03

Drug Development, Quality, and Safety

New Drug Research and Development Management and Clinical Trials
Drug Quality and Safety
Drug Marketing and Labeling

03

PharmaEssentia focuses on innovative breakthroughs in self-developed technologies. We aim to drive progress in the biotechnology and pharmaceutical industries while enabling better patient health and well-being. We strictly comply with all relevant regulations and quality standards at every stage from new drug research and development, production and manufacturing, distribution, to product launch.

We also emphasize post-marketing risk management and fulfill our duty of safeguarding patient rights through continuous pharmacovigilance activities and drug safety surveillance.

In terms of product marketing, we uphold professional marketing integrity and ethics, ensuring that all promotional content is accurate and transparent, does not exaggerate product benefits, and fully discloses necessary safety information. We strictly comply with product labeling regulations to ensure that disclosed information is clear and easy to understand, enabling healthcare professionals and patients to make appropriate decisions based on accurate information, further enhancing medication safety.

Main Stakeholders

Achievement Highlights

- R&D capacity growth: In 2025, we continued to increase our R&D investments. There are **14 items** in our R&D product pipeline encompassing products for hematologic diseases, solid tumors, and immune diseases. R&D expenditure and headcount increased significantly compared with the previous year.
- Significant progress on flagship drug: We continued to expand Ropeg indications. Phase III trials for ET have been completed and we have applied for marketing authorizations in multiple countries to strengthen our leadership in the MPN domain.
- **ZERO** quality and safety violations: We did not have any product recalls, violations of health and safety regulations, or fatalities in 2025; all pharmaceutical safety reports were filed within statutory deadlines.
- Global manufacturing compliance and production capacity enhancements: Our Taichung Plant passed **GMP** inspections conducted by competent authorities from multiple countries, and completed establishment of a second DS production line, doubling capacity and enhancing supply resilience.
- Full compliance with marketing ethics and labeling regulations: **100%** of marketing materials were reviewed in accordance with established procedures. We incurred zero marketing and labeling violations over the past five years, and we continue to implement anti-counterfeiting serialization procedures to enhance product safety.

3.1 New Drug R&D Management and Clinical Trials

Material Topics	New Drug Research and Development Management and Clinical Trials
Significance for PharmaEssentia	New drug R&D and clinical trial management are key components driving PharmaEssentia's competitiveness and technological platform development. We address unmet medical demands, enhance patient well-being, and improve product value through innovation-driven R&D and expansion of multiple indications; our comprehensive clinical trial quality and audit system ensures participant safety and improves legal compliance. These measures involve high developmental costs, intellectual property risks, and regulatory liabilities, which, if not properly managed, may affect our corporate reputation and operational sustainability. Therefore, effective R&D and clinical trial management are critical for PharmaEssentia.
Policies and Commitments	PharmaEssentia is committed to solving unmet medical needs. After achieving breakthroughs in the MPN domain, we adhered to the spirit of the Access to Medicine Index and continued to invest in research on blood disorders and solid tumors. We are also working with external research institutes and biotechnology companies to jointly develop cell therapies. PharmaEssentia works with domestic and international research institutes that hold Good Laboratory Practice (GLP), ISO 17025 (international laboratory competence standard), and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) certifications to ensure research personnel rigorously adhere to all relevant regulations during R&D processes for new drugs and abide by strict animal welfare requirements when conducting pre-clinical animal trials.
Responsible Units	・Research and Development of New Drugs Center: Responsible for new drug discovery, and has established the "Project Evaluation Team" to serve as the research decision-making unit. Team members include colleagues and senior managers from different departments. Projects are initiated following approval at "Project Review Meetings," and project supervisors coordinate project progress and make regular progress reports. ・Clinical operations department: PharmaEssentia has developed 30 standard operating procedures for clinical trials to ensure the safety of trial participants and enable data management. We have established monitoring and audit mechanisms at all stages to maintain trial quality, and conduct Phase I, II, and III clinical trials in accordance with approved trial protocols and local regulatory requirements. ・Executive Center for Corporate Sustainability Product Ethics and Safety Team: Responsible for compiling and managing material sustainability topics.

Material Topics	New Drug Research and Development Management and Clinical Trials
Response Strategies, Associated Measures, and Management Actions	**Resources invested** Manpower resources: A total of 180 R&D and clinical personnel around the globe, an increase of 9.1% compared to the previous year Financial resources: In 2025, PharmaEssentia invested a total of NT$3.467 billion to build R&D capacity, an increase of 34% compared to the previous year R&D resources: ・Key R&D pipeline products in 2025 included long-acting interleukin-2 (PEG-IL2) for treatment of inflammatory and autoimmune diseases, bispecific antibody fusion protein PD1-IL2, ADCs, and two cell therapies (NY-ESO-1 TCR-T and innovative TCR-T therapy). Many of our other products are undergoing Phase I, Phase II, Phase III, and post-marketing Phase IV clinical trials as well as investigator-initiated trials (IITs). ・In 2025, our data science team worked to upgrade our computational infrastructure, established an AI-native R&D environment, and successfully developed proprietary computing engines and AI agents to accelerate early-stage drug discovery processes and reduce clinical trial risks. We continue to recruit talent with drug development expertise and utilize AI/ML technologies in new drug design and early-stage development stages to enhance R&D efficiency and innovation capabilities. **Remediation and grievance measures:** ・We collect grievances and feedback from external stakeholders through the "Contact us" page on our official website. ・PharmaEssentia has established a customer hotline to handle product quality issues and general customer complaints, and to safeguard consumer, client, and patient rights.
Evaluation Mechanisms	・New drugs have to pass feasibility studies, pre-clinical animal trials, clinical trials, product manufacturing, and market authorization reviews before launch; all R&D processes undergo product quality assurance, drug safety and efficacy, and regulatory compliance mechanisms that serve as a basis for determining whether development should be continued ・Our R&D department manages and reviews schedules for all R&D projects each month and makes quarterly reports to the Board ・Our R&D expenditures were approved by the Board in December 2024. Our finance department tracks actual and budgeted expenditures of R&D projects every quarter, and compiles reports to the Board ・Our audit department regularly audits R&D management mechanisms in accordance with annual audit plans approved by the Board to ensure R&D compliance and quality. We actively cooperate with on-site inspections and audits conducted by contract research organizations (CROs) at clinical trial institutes, undergo internal audits conducted by clinical trial quality assurance units, and comply with inspections and supervisory checks conducted by competent health authorities in accordance with relevant regulatory requirements to ensure adherence to safety, transparency, and regulatory compliance standards when implementing clinical trials. ・For key Phase III clinical trials, we assess risk levels and need for interim analysis for each trial to determine whether it is necessary to establish an independent Data and Safety Monitoring Board (DSMB). The DSMB regularly reviews safety and efficacy data, and provides recommendations on whether the trial should continue or be adjusted, thereby strengthening risk management and protection measures for trial subjects.
Targets for 2025	・R&D intensity indicator: Continue to maintain R&D expenditures at a certain proportion of revenue ・Continue to obtain approval for clinical trials from competent authorities in various countries

Material Topics	New Drug Research and Development Management and Clinical Trials
Achievements in 2025	• R&D expenditures as a percentage of revenues: 22.18% • The H PMF clinical trial was approved by competent authorities in the US, Canada, Japan, Korea, China, Taiwan, Hong Kong, Singapore, and Jordan. • Completed Phase III clinical trials for ET and formally submitted marketing authorization applications for ET in multiple countries, including Taiwan, the US, Japan, and China. In 2025, we completed the AOM for our new ET indication in the US and formally submitted marketing authorization applications in the US. FDA reviews are expected to be competed on August 30, 2026. We were currently conducting ET market research in Taiwan, the US, Japan, Korea, China, and other countries in advance of obtaining marketing authorizations to understand current treatments, and are also formulating drug prices, drug launch strategies, and timelines.
Short-Term Targets (1 Year)	• R&D intensity indicator: Continue to maintain R&D expenditures at a certain proportion of revenue • Complete clinical trial application submissions and obtain approval from competent authorities, complete subject enrollment and database lock, and compile clinical study reports (CSRs).
Mid-Term Targets (3-5 Years)	• Develop PEG platform: Leverage PEC independently developed PEG platform to develop long-acting cytokines • Develop other technologies such as BiC/FiC PEGylated cytokines (GCSF, IL-2, IFN-g) • Cell therapies: TCR-T targets cancer antigens on the cell membrane as well as intracellular cancer antigens. • Develop drugs targeting autoimmune diseases or solid tumors with low response rates such as renal cancer and pancreatic cancer, and commence clinical trials
Long-Term Targets (More Than 5 Years)	• Develop a top-tier R&D platform: Develop Best-in-Class/First in-Class products • Apply novel BiC/FiC immune checkpoint molecules to treatment of solid tumors and hematologic diseases • Complete Phase III clinical trials and obtain marketing authorizations • Continue to conduct pharmacovigilance activities, collect and analyze adverse events (AEs) in accordance with trial protocols, and track participant survival statuses to assess overall survival (OS) and related efficacy indicators.

R&D Focus

As an innovative pharmaceutical company focused on R&D of new drugs and biopharmaceuticals, PharmaEssentia continues to invest in research on rare diseases amid rapid advances in medical technologies and global aging trends, particularly emphasizing R&D on MPN drugs. MPN mainly encompasses four main disease categories:

Polycythemia vera (PV)

Essential thrombocythemia (ET)

Chronic myeloid leukemia (CML)

Primary myelofibrosis (PMF)

Many patients around the world are facing long-term health challenges caused by MPN, and the biopharmaceutical industry is actively working to develop related treatments. We leveraged our independently established PEGylation technological platform to optimize existing therapies and develop a new-generation PEG long-acting interferon alfa2b (Ropeg). This drug has multiple indications and breaks through traditional limitations in interferon administration and treatment. We have already obtained marketing authorizations for PV, and continue to expand into other indications to enhance the therapeutic value of this drug.

PharmaEssentia has also extended the PEGylation technology platform to other R&D product lines, including:

Long-acting interleukin PEG-IL-2

Bispecific antibody fusion protein PD-1/IL-2

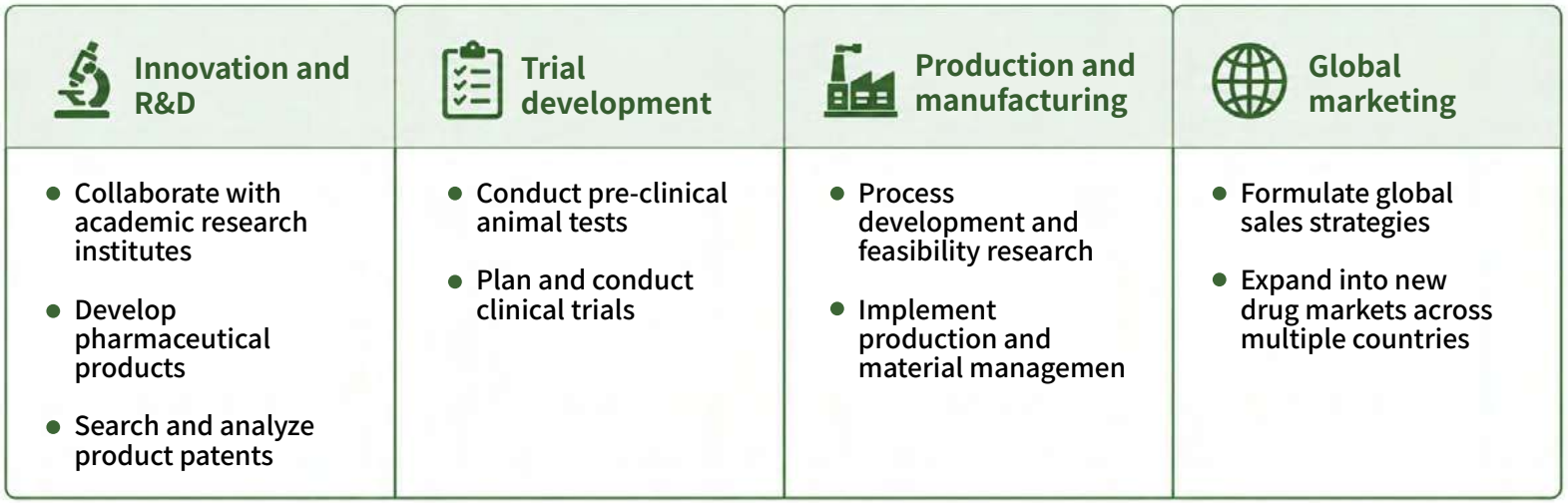
Antibody-drug conjugates (ADCs)

Two cell therapies (NY-ESO-1 TCR-T and innovative TCR-T)

We strive to provide novel treatments for multiple diseases by expanding our technological applications to enhance medical accessibility and treatment efficacy.

Although the development of new drugs involves significant technological challenges, long development timelines, and substantial capital investment, we have consistently upheld a “patient-oriented” philosophy which leverages our pharmaceutical expertise and industry experience. We continue to invest in innovation and R&D so we can improve patient quality of life, deliver clinical value, and steadily work to become a global benchmark company in the biotechnology and pharmaceuticals industry.

R&D to Marketing Processes



Governance

To ensure quality, safety, efficacy, and compliance with regulatory requirements throughout drug development processes from early discovery, feasibility studies, pre-clinical animal testing, clinical trials, product manufacturing, and obtaining marketing authorizations for product launch, we established a comprehensive drug development governance framework which defines the roles and processes of all responsible units throughout the R&D process, thereby advancing R&D progress and enhancing management effectiveness.

Our Research and Development of New Drugs Center reports directly to the chief executive officer and is responsible for R&D of drug technologies. We have also established the “Project Evaluation Team” to make decisions regarding R&D matters. Team members mainly include personnel from the R&D team, the intellectual property department, and senior executives from PharmaEssentia Taiwan and PharmaEssentia USA. Personnel from other departments such as the corporate planning/market development department, finance department, and legal department attend meetings based on their respective functions and R&D needs.

Before launching R&D projects, each unit conducts feasibility assessments in accordance with internal control procedures encompassing proof of concept, literature reviews and analysis of market potential, competitive environment assessments, and preliminary collection of experimental data. Projects enter the fundamental research stage following formal initiation. Meeting minutes are recorded for all meetings, and ongoing reviews and adjustments are implemented to ensure decision-making transparency and process traceability.

Project progress is reported at “Project Review Meetings” for deliberation. Review committee members assess each project’s competitive potential, development potential, and potential infringement risks based on project characteristics and experimental data, and subsequent project developments are determined by the “Project Evaluation Committee,” which is composed of senior executives. After the project has been approved, project supervisors coordinate project progress and invite internal patent attorneys to conduct assessments or provide recommendations as appropriate based on innovativeness, progressiveness, freedom to operate (FTO), and other important aspects to ensure that developed technologies are operable, free from infringement concerns, and align with market values.

In addition to the Research and Development of New Drugs Center and the intellectual property department, we have also established a medical research center to formulate medical strategies for products and clinical trial plans. Our Taichung Plant is responsible for developing manufacturing processes and implementing material management to ensure that R&D achievements align with manufacturing requirements. Our global operations division is responsible for coordinating global strategies and market development plans, ensuring that our R&D achievements closely align with market demands while enhancing our international competitiveness.

Please refer to 3.2 Drug Quality and Safety for more information on drug quality and safety management during manufacturing processes

Strategy

In 2025, PharmaEssentia continued to focus on development of new drugs and product line expansions, concentrating on advancing the progress of R&D projects at each stage and strengthening competitiveness in hematologic diseases, solid tumors, and immunological diseases. As of year-end 2025, our product portfolio includes only one innovative drug (BESREMi), which accounted for 100% of our revenue in 2025. We have 6 drugs in various stages of development from pre-clinical trials; Phase I, Phase II, Phase III clinical trials; and marketing authorization applications, demonstrating a robust and diverse product pipeline. Drugs under development include:

· P1101 (Ropeg): Expand indications for multiple hematologic diseases (such as ET, early PMF, ATL, and CTCL)

PEG-IL-2, anti-LILRB1/2, PD-1/IL-2 fusion protein, anti-PD-1 (P1801), and other novel immunomodulatory and antibody-based drugs

TCR-T, PEG-GCSF, PEG-cytokine X/Y, novel checkpoint Abs, and other cell therapies and novel immunological mechanisms

Our R&D focus centers on enhancing the maturity of product lines, expanding indications, and accelerating marketing authorization applications and market deployment for key indications as we continue to strengthen our competitive advantage in the global biotechnology and pharmaceuticals market.

The following is a summary of R&D and clinical trial progress made on PharmaEssentia drugs in 2025:

Therapeutic Area	Drug Candidate	Indications	Market	Pre-clinical	Phase I & II	Phase III	Registration	Launch
Hematology	Ropeginterferon alfa 2b (P1101)	PV	Europe					
			United States, Taiwan, Korea, Japan, China, Malaysia, Singapore, Hong Kong, Brazil, Argentina					
			Mexico, Columbia, Canada					
		ET	Taiwan					
			United States, China, Japan					
			Korea, Hong Kong, Singapore, Canada					
		Pre-PMF	Global					
		Adult T-cell leukemia/ lymphoma	Japan, Taiwan, China					
		Chronic myeloid leukemia	Korea					
Solid tumors	TCR-T	Solid tumors	Taiwan					
	P1101 + anti PD-1	Hepatocellular carcinoma	Taiwan					
	anti PD-1 (P1801)	Solid tumors	Taiwan					
	PEG-GCSF	Neutropenia	Taiwan					
	PEG-cytokine X, Y	Solid tumors	Global					
	Novel checkpoint Abs	Solid tumors	Global					

Innovation and R&D Focuses

PharmaEssentia completed Phase III clinical trials for ET (LPLV) on Ropeg in 2024. In 2025, we submitted marketing authorizations for ET in Taiwan, the US, Korea, and China to deliver more clinical value to the MPN field and strengthen PharmaEssentia's leadership in this domain.

Preparations for ET marketing authorization applications and market launch

- PharmaEssentia Taiwan completed Ministry of Health and Welfare Food and Drug Administration Good Clinical Practice (GCP) audits on November 28 and December 2, 2025, and officially obtained marketing authorization on May 27, 2026.
- FDA reviews are expected to be competed on August 30, 2026.
- We are formulating drug prices, drug launch strategies, and timelines.
- We are conducting national market surveys of ET in Taiwan, the US, Japan, Korea, and China to better understand current treatments.

Benefits of obtaining ET marketing authorizations

- PharmaEssentia's established MPN physician network for the PV indication can be directly leveraged for ET marketing, enabling rapid market expansion without additional clinical or market deployments, meaning we only need to track patient distributions to significantly improve marketing efficiency.
- At present, there are limited treatment options for ET on the market, and many drugs are associated with severe side effects and poor patient compliance. By contrast, the results of our Phase III clinical trial showed that Ropeg not only demonstrated significant efficacy, but also exhibited a more favorable safety profile and higher patient compliance, making it a promising treatment option for ET.

Apart from MPN, we also leveraged our patented PEGylation technology to develop a PEG-IL-2 drug for treatment of inflammatory and autoimmune diseases, as well as an anti PD-1 antibody and IL-2 fusion protein product. We plan to submit applications for Phase I clinical trials in 2026. We also jointly developed a TCR-T cell therapy through external collaborations and expect to submit an investigational new drug (IND) application in 2027.

PharmaEssentia Innovation Research Center (PIRC): Transforming into an AI-Native R&D Organization

To accelerate our speed and success in early drug discovery and clinical development, our PIRC has led an AI-native R&D transformation since 2025, and we have gradually established the data, modeling, and computing capabilities needed to support long-term R&D growth through several phases of strategic implementations. This approach strengthened our scientific basis in target discovery, clinical risk assessment, and R&D decision-making, helping us build innovative capabilities and competitiveness for the future. Main achievements were as follows:

1.Proprietary discovery engine (PIRC framework)

- PIRC engine proof-of-concept: We successfully developed and deployed a PIRC target identification engine proof-of-concept (PoC). This internal computing framework integrated multiomics and advanced AI technologies to enable precise identification of novel targets.
- R&D product line applications: We used the PIRC engine to validate active R&D projects, generating insights on feasibility and impacting target selection decisions.

2.AI agents and workflow automation

- PIRC-developed AI agents can help to organize scientific information, track intelligence on competitors, compile meeting information, and conduct literature reviews.
- These automated tools significantly reduced the team's manual data processing workloads, enabling researchers to focus on more valuable R&D decisions.

3.Strategic data partnerships & real-world evidence (RWE)

- PIRC collaborated with Qiagen and leveraged knowledge graphs to support strategic decisions on IL-2 indications.
- We also obtained Tempus's RWE and PDO data packages, which provided a key foundation for clinical translation and indication expansion.
- This data foundation reduced clinical uncertainty and improved decision-making accuracy.

Short-Term Targets (1-2 Years)

- Commercialize PIRC engine: Drive widespread internal adoption and develop ADC-specific graphs to support data-driven ADC design strategies
- Integrate AI processes: Embed AI agents, automation, and data frameworks into daily R&D workflows to improve operational efficiency and reduce manual workloads

Long-Term Strategies (3-5 Years)

- End-to-end AI transformation: Expand AI development and data platforms encompassing entire early-stage drug discovery lifecycles to form sustainable and replicable R&D capabilities
- Shorten R&D cycles: We hope to shorten the time from target validation to IND through predictive modeling, automated insights, and computing techniques, thereby enhancing R&D efficiency and success rates.

Adopt Intellectual Property Strategies to Protect Innovative R&D Technologies

We continually research our core products and platform technologies. Our in-house patent attorneys and senior R&D personnel continually engage in "Invention Mining" processes to analyze research outcomes, uncover new patent opportunities, and design additional experiments to obtain stronger supporting evidence when necessary. The Group also continues to explore opportunities by collaborating with medical teams and international institutes. We have submitted patent applications for several new therapies and indications to enhance the technological value of our products and strengthen our legal protections as we work toward our product sustainability goals.

Our in-house patent attorneys continually conduct infringement analysis on future product lines that are still in the early-stage drug development phase, and also file US provisional patent applications when appropriate to secure a strategic position at an early stage while ensuring early patent protection for important technologies. We then establish complete patent application strategies for these technologies based on R&D progress.

Risk Management

Clinical Trial Quality Maintenance and Participant Safety in Clinical Trials

PharmaEssentia has developed 20 standard operating procedures for clinical operations to ensure participant safety and maintain clinical trial quality. We have established monitoring, audit, and inspection management mechanisms for all clinical trial stages, and conduct Phase I, II, and III clinical trials in accordance with approved trial protocols and local regulations. Trials are implemented in multiple countries, including Taiwan, the US, Canada, China, Hong Kong, Japan, Korea, Singapore, and Jordan. We convene regular meetings with contract research organizations (CROs) to review the frequency of site monitoring across trial centers in all regions, ensure all participants signed informed consent forms after fully understanding trial information, and received nutrition allowances and transportation reimbursements corresponding to their follow-up visits. None of our clinical trials were suspended by competent authorities due to Good Clinical Practice (GCP) violations in 2025.

Phase I Clinical Trial Safety Exploration	**Trial Design**
	Evaluate potential risks of trial procedures based on pre-clinical data, drug characteristics, and clinical trial designs; require CROs to formulate case-specific "Monitoring Plans" and "Audit Plans" based on risk levels to implement QC (quality control) and QA (quality assurance) procedures; and ensure that clinical trial processes, data records, and reports all adhere to trial protocols and GCP regulations, thereby protecting the rights and well-being of trial participants. **Quality Assurance (QA)** ・Emcompasses independent audit system and commissioning of alternate CROs or independent consultants to conduct audits during the later phases of clinical trials to ensure trial quality and consistency. Identified issues are assessed and tracked appropriately, and auditees must submit relevant corrective actions and preventive actions to auditors for review. ・Data Safety Monitoring Committee (DSMC): Monitors patient safety and drug efficacy of clinical trials **Quality Control (QC)** ・Monitoring and co-monitoring
Phase II Clinical Trial Preliminary Efficacy Research and Dose Exploration	**Before the Trial**
	・Trial protocols and related documents must be reviewed and approved by health regulatory authorities and the trial institute Institutional Review Board (IRB) ・Investigator meeting: Conduct training related to the trial. ・Informed consent from participants: Participants must be fully informed of clinical trial information and give written consent to voluntarily participate in clinical trials after careful consideration before trial screening can commence ・Participant screening: Rigorously screen participants based on the inclusion and exclusion criteria outlined in trial protocols
Phase III Clinical Trial Large-Scale Confirmatory Efficacy Study	**During the Trial**
	・The clinical operations department conducts joint monitoring with CROs contracted for monitoring services ・Audits are carried out in accordance with audit plans to ensure that CRO services meet quality standards ・All other procedures are the same as those for Phase I trials
	After the Trial
	・Efficacy and safety data are compiled in clinical study reports (CSRs), and marketing authorization is obtained following document review, on-site inspection, and risk and benefit assessment by competent health authorities.

Commitment to Animal Welfare in Pre-Clinical Animal Experiments

Pre-clinical animal testing during the drug development stage strictly adheres to internationally recognized 3R principles (Replacement, Reduction, Refinement). All tests are conducted in accordance with local animal protection regulations as well as international non-clinical safety assessment guidelines to ensure animal welfare, research quality, and fulfillment of corporate social responsibilities.

During the research planning stage, we first determine whether animal testing can be replaced by in vitro testing, computer simulations, or other alternatives. If animal testing is deemed to be necessary, we minimize the number of animals used through appropriate statistical methods and experimental designs. All trials are conducted by professionally trained personnel, and we continue to optimize administration and operating procedures, anesthetic and analgesic doses, veterinary supervision, and environmental enrichment to reduce animal discomfort and stress. All animal experiments must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC), and animal conditions and welfare are continuously monitored during trial periods.

We adopt the same management standards for pre-clinical trials conducted by CROs. Before commencing collaborations, we first assess whether the external institutes meet our required quality and ethical standards, and if they hold relevant certifications such as GLP, ISO 17025, or AAALAC certifications. During the collaboration period, we learn more about the testing institute's experience, capabilities, and progress on the trial through online or on-site visits and audits, and review collaboration contracts and technical agreements to ensure that the responsibilities of both parties and research regulations are clearly defined. We continue to conduct oversight and data review during trial implementation and close-out stages to ensure that research procedures comply with regulations and our internal standards, and to maintain data reliability and consistency.

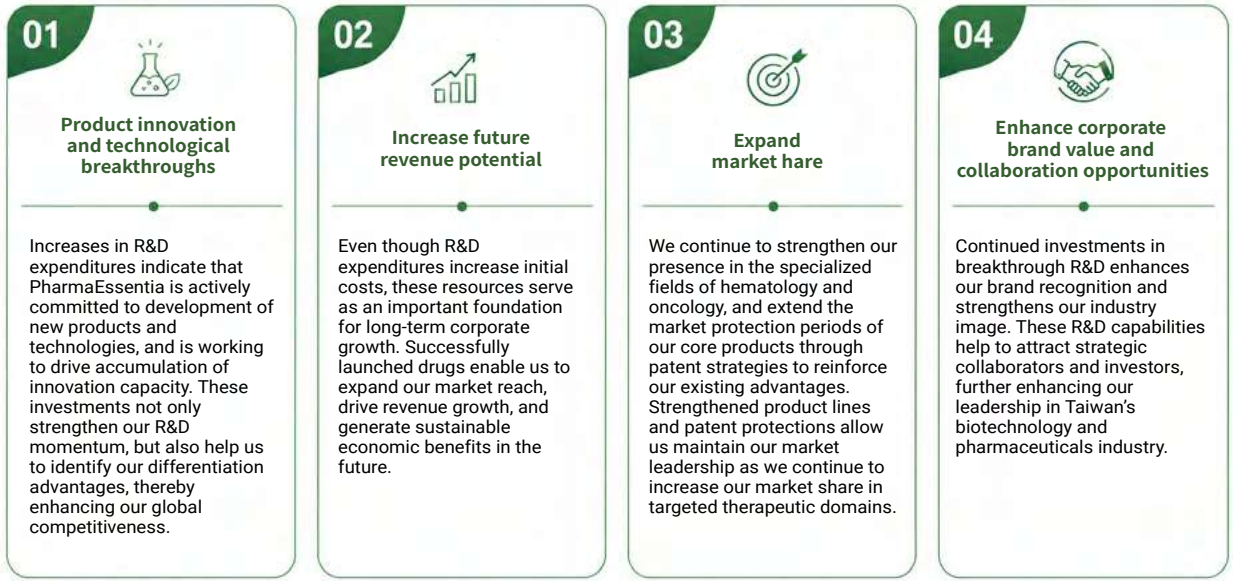
Given that the global pharmaceutical industry's long-term use of the horseshoe crab for endotoxin testing has caused population declines, the Pharmaceutical Supply Chain Initiative (PSCI) called on the industry to reduce dependencies on these arthropods and adopt alternative solutions. PharmaEssentia only procures necessary amounts of LAL reagents and requires suppliers to implement 3R principles by developing alternative reagents, using microfluidic technologies to reduce consumption of horseshoe crab materials by 95%, and continually improving existing LAL formulations. We have never used other endangered species during trial processes, and we are taking practical actions to support biodiversity and ecological conservation efforts.

Metrics and Targets

R&D Expenditures Over Past Five Years

Year	2021	2022	2023	2024	2025
Global R&D expenditures (NT$ thousands)	1,272,776	1,425,964	2,224,054	2,587,570	3,467,828
Expenditure increases compared to previous period (NT$ thousands)	350,396	153,020	798,090	363,516	880,258
Expenditure growth rate	38%	12%	56%	16%	34%
Global R&D personnel (persons)	83	123	142	165	180
Personnel increases compared to previous period (persons)	9	40	19	23	15
Personnel growth rate	12.2%	48.2%	15.4%	16.2%	9.1%

Continued increases in R&D expenditures brings four main benefits for PharmaEssentia:



Development Focuses for Next Five Years (2026-2030)

Continued growth in BESREMi operations	· Continue to increase patient numbers and patient experiences in existing markets · PV indication: We obtained marketing authorizations in China, Singapore, and Malaysia in 2024 · ET indication: We applied for US marketing authorization in 2025, and expect approval to be granted in August 2026
Expansion of BESREMi indications	· Currently conducting global Phase III pivotal clinical trials for early PMF and planning to submit FDA marketing authorization applications in 2027 · Other blood disorders: Research into ATL, CTCL, and other application areas
Expand global production capacity	· Aim to fulfill demand for more than 110,000 patients around the world · Initiated construction of Zhubei Plant in response to market demand, with completion projected for 2026
Top-tier platform	· Utilize novel immune checkpoint molecules and cytokines for treatment of solid tumors, blood disorders, and immune diseases · Cell therapy: TCR-T targets cancer cell antigens and can be used for treatment of solid tumors · Antibody-drug conjugate (ADC) technology: Establish new biologic development capabilities

3.2 Drug Quality and Safety

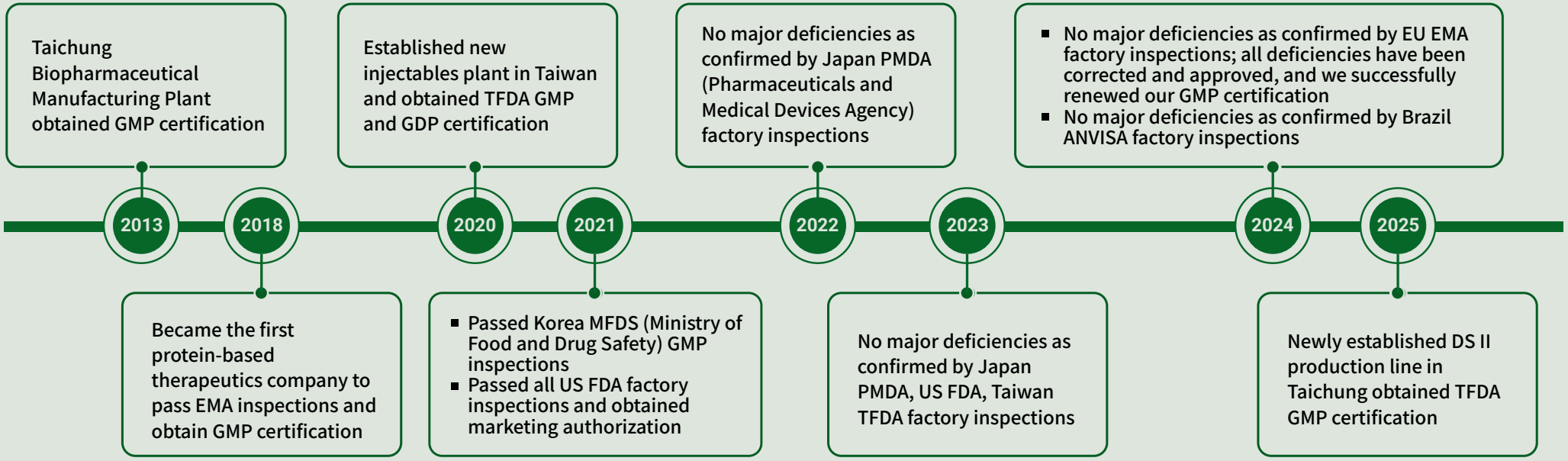
Material Topics	Drug Quality and Safety
Significance for PharmaEssentia	PharmaEssentia prioritizes patient health and well-being, adheres to ethical management principles and medical ethics when marketing registered drugs, and provides patients with professional and trustworthy products. We actively track and report adverse events, and teach our colleagues to uphold “Quality First and Patient Safety” principles when managing drug risks and protecting patient safety.
Policies and Commitments	PharmaEssentia’s Taichung Plant rigorously adheres to the Quality Risk Management Procedure, Equipment Risk Assessment Procedure, and Change Control Procedure; has incorporated risk management procedures into production processes, environmental controls, and material supplies; and conducts annual quality reviews to minimize quality hazards. Production: We comply with quality management regulations for all manufacturing stages set by local competent authorities, and continue to maintain GMP certifications Transportation: We rigorously adhere to GDP regulations, meet local standards for marketing authorization, and strictly control all packaging and transportation processes
Responsible Units	・PharmaEssentia (Taiwan) production, transportation, quality management, and auditing departments ・Products: PharmaEssentia (Taiwan)’s quality control department, quality assurance department, and Product Ethics and Safety Team maintain and monitor the quality of registered and clinical drugs ・Patients: PharmaEssentia (Taiwan) and subsidiary Product Safety & Risk Management (PSRM) teams; these teams are composed of pharmacovigilance personnel which are overseen by the global pharmacovigilance executive director. Pharmacovigilance quality assurance personnel maintain and oversee the quality of pharmacovigilance implementations. ・Executive Center for Corporate Sustainability Product Ethics and Safety Team: Responsible for compiling and managing material sustainability topics
Response Strategies, Associated Measures, and Management Actions	・In 2022, we hired a global pharmacovigilance executive director to conduct global pharmacovigilance tasks ・We have established dedicated pharmacovigilance personnel at PharmaEssentia (Taiwan) and our operational sites around the world ・Commissioned a pharmacovigilance CRO institute to form a project team responsible for managing the Ropeg pharmaceutical safety database and assisting with pharmacovigilance, reporting, handling, exchanges, and regular submission of safety reports to international regulatory authorities ・Introduced Trackwise electronic system to perform deviation management, corrective actions and preventive actions, supplier management, laboratory surveys, and other procedures included in our quality system ・Production & manufacturing quality management and risk management: We host global interdepartmental risk assessment team meetings to jointly review risk issues and correction measures in factory areas ・Invested more than NT$33 million in global pharmacovigilance tasks Remediation and grievance measures: ・We collect grievances and feedback from external stakeholders through the “Contact us” page on our official website. ・PharmaEssentia has established a customer hotline to handle product quality issues and general customer complaints, and to safeguard consumer, client, and patient rights.
Evaluation Mechanisms	・Internal audits: Each department undergoes at least 1 internal quality audit each year, which is conducted by the quality assurance department or an independent third-party organization ・External audits: Audits conducted by international and domestic drug safety competent authorities; foreign experts are also invited to conduct quality audits as needed ・Regular safety reports: We regularly submit DSURs and PSURs to competent authorities in different countries, and competent authorities (such as the US FDA, EU EMA, and TFDA) conduct regular GMP audits ・Post-marketing pharmacovigilance: Issue timely reports and maintain normal operations of real-time reporting mechanisms in accordance with the regulations set by competent authorities in each country ・Assess operational status of real-time reporting mechanisms ・Assess operational status of drug safety reporting hotlines (Taiwan, US, Korea, and Japan) ・No recalls for defective products ・Regularly submit annual drug safety reports to the US FDA, EU EMA, and Taiwan TFDA each year as well as real-time drug safety notifications

Material Topics	Drug Quality and Safety
Targets for 2025	• PharmaEssentia (Taiwan) and subsidiaries report drug safety information within the time periods stipulated by regulations • PharmaEssentia (Taiwan) and Panco employees complete annual pharmacovigilance training and pass examinations • Complete and file Ropeg DSURs in accordance with regulations • Complete Ropeg and Tirbanibulin PSURs in accordance with regulations • Complete quarterly safety signal monitoring reports • Regularly implement and pass internal and external audits • Convene regular global pharmacovigilance follow-up meetings • Complete construction on our Zhubei Plant in the Hsinchu Biomedical Science Park; construction was scheduled to be completed at the end of 2025 • Complete construction of Taipei Bioinnovation Park site and commence production of Phase I and Phase II clinical APIs • Continue to maintain pharmaceutical quality and our record of zero product recalls • Complete GMP/GDP education and training
Achievements in 2025	• PharmaEssentia headquarters and all subsidiaries reported all drug safety information within time periods stipulated by regulations • PharmaEssentia (Taiwan) and Panco employees completed annual pharmacovigilance training and passed examinations, achieving a training completion rate of 100% • Completed and filed seventh Ropeg DSUR in accordance with regulations • Completed sixth Ropeg PSUR and third Tirbanibulin PSUR in accordance with regulations • Completed 4 quarterly safety signal monitoring reports • Regularly implemented and passed internal and external audits; we completed a total of 1 internal audit • Convened 12 global pharmacovigilance follow-up meetings • Our DS II production line was granted approval in Taiwan, the US, Europe, Japan, Korea, Singapore, and Malaysia; our drug substances can now be shipped to the above markets • Our Taichung Plant officially began producing commercial API batches in 2025 • Civil engineering work and the five major utility pipelines of our Zhubei Plant are nearing completion, and we have submitted an occupancy permit application for the main facilities. • Completed construction of Taipei Bioinnovation Park site and commenced production of clinical APIs • Completed construction of mammalian cell and microbial production lines at Taipei Bioinnovation Park site, and validated all related equipment. • Commenced production of clinical antibody drugs in the fourth quarter of 2025 • Total GMP/GDP education and training hours amounted to 20,323 hours
Short-Term Targets (1 Year)	• PharmaEssentia (Taiwan) and subsidiaries report drug safety information within the time periods stipulated by regulations • PharmaEssentia (Taiwan) and Panco employees complete annual pharmacovigilance training and pass examinations • Complete and file Ropeg DSURs in accordance with regulations • Complete Ropeg and Tirbanibulin PSURs in accordance with regulations • Complete quarterly safety signal monitoring reports • Regularly implement and pass internal and external audits • Convene regular global pharmacovigilance follow-up meetings • Obtain regulatory approval for second API production line at Taichung Plant and officially begin production of APIs that comply with the regulations of different countries • Complete construction of new Zhubei Plant as well as various validation processes, and obtain GMP certifications across multiple countries • Complete construction of Taipei Bioinnovation Park site and commence production of Phase I and Phase II clinical APIs
Mid-Term Targets (3-5 Years)	• Pass 100% of competent authority pharmacovigilance (PV) audits • Complete 100% of Individual Case Safety Reports (ICSRs) within the time periods stipulated by regulations • Continue to maintain drug quality and our record of zero product recalls. Commence API production processes that comply with the regulations of different countries at our Zhubei Plant, and also commence cell therapy production processes as a GTP-certified cell preparation facility. • Obtain GMP certifications for Houli Plant across different countries and commence production of GMP-compliant PEG intermediates
Long-Term Targets (More Than 5 Years)	• Maintain 100% drug safety compliance to ensure patient safety • Establish production factories in Europe and the US to enable local production and make strides toward net zero targets • Continue to maintain drug quality and sustain a long-term record of zero product recalls • 100% compliance rate in handling major adverse events related to patient safety

Quality Governance and Management System

PharmaEssentia Global Certification Landscape

We use practical actions to achieve vertical integration within our supply chain from production, quality control, filling, to delivery, and work to expand our global market reach while actively realizing our vision of becoming a world-class pharmaceutical company.



In 2025, we underwent only one TFDA inspection before obtaining related certification. The inspection identified no deficiencies associated with violations of Good Manufacturing Practice (GMP) or equivalent standards, and no corrective measures were required due to any violations. We received no Form 483 Observations, FDA Warning Letters, or other warning letters of an equivalent standard this year. We did not suffer any losses of annual revenue due to plant or facility impacts, or any revenue impacts resulting from suspended production in 2025.

Internal and External Audits

PharmaEssentia's Taichung Plant was the first biologics manufacturer in Taiwan to pass EU EMA inspections and obtain GMP certification. Starting in 2020, we underwent a series of external inspections conducted by Korea MFDS, US FDA, Japan PMDA, and Brazil ANVISA. These inspections found no major deficiencies involving violations of GMP regulations or health & safety regulations, and we submitted CAPA plans within specified time limits for all non-major deficiencies.

The following table shows the frequencies of internal and external audits implemented by PharmaEssentia:

Frequency of internal audits:	Frequency of external audits:
• At least 1 internal audit each month (each department undergoes at least 1 random audit each year) • If audits identify deficiencies, CAPA plans are submitted within specified time limits based on deficiency levels, and related procedures are completed	• Regular official GMP inspections every 2-3 years

Internal audits on drug quality impacts at PharmaEssentia USA are controlled and managed by PharmaEssentia (Taiwan), and external audits at all subsidiaries are implemented by the PharmaEssentia (Taiwan) QA team. Panco passed GDP pharmaceutical wholesaler re-evaluations in 2025; internal quality audits were also conducted on Panco's logistics center, and no major deficiencies involving quality system deviations were discovered.

Manufacturing Processes and Quality Risk Management

International Standard Manufacturing Processes

PharmaEssentia's product Ropeg undergoes four critical stages in production: fermentation and cell processing, P1040 extraction and purification, PEGylation, and Ropeg DS purification. Sterile filling, labeling, and packaging processes all rigorously comply with GMP and international standards for quality management and standard operating procedures. In response to commercialization and mass production demands, we continue to enhance all production stages as well as overall production capacity to reduce supply chain risks and improve supply stability.

All PharmaEssentia USA product manufacturing processes, achievements, and benefits for the year were recorded by the quality assurance/regulatory affairs team in Taichung and included in annual product review reports submitted to the FDA. All critical suppliers (including syringe filling CDMOs, syringe labeling and packaging companies, and third-party logistics companies) have passed supplier qualification reviews conducted by PharmaEssentia (Taiwan)'s QA team.

Enhancing Production Capacity and Production Resilience

Aim	Introduce second and third material sources	Establish second purification production line
Goals and benefits	To stabilize material supply, we completed 3 second-material source projects in 2025 and 3 more projects are undergoing testing. In response to major impacts on global supply chains caused by international situations, the pandemic, and extreme weather conditions, we introduced these projects to significantly reduce production risks and ensure stability of drug supplies.	Completed construction of second DS production line in 2025, and obtained GMP certifications from different countries, increasing production capacity by 100%.

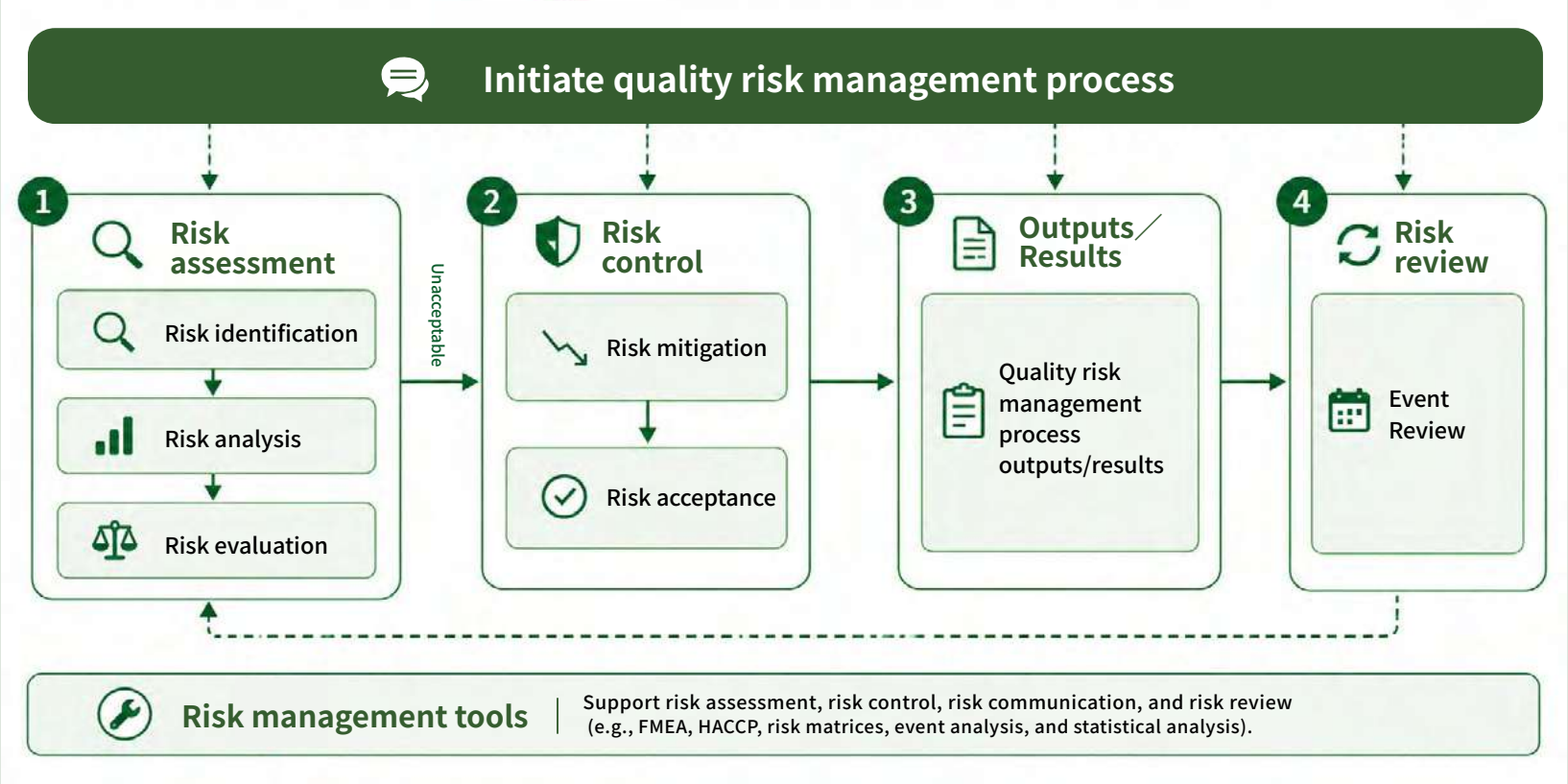
Process Risk Screening and Controls

As an API and drug formulation production base which has obtained GMP certifications across multiple countries, our Taichung Plant has established comprehensive procedures and clear organizational operating guidelines. In 2025, we continued to monitor and track production environment trends associated with our air-conditioning system, water system, compressed air, and biosafety cabinets, ensuring that our operating conditions comply with design specifications and regulatory requirements.

Process Risk Screening and Controls

As an API and drug formulation production base which has obtained GMP certifications across multiple countries, our Taichung Plant has established comprehensive procedures and clear organizational operating guidelines. In 2025, we continued to monitor and track production environment trends associated with our air-conditioning system, water system, compressed air, and biosafety cabinets, ensuring that our operating conditions comply with design specifications and regulatory requirements.

Quality Control and Management Process



The Ropeg product sold by PharmaEssentia Japan is manufactured and produced at PharmaEssentia (Taiwan), where we ensure that production processes adhere to procedures that have been verified by the Japanese government. If any deviations occur during the manufacturing processes, the quality control department at PharmaEssentia Japan will work with quality control personnel at PharmaEssentia (Taiwan) to conduct appropriate assessments that guarantee product quality. We also commissioned a Japanese testing institution to perform necessary tests (such as product purity tests) on products imported from Taiwan, and outsourced product packaging to a Japanese pharmaceutical manufacturer.

CRO and CMO Risk Management

Filling and packaging operations are mostly conducted at our sterile formulation filling plant in Taichung, but we also outsource filling and packaging processes to internationally GMP-certified CMO facilities in the US, Germany, and Japan to ensure proximity to local patients. PharmaEssentia USA enhanced its syringe labeling and packaging capabilities to meet the demands of the US and Latin American commercial markets. Our supplier responsible for labeling and packaging commercial syringes is expected to obtain FDA approval in 2026, following which it will be able to label and package pen injectors.

Quality Education & Training System and Management Documents

Our Taichung Plant emphasizes product quality and safety management. Each year, we organize education and training on product safety and GMP regulations for plant employees to help them incorporate quality management into routine procedures.

Education & Training/ Management Documents	Type	Statistical Data
Education and training	GMP/GDP regulations	PharmaEssentia organized 662 sessions over a total of 20,323 training hours
	GMP/GDP adverse event and product complaint reports	PharmaEssentia USA organized 243 sessions over a total of 486 training hours
Established relevant work procedures for factories across multiple countries that produce GMP-compliant APIs and drug formulations	Quality manual, quality policies, master validation plans	29
	SOP guidelines	103
	Operational SOPs	482
	Record forms	>1000

Pharmaceutical Risk Management and Safety Monitoring

Pharmaceutical Risk Management Plan

PharmaEssentia implements standard operating procedures associated with drug safety risks formulated by collaborating CROs and has established “Drug Risk Management Plans” that adhere to the pharmacovigilance regulations of each country. PharmaEssentia (Taiwan) established pharmacovigilance plans in accordance with the “Regulations for Pharmacovigilance Management” in Taiwan, and completed periodic amendments in June 2025 in response to global CRO supplier changes. Amendments included updates to pharmacovigilance records, internal audit records, and pharmacovigilance quality system reviews; updates to timelines for submitting periodic safety reports to regulatory authorities; continued monitoring of drug risks and benefits. These amendments ensure that our pharmacovigilance organizational chart, procedures at all operational stages, and responsibilities remained aligned with current conditions.

Our subsidiaries in Japan, China, Korea, and other locations have also established “Drug Risk Management Plans” in accordance with local regulatory requirements. Current regulations require collection of post-marketing clinical data to determine whether long-term use by patients result in chronic side effects. This information is also included in “Drug Risk-Benefit Assessments.” Although PharmaEssentia (Taiwan) and PharmaEssentia USA are not yet required by regulatory authorities to submit drug risk management plans, we still collect safety data in countries where our drugs have been approved, and regularly update our safety reports and assess Ropeg risks.

Pharmacovigilance Management

Our Pharmacovigilance Team established under the Medical Research Department works in coordination with relevant units to carry out their duties according to our “Global Product Safety and Risk Management Standard Operating Procedures,” “Post-Marketing Adverse Event Reporting Standard Operating Procedures,” and “Global Post-Marketing Safety Data Collection Standard Operating Procedures,” as well as Taiwan’s “Regulations for Reporting Serious Adverse Reactions of Medicaments” and “Regulations for the Management of Drug Safety Surveillance.” We also commission professional CROs to conduct pharmacovigilance tasks. Our pharmacovigilance procedures include both passive monitoring and active monitoring:

Passive monitoring

We are legally required to submit PSURs and collect spontaneous safety case reports from healthcare professionals and the public. Safety information is registered in our safety database system for further processing.

In 2025, PharmaEssentia (Taiwan), PharmaEssentia USA, and PharmaEssentia Japan submitted the latest PSURs to local competent authorities. All adverse events were reported in accordance with regulatory requirements, and there were no violations of product health & safety regulations or voluntary codes. Our reports found no new safety information that affect Ropeg safety.

We obtained marketing authorization in Taiwan for our in-licensed drug Tirbanibulin in 2022; according to the Pharmaceutical Affairs Act, Regulations for the Management of Drug Safety Surveillance, and TFDA announcements, we are required to submit annual PSURs until 2028.

Active monitoring

We actively implement safety signal detection procedures, monitor and review pharmaceutical alerts and safety signals issued by medically advanced countries, and actively gather information through registration trials/IITs and patient support programs (PSP).

Pharmacovigilance Reporting Education and Training

We conduct pharmacovigilance education and training for PharmaEssentia (Taiwan) employees and pharmacovigilance-related suppliers in accordance with annual pharmacovigilance education and training plans. Training content covers pharmacovigilance regulations and adverse event reporting procedures, and aims to enhance understanding of fundamental pharmacovigilance concepts and adverse event reporting processes.

PharmaEssentia (Taiwan) pharmacovigilance education and training information for 2025

Course Title	Course Content	Number of Participants	Number of Classes	Total Training Hours
New employee pharmacovigilance training	Pharmacovigilance regulations and reporting procedures	67	New employees are required to complete online courses and examinations within one month of commencing work	56
Company-wide pharmacovigilance training		347 (including Panco employees)	1	289
CMO pharmacovigilance training		9	2	9

All Panco employees in Taiwan are required to complete PharmaEssentia (Taiwan) pharmacovigilance training courses and pass examinations. PharmaEssentia (Taiwan) and all subsidiaries convened 12 routine meetings with CROs to ensure thorough collection and reporting of global drug safety information.

Pharmacovigilance education and training for overseas subsidiaries:

PharmaEssentia Japan	PharmaEssentia USA
All employees at our Japanese subsidiary are required to undergo 1 safety training session each year encompassing definitions of adverse events and side effects, procedures for reporting safety information, and safety management systems. Our sales department undergoes annual training in accordance with our SOPs. Local safety information is collected and submitted to the safety department for formulation of supporting measures such as collection methods for safety information, reporting procedures, and penalties for delayed reports.	PharmaEssentia US conducts education and training for new employees that encompasses collection of post-marketing safety data and reporting of severe adverse drug reactions; if amendments are made to related regulations or operating standards, training is also carried out for amended content. We hosted an annual advanced course on reporting severe adverse drug reactions in the second half of 2025 for continued strengthening of professional pharmacovigilance knowledge. We will continue to implement education and training in 2026.

Drug Safety Reporting Mechanisms

Taiwan	• Severe adverse reactions that occur during general usage conditions for marketed drugs can be reported through the following channels:
	  • Medical personnel and members of the public can register for an account on the TFDA online reporting system (https://adr.fda.gov.tw) and fill out the "Post-Marketing Adverse Drug Reaction Reporting Form" or send an email to adr@tdrf.org.tw
	  • Pharmaceutical companies can select, fill out, and submit the "Post-Marketing Adverse Drug Reaction Reporting Form" on the online reporting system
	  • After receiving relevant reports, PharmaEssentia will submit reports via the online reporting system (https://adr.fda.gov.tw) or email (adr@tdrf.org.tw) in accordance with "Post- Marketing Adverse Drug Reaction Reporting Form Guidelines"
	• In 2025, none of our drugs in Taiwan were recalled due to adverse events

US	• PharmaEssentia USA is assisted by qualified third-party logistics vendors, and has established drug supply chain management mechanisms which adhere to the Drug Supply Chain Security Act (DSCSA) and drug tracking regulations. We submit transaction history (TH), transaction information (TI), and transaction spreadsheets (TS) for review. In terms of production traceability mechanisms, we completed drug serialization procedures in 2020. • PharmaEssentia USA has established the PEC US Call Center reporting management center exclusively for the US market. The Center is managed by the medical affairs team; is responsible for handling reports and information related to drug quality, safety, and adverse events; and carries out subsequent assessment and reporting procedures in accordance with FDA post-marketing pharmacovigilance and adverse event reporting regulations. • The US FDA has established official drug safety reporting channels, MedWatch and the FDA Adverse Event Reporting System (FAERS), for healthcare professionals, pharmaceutical companies, and the public to report adverse drug reactions and safety events. Relevant reports can be submitted through the online FDA MedWatch system (https://www.fda.gov/medwatch), by phone at 1-800-FDA-1088, or by fax at 1-800-FDA-0178.
Japan	• Medical representatives collect information on drug safety issues or adverse reactions during visits to physicians or pharmacists, and report relevant information to the safety department through the adverse event reporting system or adverse event paper forms. • The medical information department and patient support program department are responsible for handling incoming calls from physicians, pharmacists, and patients relating to adverse reactions and safety issues. These departments report relevant information to the safety department through the adverse event reporting system or adverse event paper forms. • In addition to the aforementioned sources, the safety department also obtains and assesses adverse events through general drug use surveys and literature screening. • Our pharmaceutical facilities conduct potential risk assessments on reported serious or non-serious adverse events, and carry out further investigations alongside informants if necessary. Relevant reports are filed on the online reporting system (https://www.pmda.go.jp/english/0002.html; the Japan PMDA reporting website) or other applicable reporting channels within stipulated time limits

Taiwan's "Regulations for Reporting Serious Adverse Reactions of Medicaments" require reporting of adverse reactions and collection of safety data within specified time limits. A total of 287 serious adverse events were reported from February 2024 to February 2025, and relevant reports were filed in accordance with regulatory requirements. We will continue to comply with relevant reporting regulations, monitor safety information following product use, reduce patient risks, and ensure implementation of pharmaceutical safety management responsibilities.

We comply with pharmacovigilance principles, continuously monitor post-marketing safety information for our products, regularly evaluate product risks and benefits, and initiate corresponding risk control measures when necessary. We ensure early detection and proper handling of potential risks through timely reports, tracking of adverse events, signal detection, and regular safety reports to safeguard patient safety.

No violations of product health and safety regulations occurred in 2025.

Product Traceability and Recall Mechanisms

Product Traceability System

PharmaEssentia has established a global product traceability mechanism and incorporated drug serialization. We regulate packaging and serialization processes at our Taichung injectables plant and CMOs to achieve our goal of full traceability for all individual product flows and usage records. Drug serialization procedures have also been fully implemented for Ropeg sold in the US, Taiwan, Korea, and China, and a qualified injectables facility packages and serializes drugs in accordance with the Drug Supply Chain Security Act (DSCSA) to maintain drug quality and safety.

Product Recall Mechanisms

PharmaEssentia's "Return and Recall Procedures" clearly stipulate use of a product traceability system to improve drug recall mechanisms, which allows for rapid and effective drug recalls when product quality concerns emerge, and provide an additional safety mechanism for patients when using medications. Recall simulation drills are conducted every year to ensure accuracy and familiarity with recall actions.

Initiation time: When learning that a product has known or possible manufacturing defects, spoilage concerns, counterfeits, or any other serious quality issues.

Recall procedures: The quality assurance department initiates product recall procedures in accordance with our "Return and Recall Procedures," submits the "Recall Operational Plan Application Form," and proposes recall actions.

Proactive reporting: Remove products from usage channels within certain time limits based on drug hazard levels, appropriately handle recalled products, and simultaneously notify local competent authorities.

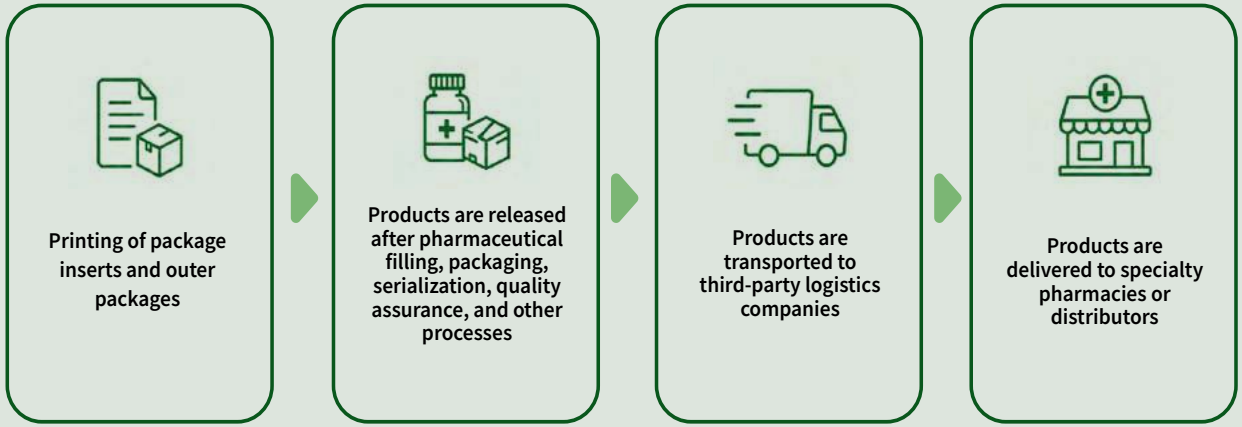
To date, we have not experienced any incidents associated with counterfeit products that

Safe Pharmaceutical Distribution and Warehousing

Distribution Quality Control

Our secure distribution processes strictly adhere to GDP regulations and ensure proper management of pharmaceuticals throughout the transportation process. Our safety distribution management framework has not undergone any material system changes and continues to be fully compliant with GDP requirements. We adopted the following measures to optimize our existing systems in response to global supply chain risks and climate change impacts on transportation stability:

- Strengthened transportation risk assessment mechanisms by incorporating extreme climate, flight instability, and geopolitical factors into annual supply chain risk inventories.
- Actively expanded our list of qualified transportation suppliers to reduce disruption risks from single logistics sources.
- Improved timeliness of temperature monitoring and deviation reporting.
- Strengthened coverage of internal GDP audits and continued to implement spot checks on processing and labeling procedures.



The Panco Healthcare Logistics Center continues to comply with GDP requirements and ensures supply chain safety and traceability for clinical and commercial products through annual self-audits and supplier assessments. This logistics center assists PharmaEssentia in supplying clinical drugs and market products while implementing quality management for logistics management, warehousing management, and processing and labeling procedures.

For example, as injectable drugs are highly sensitive to temperature changes, we established a comprehensive end-to-end cold chain data traceability and serialization system. We maintain 24-hour uninterrupted temperature monitoring throughout the entire process from warehousing, transportation, and delivery to medical institutions to ensure quality. Digital serialization technology, which assigns a unique identification code to each package and injectable to achieve end-to-end process monitoring, has been implemented in Taiwan, the US, and Korea. Our drugs are transported in refrigerated containers equipped with temperature monitoring devices when they are delivered to medical institutions. Hospital pharmacists complete online system records and terminate tracking after accepting deliveries to establish a closed-loop quality verification process across the entire transportation process.

PharmaEssentia USA third-party commercial distribution logistics are handled by FedEx. FedEx's air cargo and express delivery services have been approved in accordance with our supplier qualification review processes and are managed in accordance with US GDP pharmaceutical supply chain requirements. All transportation routes have also been verified. Cardinal Health's EPTN transportation routes have also passed supplier qualification and quality management system validation.

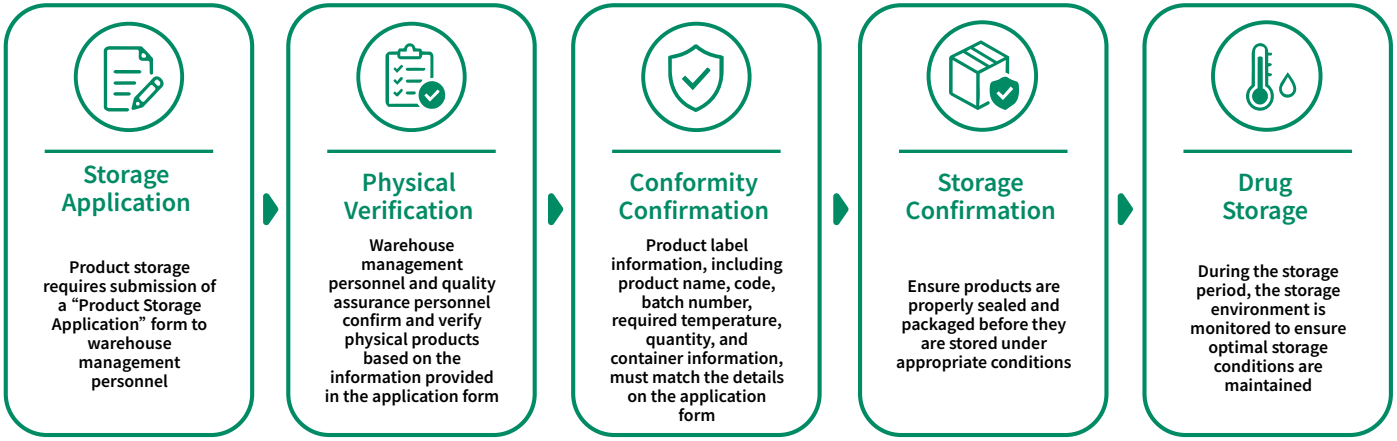
International Transportation and Warehousing Management Strategies

PharmaEssentia has established the "Product Receipt and Storage Management Operation Standards" and "Storage and Distribution Policy" to prevent negative impacts on product quality from environmental and operational factors. The Panco Logistics Center has established a "Storage Area Temperature Calibration Plan" which stipulates that temperature calibration should be conducted twice every three years to ensure warehouse environment quality.

Policies and systems	Strengthening actions	Management achievements
We continue to manage global transportation and warehousing in accordance with the following systems: ・Storage and Distribution Policy ・PIC/S GDP-compliant Product Distribution Management Procedure ・Import and Export Transportation Management Procedure ・Emergency Response and Handling Procedure	1.Enhance supply chain resilience ・We maintain at least 4 months of safety stock in the US in anticipation of climate change, natural disaster, and supply chain risks to ensure that patients in the US can receive their medications in a timely manner; relevant inventory data is considered to be sensitive information, and is therefore not disclosed. ・PharmaEssentia Japan's distribution system continues to align with Japanese GDP standards. ・We have expanded the number of collaborators in China and complete transportation verifications. 2.Climate risk adaptation ・We have incorporated extreme climate event scenario simulations. ・We strengthened backup solutions for coldchain equipment. 3.Optimize warehousing management ・Panco Logistics Center continues to implement temperature calibration procedures. ・We enhanced automation of environmental monitoring system data collection.	・Number of major transportation temperature deviations in 2025: 0 ・GDP-related major audit deficiencies: 0 ・Clinical and commercial product delivery interruptions: 0

Commercial supply and inventory data at PharmaEssentia USA is tracked and managed using the Anaplan enterprise system, which is used for monthly sales and operations planning (S&OP) processes in the US, as well as for meetings with the Taichung team which are convened every two weeks. Rolling demand forecasts are provided to PharmaEssentia (Taiwan)'s finance and CMC teams to monitor demand and maintain inventory levels.

Product Entry and Storage Process



Quality Control in Shipping and Transportation

PharmaEssentia has established the “Product Shipping Operations Standards” to ensure that distribution processes for products manufactured at our Taichung Plant and CMOs, as well as packaging and transportation processes at storage warehouses, are appropriately managed and all pharmaceuticals are transported under prescribed temperature conditions to uphold global drug transportation safety. No transportation incidents affecting product quality occurred in 2025.

Packaging operations	Transportation process
• Confirm that transportation boxes are clean and temperatures meet appropriate product storage conditions; a temperature recorder is placed in each box to monitor temperatures. • Ropeg, for example, must be stored between 2~8° C	• Comply with the “Storage and Distribution Policy” in executing appropriate storage and distribution procedures • Conduct pre-analysis scenario simulations to confirm that cooling conditions and equipment specifications meet product needs • Regularly check raw materials, intermediates, and products to ensure they are stored and managed appropriately

We continue to manage shipment and transportation quality in accordance with the “Product Shipping Operations Standards,” and strengthened the following monitoring measures:

Packing and pre-shipment verifications	Transportation process monitoring	Quality verifications
• Conduct scenario simulation and insulation performance analysis • Use verified temperature-controlled packaging materials • Place temperature loggers inside shipping containers, and increase deployment ratios	• Collect all temperature data throughout the transportation process • Implement timely notification mechanism for abnormal temperature events • Analyze temperature changes to prevent potential risks	• Add transportation route verification and confirmation processes • Track deviations and improvement measures through CAPA system

3.3 Pharmaceutical Marketing Ethics and Labeling

Product Marketing Ethics Principles

PharmaEssentia has established clear drug marketing ethical standards for employees who interact with healthcare professionals, and we continue to promote relevant policies each year. In 2025, we launched online training courses and established a comprehensive review process and management mechanism for all marketing activities, promotional materials, and routine operations.

We comply with the following 9 pharmaceutical marketing ethics principles:

- Prioritize patient well-being.
- Achieve quality, safety, and efficacy standards that meet regulatory requirements.
- Maintain professionalism and ethical conduct when interacting with medical and related organizations, and do not provide or supply any goods or services that may directly or indirectly cause undue influence.
- Provide accurate, balanced, and scientifically based product information.
- Ensure that marketing activities and promotional content are ethical and do not contain misleading information. Product marketing materials should include accurate information on product risks, risk-benefit assessments, and appropriate usage methods.
- Respect and protect patient privacy and personal information.
- Sponsor external clinical research and scientific activities to promote medical advancement and enhance patient benefits, and to maintain transparency of industry-sponsored human clinical trials.
- All materials that may be viewed by the FDA as being used for promotional or external communication purposes (including promotional materials, non-promotional materials, advertisements, and digital media) are required to undergo triple Medical-Legal-Regulatory (MLR) review by the MLR Committee to ensure they contain no misleading information, comply with regulations, and contain scientifically accurate information.
- Implement drug safety and risk management, report adverse reactions, and publicly disclose drug approval statuses. We also disclose pharmacological effects, indications, pregnancy classifications, dosages and administration methods, side effects, contraindications, and precautions to provide a balanced report on benefits and risks.

Material Topics	Drug Marketing and Labeling
Significance for PharmaEssentia	PharmaEssentia prioritizes patient health and well-being, adheres to ethical management principles and medical ethics when marketing registered drugs, and provides patients with professional and trustworthy products. We regulate the drug marketing behaviors of our colleagues, organize annual internal promotions of drug marketing ethics policies for employees who have business interactions with healthcare professionals, and review processes for marketing promotions and business activities to avoid legal violations.
Policies and Commitments	PharmaEssentia adheres to the Ethical Corporate Management Best Practice Principles and the Operational Procedures and Code of Conduct for Ethical Management, and implements pharmaceutical marketing and labeling management in accordance with core integrity, transparency, and accountability principles. We ensure all of our promotional information is authentic, complete, and compliant with regulatory requirements, and we regularly review marketing compliance, labeling accuracy, and risk control so that patient rights and product trust are not jeopardized by misleading information or improper business dealings. We continue to strengthen employee awareness of marketing ethics and compliance requirements through education and training, ensuring that global market operations comply with the highest professional and sustainable development standards.
Responsible Units	• PharmaEssentia Taiwan and subsidiary marketing departments and medical affairs teams • US Medical, Legal, and Regulatory Affairs Review Committee: Conducts medical, legal, and regulatory reviews to ensure the appropriateness and regulatory compliance of advertising and promotion content • Sustainability Development Center Product Ethics and Safety Team and Access to Medicine Team: Responsible for compiling and managing material sustainability topics
Response Strategies, Associated Measures, and Management Actions	Related teams regularly conduct internal inspections to ensure effective execution Remediation and grievance measures: • We collect grievances and feedback from external stakeholders through the “Contact us” page on our official website. • PharmaEssentia has established a customer hotline to handle product quality issues and general customer complaints, and to safeguard consumer, client, and patient rights.
Evaluation Mechanism	Compliance and ethics of marketing activities are regularly reviewed and assessed by the marketing, medical affairs, and MLR committees
Targets for 2025	Zero marketing ethics violations
Achievements in 2025	• In 2025, PharmaEssentia (Taiwan) and all subsidiaries complied with pharmaceutical marketing ethics regulations, and incurred zero marketing communications violations.
Short-Term Targets (1 Year)	• Achieve internal review completion rate of 100% for marketing materials and promotional activities • Incur zero marketing or labeling non-compliance incidents that result in penalties or corrective measures by competent authorities • Achieve annual regulations and ethics training completion rates of 100% for marketing, sales, and medical affairs personnel • Achieve post-training examination pass rates exceeding 90%
Mid-Term Targets (3-5 Years)	• Strengthen collaboration among marketing, medical affairs, and regulatory review units to ensure accuracy and compliance. • Establish consistent and serialized marketing and labeling management processes to lower violation risks
Long-Term Targets (More Than 5 Years):	• Build a corporate culture that prioritizes patient health and well-being through drug marketing and labeling • Continue to enhance marketing ethics and information transparency to enhance the trust of healthcare professionals and the public • Keep the number of compliance grievances and disputes relating to healthcare professionals low or at zero over the long term

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We comply with the following 9 pharmaceutical marketing ethics principles:

1.Prioritize patient well-being.

2.Achieve quality, safety, and efficacy standards that meet regulatory requirements.

3.Maintain professionalism and ethical conduct when interacting with medical and related organizations, and do not provide or supply any goods or services that may directly or indirectly cause undue influence.

4.Provide accurate, balanced, and scientifically based product information.

5.Ensure that marketing activities and promotional content are ethical and do not contain misleading information. Product marketing materials should include accurate information on product risks, risk-benefit assessments, and appropriate usage methods.

6.Respect and protect patient privacy and personal information.

7.Sponsor external clinical research and scientific activities to promote medical advancement and enhance patient benefits, and to maintain transparency of industry-sponsored human clinical trials.

8.All materials that may be viewed by the FDA as being used for promotional or external communication purposes (including promotional materials, non-promotional materials, advertisements, and digital media) are required to undergo triple Medical-Legal-Regulatory (MLR) review by the MLR Committee to ensure they contain no misleading information, comply with regulations, and contain scientifically accurate information.

9.Implement drug safety and risk management, report adverse reactions, and publicly disclose drug approval statuses. We also disclose pharmacological effects, indications, pregnancy classifications, dosages and administration methods, side effects, contraindications, and precautions to provide a balanced report on benefits and risks.

We executed the following practices in accordance with our marketing ethics policies in 2025:

1. Provided accurate, balanced, and scientifically based product information	• Complete product benefits and risks were disclosed in all marketing materials, and we did not include any misleading information.
2. Ensured that interactions with healthcare professionals and patient organizations complied with ethical standards	• Prohibited provision of any goods or services that could affect professional judgment. • Maintained independence of collaborating organizations and partners.
3. Implemented transparent MLR reviews	• All marketing and non-promotional materials were jointly reviewed by the medical, legal, and regulatory departments to ensure that the information was compliant, scientific, and complete. • Regularly updated review standards in accordance with the latest regulations.
4. Continued to strengthen disclosures of drug safety information	• Continuously monitored post-marketing safety, collected safety information from all countries where our products have been approved, and used collected information to update DSURs/PSURs, and to assess BESREMi® risks and benefits. • Actively conducted safety signal detection procedures, and monitored and conducted literature reviews on pharmaceutical alerts and safety signals issued by medically advanced countries. • Actively collected information via registration trials/IITs and patient support programs
5. Monitored digital and social media information	• The MLR Committee reviewed all digital materials that could potentially be considered promotional

Product Labeling

All drug labels complied with local regulations and included the content required by the competent authorities of the countries where our products have been approved, including permit numbers, product names, item numbers, instructions, batch numbers, expiration dates, and manufacturer/importer information. We also adopted anti-counterfeiting designs for serialized products by:

- Adding unique product identification codes on outer packaging
- Using holographic seals with anti-counterfeiting features and traceable serial numbers to reduce counterfeiting risks

We did not incur any incidents of non-compliance concerning marketing communications or any related legal litigations in 2025, and have not experienced any disputes or legal litigations related to misleading marketing information over the past five years. Therefore, we did not suffer any associated monetary losses.

PharmaEssentia has established a customer hotline to safeguard consumer, client, and patient rights. Complaints are mainly divided into two categories:

1. Product quality-related grievances (including refunds or replacements handled in accordance with quality management procedure)
2. General customer complaints