Short-term Goals	Implementation and Performance as of December 31, 2021
Access to medicine strategies	4. Implement health education programs to raise awareness of MPN disease and provide medical education to help patients understand the disease or obtain proper diagnosis and treatment, such as sponsoring the creation of the International Symposium on Myeloproliferative Neoplasms in Asia (MPN Asia), the American Society of Hematology (ASH).	Goal achieved.
	5. Strive to provide patients, families, physicians, caregivers, and other stakeholders in many different regulatory settings with appropriate information and opportunities to properly understand disease and the proper use of medicines.	Goal achieved.
	6. Establish a global logistics supply chain management system to provide stable, safe, and high-quality pharmaceutical products through reliable manufacturing, and to effectively and responsibly manage the transportation and retrieval of pharmaceutical products to ensure that high quality products reach patients at the right time.	Goal achieved.
	7. Address unmet disease needs through innovative medicines such as value creation through innovation, access to medicine programs that integrate global pipelines, initiation of multi-country, multi-center clinical trials, planning of short- to mid-term worldwide regulatory marketing approval programs, transnational industry collaborations, and the provision of compassionate care for patients not enrolled in clinical trials in Taiwan.	Goal achieved.

Appendix 5 Statement of Independent Assurance Opinion GRI | 102-56



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By Royal Charter

INDEPENDENT ASSURANCE OPINION STATEMENT

2021 PharmaEssentia Corporation Sustainability Report

The British Standards Institution is independent to PharmaEssentia Corporation (hereafter referred to as PharmaEssentia in this statement) and has no financial interest in the operation of PharmaEssentia other than for the assessment and verification of the sustainability statements contained in this report.

This independent assurance opinion statement has been prepared for the stakeholders of PharmaEssentia only for the purposes of assuring its statements relating to its sustainability, more particularly described in the Scope below. It was not prepared for any other purpose. The British Standards Institution will not, in providing this independent assurance opinion statement, accept or assume responsibility (legal or otherwise) or accept liability for or in connection with any other purpose for which it may be used, or to any person by whom the independent assurance opinion statement may be read.

This independent assurance opinion statement is prepared on the basis of review by the British Standards Institution of information presented to it by PharmaEssentia. The review does not extend beyond such information and is solely based on it. In performing such review, the British Standards Institution has assumed that all such information is complete and accurate.

Any queries that may arise by virtue of this independent assurance opinion statement or matters relating to it should be addressed to PharmaEssentia only.

Scope

The scope of engagement agreed upon with PharmaEssentia includes the followings:

1. The assurance scope is consistent with the description of 2021 PharmaEssentia Corporation Sustainability Report.
2. The evaluation of the nature and extent of the PharmaEssentia's adherence to AA1000 AccountAbility Principles (2018) in this report as conducted in accordance with type 1 of AA1000AS v3 sustainability assurance engagement and therefore, the information/data disclosed in the report is not verified through the verification process.

This statement was prepared in English and translated into Chinese for reference only.

Opinion Statement

We conclude that the 2021 PharmaEssentia Corporation Sustainability Report provides a fair view of the PharmaEssentia sustainability programmes and performances during 2021. The sustainability report subject to assurance is free from material misstatement based upon testing within the limitations of the scope of the assurance, the information and data provided by the PharmaEssentia and the sample taken. We believe that the 2021 economic, social and environmental performance information are fairly represented. The sustainability performance information disclosed in the report demonstrate PharmaEssentia's efforts recognized by its stakeholders.

Our work was carried out by a team of sustainability report assurors in accordance with the AA1000AS v3. We planned and performed this part of our work to obtain the necessary information and explanations we considered to provide sufficient evidence that PharmaEssentia's description of their approach to AA1000AS v3 and their self-declaration in accordance with GRI Standards: Core option were fairly stated.

Methodology

Our work was designed to gather evidence on which to base our conclusion. We undertook the following activities:

- a top level review of issues raised by external parties that could be relevant to PharmaEssentia's policies to provide a check on the appropriateness of statements made in the report.
- discussion with managers on approach to stakeholder engagement. However, we had no direct contact with external stakeholders.
- 12 interviews with staffs involved in sustainability management, report preparation and provision of report information were carried out.
- review of key organizational developments.
- review of the findings of internal audits.
- review of supporting evidence for claims made in the reports.
- an assessment of the organization's reporting and management processes concerning this reporting against the principles of Inclusivity, Materiality, Responsiveness and Impact as described in the AA1000AP (2018).

Conclusions

A detailed review against the Inclusivity, Materiality, Responsiveness and Impact of AA1000AP (2018) and GRI Standards is set out below:

Inclusivity

This report has reflected a fact that PharmaEssentia has sought the engagement of its stakeholders and established material sustainability topics, as the participation of stakeholders has been conducted in developing and achieving an accountable and strategic response to sustainability. There are fair reporting and disclosures for economic, social and environmental information in this report, so that appropriate planning and target-setting can be supported. In our professional opinion the report covers the PharmaEssentia's inclusivity issues.

Materiality

PharmaEssentia publishes material topics that will substantively influence and impact the assessments, decisions, actions and performance of PharmaEssentia and its stakeholders. The sustainability information disclosed enables its stakeholders to make informed judgements about the PharmaEssentia's management and performance. In our professional opinion the report covers the PhamaEssentia's material issues.

Responsiveness

PharmaEssentia has implemented the practice to respond to the expectations and perceptions of its stakeholders. An Ethical Policy for PhamaEssentia is developed and provides the opportunity to further enhance PharmaEssentia's responsiveness to stakeholder concerns. Topics that stakeholder concern about have been responded timely. In our professional opinion the report covers the PharmaEssentia's responsiveness issues.

Impact

PharmaEssentia has identified and fairly represented impacts that were measured and disclosed in probably balanced and effective way. PharmaEssentia has established processes to monitor, measure, evaluate and manage impacts that lead to more effective decision-making and results-based management within the organization. In our professional opinion the report covers the PharmaEssentia's impact issues.

GRI Sustainability Reporting Standards (GRI Standards)

PharmaEssentia provided us with their self-declaration of in accordance with GRI Standards: Core option (For each material topic covered by a topic-specific GRI Standard, comply with all reporting requirements for at least one topic-specific disclosure). Based on our review, we confirm that social responsibility and sustainable development disclosures with reference to GRI Standards' disclosures are reported, partially reported or omitted. In our professional opinion the self-declaration covers the PharmaEssentia's social responsibility and sustainability topics.

Assurance level

The moderate level assurance provided is in accordance with AA1000AS v3 in our review, as defined by the scope and methodology described in this statement.

Responsibility

The sustainability report is the responsibility of the PharmaEssentia's chairman as declared in his responsibility letter. Our responsibility is to provide an independent assurance opinion statement to stakeholders giving our professional opinion based on the scope and methodology described.

Competency and Independence

The assurance team was composed of Lead auditors experienced in relevant sectors, and trained in a range of sustainability, environmental and social standards including AA1000AS, ISO 14001, ISO 45001, ISO 14064 and ISO 9001. BSI is a leading global standards and assessment body founded in 1901. The assurance is carried out in line with the BSI Fair Trading Code of Practice.

For and on behalf of BSI:

Peter Pu, Managing Director BSI Taiwan

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Statement No: SRA-TW-2021035
2022-04-10

Taiwan Headquarters: 2nd Floor, No. 37, Ji-Hu Rd., Nei-Hu Dist., Taipei 114, Taiwan, R.O.C.

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Disclaimer

The information provided herein is for reference only and is not to be relied upon as making a complete description of the Company's operations. Shall the content involve any predictions, the Company does not imply, declare nor guarantee the correctness or reliability of the information provided. Users shall be solely responsible for their judgment and their undertaking of risks.

Forward-Looking Statement

Some of the statements included in this press release, particularly those relating to the results of clinical trials, the clinical benefits to be derived from Ropeginterferon alfa-2b-njft, regulatory submissions and the timing of any such review, approvals, the commercial opportunity, and competitive positioning, and any business prospects for Ropeginterferon alfa-2b-njft, may be forward-looking statements that involve several risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and similar legislation and regulations under Taiwanese law. Among the factors that could cause our actual results to differ materially are the following: acceptance of the BLA filing does not represent a final evaluation of the adequacy of the data submitted in the BLA; whether the FDA will complete its review of the BLA on a timely basis; the risk that the FDA ultimately denies approval of the BLA; whether the FDA concurs with our interpretation of our phase 3 study results, supportive data, or the conduct of the studies; whether Ropeginterferon alfa-2b-njft, if approved, will be successfully launched and marketed, and other risk factors identified from time to time in our reports filed with any global securities regulator or agency.

PharmaEssentia Corporation

2021 Sustainability Report

Better science, Better lives

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