

# **Summary of 2022**







**Highlights Performance** 

The stable operation and governance are the key to PharmaEssentia's continuous improvement in the biopharmaceutical industry and sustainable development. We have been actively establishing a solid corporate governance framework and strengthening the functions of the board of directors to drive overall development, and we particularly emphasize legal compliance, integrity in business, and information security. In the face of various risks and uncertainties in recent years, PharmaEssentia has relied on its solid operational capabilities to create new peaks in operational performance.

# **Material Topic**

→ Legal Compliance and Business Ethics



Female directors



No violation of business ethics and Ethical code of conduct



97.2%

Attendance rate of Audit Committee



100%

Coverage rate of compliance education and training for US employees and vendors



100%

Attendance rate of Remuneration Committee



100%

Completion rate of improvement for audit deficiencies



# 185 participants

Set up Cyber Security promotion team to conduct 2 social engineering education & trainings





# **6.1 Corporate Operational Performance**

### **Diverse Board Structure**

GRI 2-9/2-10/2-11/2-15/405-1

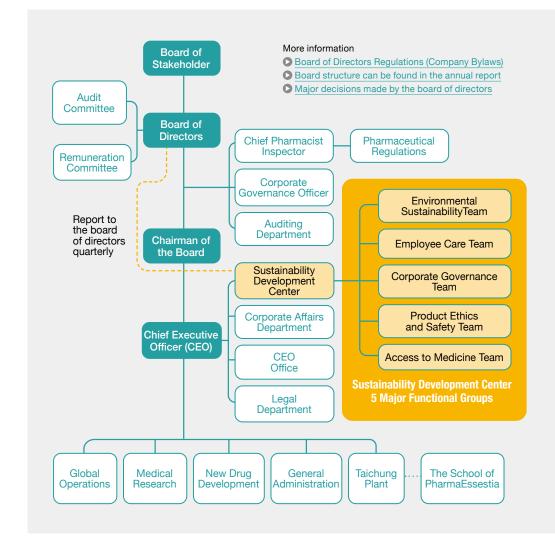
The board of directors of PharmaEssentia, which includes all subsidiary boards, operates under a unitary system of governance with a term of three years. The board consists of 11 members, with their term beginning on August 5, 2021 and ending on August 4, 2024, have an average tenure of 8.3 years. The board chairman leads the meetings and has established rules for board proceedings, as well as codes of conduct and operational procedures and Operational Procedures, Guidelines for Business Ethics and Behavioral Guidelines for Business Ethics for Integrity Management to prevent and manage conflicts of interest among directors and staff. Currently, there are no significant conflicts of interest among board members, and there is no single shareholder with absolute control. Any dual roles or relationships between the company and related parties have been disclosed in the annual report. The board of directors is diverse in their professional backgrounds.

Based on the company's Shareholder Meeting Rules, as of the end of 2022, the total voting shares of PharmaEssentia with voting rights amounted to 302,455,641 shares, and in accordance with the provisions of the Company Act, a director will be automatically dismissed if they transfer more than half of the company's shares they held at the time of their appointment during their term. In addition, in accordance with the Regulations Governing the Shareholding Ratios of Directors and Supervisors of Public Companies and the Audit Implementation, the total shareholding of all directors' registered shares also complies with legal requirements. Information on senior management shareholding can be found in the annual report, and neither the company's founder nor the founder's family members hold individual stakes greater than 5%. Government agencies' shareholding is mainly sourced from the National Development Fund, with a shareholding ratio of 7.3%, and there are no special shares involved.

PharmaEssentia's board of directors meets at least once per quarter, and the management task forces as well as financial supervisors are required to attend and answer questions. The audit supervisor reports on the audit to the board of directors. In 2022, a total of 13 board meetings were held, with an average attendance rate of 97.2% for the directors. As for Panco Healthcare, it has three directors and one supervisor. In 2022, it held five board meetings, with a 100% attendance rate. The US subsidiary has three directors and held four board meetings in 2022, with a 100% attendance rate. Information on subsidiary directors can be found in the annual report.

The board of directors plays an important role in formulating the company's sustainable strategy, overseeing management, and being accountable to the company and shareholders. The selection of board members is carried out by the shareholders' meeting in accordance with the director election procedures. In addition to considering the company's business development scale and major shareholder ownership, practical operational needs are considered, and a diversity





of board members policy has been established. The goal is to have board members from different professional and industry backgrounds, providing professional advice on operations, accounting and analysis, business management, industry affairs, and the international market. The diversity policy is continuously implemented, and multiple diversified training courses are arranged for board members to enhance their functions. Of the 11 directors in our company, three are independent directors, accounting for 27.2% of the entire board of directors. In the future, the number of independent director seats will be increased to more than one-third according to the company's operational needs. In 2022, all directors and independent directors met the required training hours, which can be found on the website.

### **Functional Committees**

GRI2-20



**97.2**%

Attendance rate of Audit Committee



Attendance rate of Remuneration Committee

PharmaEssentia has two functional committees under its board of directors, namely the <u>Audit Committee</u> and the <u>Remuneration Committee</u>. The members of these committees are all independent directors, effectively exerting the supervision and checks and balances mechanism of independent directors. The Remuneration Committee includes an <u>external expert</u> (Professor Ming-Chuan Hsieh) as a member, to strengthen the functionality of the board of directors and enhance the management mechanism.

Committee	Audit Committee	Remuneration Committee	
Responsibilities	Assist the Board of Directors in fulfilling its oversight responsibilities regarding the quality and integrity of the accounting, auditing, financial reporting processes, and financial controls	Assist the Board of Directors in establishing and reviewing policies, systems, standards, and structures for the evaluation of the performance and remuneration of 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	13	2	
Attandence	97.2%	100%	

### **Board Effectiveness**

GRI2-18

The company has established Board Performance Evaluation Guidelines and the Board Self-Evaluation or Peer Evaluation to implement corporate governance and enhance the functions of the board of directors. The guidelines aim to establish performance goals and evaluation systems. At least one internal board performance evaluation is conducted annually, and every three years, an external and independent professional organization is commissioned to conduct an annual board performance evaluation. Regular evaluations are also conducted for functional committees, and evaluation reports and specific improvement proposals are submitted to the board of directors. Items for evaluation include at least five aspects: participation in company operations, improvement in board decision-making quality, board composition and structure, selection and continuing education of directors, and internal control. The results of the internal board and director performance evaluation for 2022 were reported to the board of directors on February 24, 2023, in accordance with the law. The evaluation results were unanimously approved, and there were no other suggested improvements. Please refer to the company's website for more information.

The directors of PharmaEssentia commissioned the Taiwan Corporate Governance Association, a third-party organization, to conduct a board performance evaluation for the period from November 1, 2020, to October 31, 2021. The evaluation report (please refer to the <a href="website">website</a> for details) made four recommendations for improvement: strengthening the director nomination mechanism, developing a plan to cultivate important management talent, establishing a sound whistleblowing mechanism and communication channel, and setting up a corporate governance section on the company's website. The company has already set up a corporate governance section and a grievance channel on its website, and the other recommendations will be implemented gradually as needed in the future.

# Linking Director Remuneration Policy with Sustainable Performance GRI2-19

The director remuneration policy of our company is governed by the internal bylaws and is based on allocating up to 5% of the net profit after offsetting the accumulated losses for the year as director compensation. We also consider the level of participation, performance contributions and results of the director's board performance evaluation in determining the reasonable salary compensation for each director. Information on director and senior executive compensation can be found in the annual report. Currently, our HR department is actively developing related operational procedures for linking director remuneration policy with sustainable performance in line with our company's sustainable development process with the aim to reflect the directors' efforts in supervising and executing sustainable development goals and strategies.



## **Participation in Industry Associations**

GRI2-28

Participation in industry associations is based on the selection of the biotech and pharmaceutical associations, and membership is obtained by paying membership fees to each association. By working together with these associations, we aim to increase our influence and promote industry development.

### **External Association Participation**

Taiwan R&D-based Biopharmaceutical Association

Pharmaceutical Agents Association, Republic of China

Pharmaceuticals Development Association, Republic of China

Science Park Industries Association, Taiwan

Taiwan Association of Clinical Trials and Research

Pharmaceutical Agents Association, Republic of China

Taiwan Society of Hematology

National Biotechnology and Medical Care Industry

Taiwan Myelodysplastic Syndrome Care Association

# **Tax Strategy and Governance**

GRI207-1/207-2/207-3/207-4

Our company's tax management unit is coordinated and managed by the accounting departments of PharmaEssentia Headquarters and subsidiaries. If there are any important decisions, professional tax consultants may be consulted or appointed according to the situation. We strictly comply with the commercial laws and tax regulations of Taiwan and the local jurisdictions where we operate, and is transparent in disclosing information in accordance with regulations to strengthen the group's compliance with tax laws and commitment to fulfill its corporate social responsibility. We are committed to the following tax management policy to reduce tax risks, optimize post-tax operating results, and protect shareholder interests.



#### All operations are carried out in accordance with relevant tax laws and regulations.

- Transactions between related parties are conducted in accordance with normal market terms and follow the internationally recognized transfer pricing guidelines published by the Organization for Economic Cooperation and Development (OECD).
- Financial reporting information is transparent, and tax disclosures are handled in accordance with relevant regulations and standards.
- No transactions are conducted for the sole purpose of tax avoidance.
- Based on mutual trust and information transparency, a respectful relationship is established with tax authorities.
- The company's important decisions take into account the impact of taxes.
- Tax risks are evaluated through management mechanisms that analyze the operating environment.
- Ongoing talent development is used to strengthen tax expertise.

# Income Tax Expense and Adjustments for Accounting Profit Multiplied by the Applicable Income Tax Rate

(Unit: NTD Thousand

	(Unit: NTD Thousand			
	2020	2021	2022	
Accounting loss before tax from continuing operations	\$(1,948,016)	\$(2,810,988)	\$(1,841,871)	
Income tax expense at the statutory income tax rate	\$(389,603)	\$(562,198)	\$(368,374)	
Tax effect of deferred tax assets/liabilities	389,629	562,198	(72,399)	
Others	100	-	(26,288)	
Total income tax expense	\$126	\$0	\$(467,061)	

## **Internal Control and Internal Audit**

The company has established an Internal Auditing Office that reports to the Board of Directors, and it is staffed with two full-time auditors and a deputy. When internal control deficiencies and abnormal matters are discovered during audits, the auditors are required to record them truthfully and report them to the Audit Committee and the Board of Directors. The head of the audit department reports on the execution of audit activities to the Audit Committee and the Board of Directors on a quarterly basis, strengthening the Board's supervision of the company's audit system and arranging regular communication between the internal auditors and the independent directors. In addition, for deficiencies discovered in the internal control inspection during the annual audit plan, the company continues to track and review them to ensure that relevant units have taken appropriate improvement measures in a timely manner. Through routine and project-based audits as well as subsidiary supervision operations, the company gains an understanding of its operating status and the potential risks in its internal controls, assists the Board of Directors and management in fulfilling their responsibilities, and implements corporate governance systems. In 2022, the audit department completed 55 audit reports, discovered one deficiency, and achieved 100% improvement.



# **Annual Operating Performance**

GRI 201-1/201-4/415-1

#### **Operating Results of the Group in the Past 3 Years**

(Unit: NTD\$ Thousands)

		2020	2021	2022
Direct Economic Value	Generated Revenue	557,257	656,506	2,882,042
	Operating Costs	373,323	378,856	812,288
	Employees' Compensation and Benefits	670,560	1,489,430	1,600,415
Economic	Payment of Government Taxes	664	957	4,772
Value Distributed	Payment to Capital Providers	1,269	1,720	1,704
	Community Investments	4	3	250
	Total	1,045,820	1,870,965	2,442,086
Retained Economic Value		-488,563	-1,214,459	439,955

Note 1: The data in this table is from consolidated financial statements

Note 2: In 2022, NT\$16,263,000 in government subsidies and NT\$22,154 in maternity leave subsidies from the Ministry of Labor are included

Note 3: In 2022, no direct or indirect political contributions were made to any country or individual

Note 4: Community investments mainly refer to donations to charitable projects

Note 5: For more information on the performance and operating results of the board of directors, including CEO compensation structure, government shareholding status, family shareholding status and disclosure of voting rights, please refer to PharmaEssentia's annual report



PharmaEssentia sells its products across Europe, the United States, and Asia. We closely monitor policies and regulations in both Taiwan and abroad, and have developed a global compliance strategy framework for PharmaEssentia's operations. To reduce operational risks caused by non-compliance, the framework is based on four pillars: Structure and Governance, Policy and Action, Operation and Accountability, and Culture and Education.

GRI 3-3



#### **Internal Policies**

- Various operation management measures, including Practical Guidelines for Corporate Governance, Guidelines for Business Ethics, Code of Ethics, Operational Procedures and Behavioral Guidelines for Business Ethics, Practical Guidelines for Sustainable Development of Corporate, and Management Procedures for Internal Material Information and Preventing Insider Trading.
- Intellectual Property Management and Utilization Measures
- Lawsuit/Material Dispute Management Measures

#### **External Guidelines**

- All business activities and products must comply with the laws and regulations of the relevant regulatory authorities in each country
- The corporate governance evaluation system indicators of the Financial Supervisory Commission



- Structure and Governance: Establish a global legal compliance plan before and after the launch of products
- Policy and Action: Formulate core legal compliance areas and reasonable policies
- Operations and Accountability: Establish legal compliance operating procedures, fully implement monitoring and accountability management
- Culture and Education: Continuously conduct employee education and promotion to solidify corporate spirit



- Board of Directors of PharmaEssentia, regulatory affairs unit, legal compliance unit, personnel unit, functional departments, and business and Legal Compliance Functional Teams of each subsidiary
- Various functional departments
- Head of Corporate Governance
- ECCS Corporate Governance Taskforce



- Implement the ability to prepare financial reports independently and disclose financial information in a timely manner
- Optimize internal controls for litigation-related procedures to track the progress of significant lawsuits through more precise steps and effectively manage content control for formal legal documents
- Each functional department of PharmaEssentia and its subsidiaries shall allocate a budget for the annual legal compliance plan and submit it for approval by the board of directors
- Each functional department shall hire external professional consultants to assist with legal compliance policy projects according to the development needs of the Group



#### **Short-term Targets for 2023**

- Depending on the operational needs, establish a nomination committee to continuously better the mechanism for selecting directors
- Improve the company website to provide direct or synchronized channels for communication or for filing complaints and reports with independent directors (Audit Committee)
- Establish the Guidelines for Practices by Listed Companies for Risk Management in compliance with the law to improve the risk management system
- Strengthen legal compliance management education and training
- Formulate the highest management principle, which is the Code of Business Conduct and Ethical Standards, and related operating policy documents with details for the group
- Include compliance with laws and regulations as an item in the annual audit plan and conduct internal audits regularly
- Actively implement the evaluation indicators of the Financial Supervisory Commission's Corporate Governance 3.0 Sustainable Development Blueprint
- Establish mechanisms and training for due diligence investigation of the adoption of technology of interest
- Strengthen the intensity of contract reviews, and optimize the management process for cases and documents in the legal department

#### **Medium-term Targets for 2024-2026**

- Establish a cross-subsidiary legal compliance committee within the group to promote the inclusion of opinions from legal compliance representatives of various functional units in the senior strategic decision-making process, and ensure that operational activities comply with laws and company policies
- Promote the establishment of a global legal compliance committee to oversee the effective implementation of legal compliance plans, and establish a reporting management mechanism for Headquarters and subsidiaries
- Establish an integrity operation supervision unit under the PharmaEssentia's legal compliance committee

#### Long-term Targets (2026 and beyond)

- Establish a global legal compliance committee
- Provide a global view of legal compliance risks for each subsidiary
- Promote cross-regional identification of operational efficiency, and prevent duplicate work
- Provide a global view of legal compliance risks for each subsidiary
- Promote cross-regional identification of operational efficiency, and prevent duplicate work



#### **Management Evaluation Mechanism**

- Develop relevant measures in accordance with regulatory requirements
- Provide internal audit feedback within the year and report on implementation results to the board of directors on a quarterly basis
- Employee education and training
- Performance evaluation mechanism for directors and managers
- Financial Supervisory Commission's Corporate Governance 3.0 Evaluation System
- Board of directors' performance evaluation by external professional organizations
- Whistleblowing hotline and email

#### **2022 Evaluation Results**

- PharmaEssentia has established over 40 operational management measures
- No material violations of ethical and moral standards or any corruption or privacy breaches were found in 2022
- The Internal Auditing Office held four courses on major internal regulations and sustainable governance related to the board of directors
- The legal compliance and HR departments jointly held three courses to further the understanding of code of ethical conduct
- No violations of the operational procedures of the Taiwan Stock Exchange were found in 2022, and there were no cases of Anti-Competitive Behavior and Anti-Trust and Monopoly Practice
- The Articles of Incorporation were amended on May 27, 2022, and the registration of changes was not processed within the legal deadline, resulting in a penalty of NT\$30,000 in accordance with Article 387 of the Company Act

# **Legal Compliance and Stable Operation**

GRI 2-27/205-1/205-2/205-3/206-1

The biotech and medical industries are highly regulated due to the significant impact of pharmaceuticals on human life and health. Therefore, we ensure that all business operations and products, from research and development to clinical trials, pharmaceutical manufacturing, drug licenses registration and post-market safety monitoring comply with the regulations of each country we operate in. Our company has been conducting clinical trials in various countries and actively investing in research and development, and we have established a regulatory affairs department and a marketing unit that strictly comply with local pharmaceutical and market regulations. We have also formulated the Intellectual Property Management and Utilization Measures to regulate the acquisition, protection, maintenance and use of our intellectual property. In terms of international arbitration and litigation disputes, we have established the Lawsuit/Material Dispute Management Measures to actively strengthen our control over legal cases and major disputes, and to monitor their progress. In 2022, there were two unexpected incidents, both of which were handled properly, and improvement measures were planned, ensuring stable operations within the company.

#### **Event 1**

In 2021, the company was fined NT\$1.5 million for violating the regulations on the verification and public handling procedures for important information and the operation procedures for information declaration. Additionally, on April 28, 2022, the Securities and Futures Institute announced that the company was not evaluated for its change in trading company governance evaluation in 2021.

#### **Response and improvement measures>>**

The company convened professional legal advisors and accountants to jointly develop specific improvement measures and optimize the system. The existing internal standards and control procedures were made explicit and relevant operational procedures were added. An internal control system improvement plan was also developed and reviewed and confirmed by external lawyers and signing accountants. The company resumed normal trading operations on May 4, 2022, and the company's governance evaluation system for 2022 has also been restored to normal evaluation operations.

#### Event 2

On May 27, 2022, the company amended its articles of association and was fined NT\$30,000 for failing to provide the required documentation for registration within the specified period under Article 387 of the Company Law.

Response and improvement measures>>
The company strengthened personnel
education and training to comply with relevant regulatory requirements and meet the
processing deadlines.

#### **Standard**

#### **Action Plan**

#### Execution in 2022

#### Anti-Corruption

Focus on prohibiting any form of bribery or improper financial transactions, as well as insider trading, money laundering or illegal political donations, and implementing the company's anti-corruption plan. PharmaEssentia's Headquarters and the US subsidiaries conducted multiple education and training sessions on IRPMA (market marketing regulations) as well as related laws and codes of conduct for clinical and marketing personnel

PharmaEssentia had zero corruption and no illegal political donations

#### Corporate Social Responsibility

Focus on sponsoring corporate social responsibility activities, including financial activities related to drug donations, research sponsorship programs, and sponsorship or charity activities related to the company

PharmaEssentia had no cases of improper behavior in violating ethical drug marketing standards

#### Trade Secrets

Trade secrets are important assets of researchbased companies and should be actively protected and managed to a degree no less than the protection of intellectual property and patents

PharmaEssentia had no events that harmed customer privacy

# Conflicts

Includes the activities of the company's business operations, which should comply with relevant regulations such as fair-trade law, company law, and securities law, and companies should not engage in unfair competition or monopolies that harm the rights and interests of consumers or other stakeholders. Strengthen the concept of legal compliance among employees to avoid committing violations against Anti-Competitive Behavior and Anti-Trust and Monopoly Practice

PharmaEssentia had zero violations against fair trade, anticompetition, anti-trust, or monopoly regulations

### Global Legal Compliance Strategy - US Legal Compliance Column o



# **Establishment of the Legal Compliance Committee** and the Legal Compliance Department

No reported complaints / No incidents of violation of Corporate Code of conduct



# Conduct multiple legal compliance education and training sessions

100% of employees trained, and 99% signed commitment agreement 100% of relevant vendors trained, and 100% signed commitment agreement



# Signed compliance guidelines

Business ethics and legal compliance are regulated



# Establishment of multiple complaint channels

Real-time monitoring of regulatory compliance through multiple channels

- The US subsidiary is committed to following the highest ethical standards and all applicable laws, regulations, industry standards, company policies, and procedures. The company has established a Legal Compliance Committee and Legal Compliance Department to assist in implementing and strengthening compliance programs related to the US market.
- The Compliance Policy Book-A guide is used to guide and manage business conduct for the US subsidiary. It explicitly specifies regulations related to anti-corruption and bribery, interactions with patients or their representatives, fee-for-service, privacy, and the unique ethical standards of the biopharmaceutical industry. The management policy related to the corporate code of conduct include anti-corruption and bribery, non-discrimination, protection of privacy, conflict of interest prevention, and environmental health and safety.
- Legal compliance education and training are provided, and all employees are required to comply with the rules stipulated in the Policy on Legal Compliance Handbook, with legal compliance evaluated as part of employee performance reviews.
- A whistleblower system and diverse complaint channels have been established, including a website platform (dedicated to employees, anonymous, and handled through a third-party referral process), email, and a hotline number to receive real-time legal compliance-related information. In 2022, there were no violations of ethical business practices and corporate of codes of conduct, and no complaints were received.

# **Strengthening Ethics and Integrity Policies**

GRI2-23/2-24

In addition to compliance with laws and regulations, adherence to ethical business practices is even more important. We have established multiple policy commitments to provide employees with a comprehensive framework to follow, and clearly define the responsibilities of each department to ensure the healthy development of organizational operations as well as the implementation of integrity management and supervision. The <a href="Board of Directors Meeting Rules">Board of Directors Meeting Rules</a> further stipulate rules on the board of directors and other relevant conflict of interest. We plan to establish a supervision unit for integrity management under the Legal Compliance Committee in the future to strengthen our management of legal compliance and integrity.

All employees must abide by the 7 business and ethical regulations set by our company. The Human Resources Department will educate new employees on ethical considerations in their work. We have also established a specific reporting system for illegal behaviors (including corruption) for both internal and external personnel. The regulations specify that employees should uphold the principles of fairness and impartiality in their work, and should not use their position for personal gain or manipulate or abuse information obtained through their work. All corporate governance-related procedures and methods can be found in the download section on our company website.



### In 2022, we actively solidified our commitment to ethical behavior by:

- We adopted online training courses to enhance knowledge and awareness of ethical concepts and legal risks associated with workplace dishonesty for all employees of PharmEssentia and Panco Healthcare, with a total of 216 participants and a 70.82% attendance rate, as part of our commitment to ethical business practices as an OTC-listed company.
- We conducted two educational training sessions on the IRPMA (Industry Recommended Practices for Market Activities) for clinical and marketing staff, providing clear guidelines to support and execute activities related to product launch, with a total of 20 participants and a 71.43% attendance rate.
- We organized four training sessions for the Internal Auditing Office to prevent the company's directors, managers, or employees from using insider information to buy or sell securities, which included verification and public handling procedures for major announcements, and regulatory education for internal personnel. We also invited external professional institutions to provide courses on the trends and challenges of sustainable corporate governance for all members of the board of directors, executive officers and the Head of Corporate Governance to obtain relevant knowledge.
- In addition, to ensure the comprehensive implementation of ethical business practices, a whistleblowing system to protect whistleblowers and provide a confidential reporting hotline in the local language for suppliers, customers, and other third parties to use is being prepared at our Headquarters. The system will disclose the number and types of reports received and the measures taken, which will help to detect risks, demonstrate our commitment, and protect our reputation.

# Compliance with Regulations and Specific Actions Throughout the Product Life Cycle

SASB HC-BP-270a.1/HC-BP-270a.2

In every stage of the biopharmaceutical industry chain, there are regulations that must be strictly followed. Experimentation, manufacturing, sales and advertising cannot be conducted arbitrarily. Ethical issues unique to the biopharmaceutical industry are particularly important, with a special emphasis on the implementation of regulations related to the ethics of preclinical animal experimentation, human clinical trials and drug marketing throughout the three stages of the product life cycle.

#### **Concrete Actions for Legal Compliance**

- Establishing a legal compliance department
- Setting up an anonymous hotline for reporting violations
- Establishing a dedicated section for legal compliance-related measures
- Ensuring all functional departments adhere to legal compliance-related measures
- 100% coverage of employee training on legal compliance
- Monitoring system for meals provided to healthcare professionals
- Business rules and operations for speaking events
- Ethical guidelines for pre-clinical animal testing
- Ethical guidelines for clinical human trials

#### **Pharmaceutical Product Lifecycle**

### **International Local and Internal Ethical Standards**

New drug development and preclinical research

- ✓ Good laboratory practice (GLP)
- √ Non-clinical safety standards for drug testing established by regulatory agencies in each country

Clinical trials

Before market launch

- ✓ Good clinical practice (GCP)
- ✓ Good manufacturing practice (GMP)
- ✓ Ethical principles of the Helsinki Declaration
- ✓ Local regulations established by regulatory agencies, such as Taiwan's "Regulations for Human Clinical Trials" and "Pharmaceutical Affairs Act"

Production and manufacturing

- ✓ Good distribution practice (GDP)
- ✓ Good manufacturing practice (GMP)
- ✓ Local regulations established by regulatory agencies, such as the European Pharmacopoeia, United States Pharmacopeia, Taiwan's "Medical Care Act", "Pharmaceutical Affairs Act", and "Standard for the Establishment of Pharmaceutical Manufacturing Plants"

**Drug registration** 

Local regulations established by regulatory agencies, such as Taiwan's "Guidelines for Inspection, Registration, and Review of Pharmaceutical Products"

- Implementing a transparent reporting system
- Implementing a review process and control measures for speaking events, advisory committees, and the monitoring and auditing system for meals provided to healthcare professionals
- Implementing a compliance review process and control measures for advisory committees
- Other legal compliance policies and standard operating procedures, such as investigations, monitoring, and employee discipline
- Pharmaceutical marketing ethics guidelines

Marketing and sales

Pharmacovigilance

- ✓ Good distribution practice (GDP)
- ✓ Relevant ethical regulations established by the World Health Organization (WHO) and regulatory agencies in various countries
- ✓ Good pharmacovigilance practice (GVP)
- ✓ Local regulations established by regulatory agencies, such as Taiwan's Pharmacovigilance Management Measures

#### **Applicable ethical guidelines**

#### ICH guideline "Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals", as well as country-specific regulations such as "Non-Clinical Safety Guidelines for Drugs"

GLP

#### Our approach

- Establishment of an Institutional Animal Care and Use Committee (IACUC) to review and oversee animal experiments and animal care in our institution
- Outsourcing of animal experiments to Contract Research Organizations (CROs) that have obtained GLP certification, both domestically and internationally
- Use of healthy, infection-free experimental animals of Specific Pathogen Free (SPF) level to prevent interference from specific diseases in the test results
- Actively implementing the 3R principles for experimental animals: "Replacement", "Reduction", and "Refinement"

Our goal

To ensure that researchers in animal experiments comply with relevant legal requirements and minimize the use of experimental animals as much as possible.

#### Clinical Trial Ethics for Human Subjects

Ethical guidelines

for preclinical

animal experiments

- Internal policies on clinical trials
- The Helsinki Declaration
- GCP (Good Clinical Practice)
- Trial protocol and local regulations
- Standard operating procedures for the development and approval of trial protocols and informed consent forms for participants
- All trial protocols and informed consent forms must be reviewed and approved by the health authorities and the Institutional Review Board (IRB) before the trial begins
- Participants in clinical trials led by PharmaEssentia will be insured with clinical trial insurance to
  protect their personal rights and interests
- During the trial, the personal information and privacy of participants will be protected
- Regular monitoring and auditing will be conducted during the trial

Ensuring the safety, privacy, and rights of clinical trial participants demonstrates that PharmaEssentia is a trustworthy Biopharmaceutical company that patients can rely on.

# Ethics in pharmaceutical marketing

- World Health Organization (WHO)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
- National Council for Prescription Drug Programs (NCPDP)
- Ethics guidelines set forth by the Foreign Corrupt Practices Act (FCPA)
- Internal policies such as "HCP & HCO Interaction Policy" and "Promotional Material Policy"

- All employees must follow the ethical standards set forth by the aforementioned organizations when interacting with healthcare-related individuals or organizations
- Marketing activities must be transparent, ethical, accurate, and balanced, with no misleading information
- Marketing materials must contain correct assessments of product risks and benefits, as well as appropriate usage information
- Products may not be marketed under the guise of human research studies

We ensure that healthcare professionals receive necessary information and that patient care and welfare are protected in an ethical manner, in line with our mission and responsibilities. In 2022, there were no incidents of quota errors related to marketing.



# **6.3 IT Security/ Cybersecurity Management**

In order to strengthen information security protection and management mechanisms as well as comply with the Guidelines for Public Companies to Establish Internal Control Systems, our company passed the new Information Security Control Measures in a board meeting in 2022 and established an information security promotion organization to enhance risk control for information security. This organization is responsible for promoting, coordinating, supervising and reviewing matters concerning the management of information security, and the information security manager reports on the status of affairs to the board of directors annually. The annual information security policy and goals are approved by executives at or above the general manager level, and the policies and goals are reviewed regularly and effectively communicated to employees.

Our company has formed an information task force and recruited relevant professionals to join. In 2022, in addition to completing the SAP server drill and implementing the anti-hacking measures listed below, we invested in at least five IT personnel and spent Tens of millions of NT dollars on upgrading ERP software and hardware equipment. We also commissioned a professional vendor that complies with ISO 27001: Information Security Management System to plan, implement, maintain, manage and support our company's information system operations. Regarding education and training, the IT security task force conducted two Social Engineering Information Security Education and Training sessions for 185 employees, with an attendance rate of 71.71%; professional lecturers with abundant experience in information security service from a Taiwanese company were invited for the first time. We aim to strengthen employee awareness of information security and ensure that our company's information security management is recognized by employees through their feedback.





## **Information Security Action Plan**

Our company's information task force and hardware equipment have been gradually established and improved. In the future, we will continue to implement our Information Security Control Measures to ensure the appropriateness and effectiveness of our information security operations, regularly track and improve them, and establish a positive PDCA cycle.

We also plan to introduce ISO 27001: Information Security Management System in 2024, establishing an effective information security management mechanism to enhance everyone's awareness of information security.

### **Cybersecurity Measures of PharmaEssentia**

- ✓ Strengthening of important core information system backups
- Drafting of information security policies (compliance with the GreTai Securities Market Information Security Management Control Guidelines)
- ✓ Planning and execution of information security checkups (annual execution)
- V Planning and execution of employee social engineering training (annual execution)
- Information system and network vulnerability scanning (annual execution within the company)
- Information system and network penetration testing (annual execution from outside the company)
- ✓ Planning and implementation of file encryption systems
- ✓ Data loss prevention (DLP) endpoint device security protection
- ✓ O365 multi-factor authentication (MFA) for enhanced information security

# **Ensuring the Protection of Personal Privacy**

GRI418-1

The privacy policy of PharmaEssentia focuses on protecting personal information, including that of patients, healthcare professionals and other individuals involved in business transactions. Privacy protection is divided into two stages: clinical trial and drug launch. All of our partner research institution and hospitals for clinical trials are required to strictly follow

our internal policy and national regulations, such as the General Data Protection Regulation (GDPR) in the European Union, Good Clinical Practice (GCP), the Helsinki Declaration and Taiwan's guidelines on ethical human research to ensure the protection of personal data. In 2022, there were no complaints of privacy violations or loss of customer data.

#### Global Cybersecurity Strategy - US Cybersecurity Column •



#### Governance Responsibility

- Hired an IT Director with over 20 years of IT management experience as the highest information and network security executive, reporting directly to the VP of Business Operations
- Senior Operations Manager applied for the Certified Information Security Manager (CISM) certification
- Planning to establish relevant management processes and operating procedures before March 2023

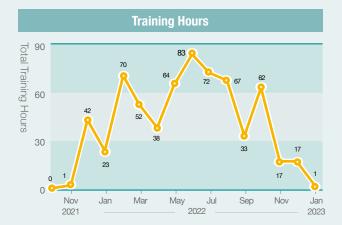


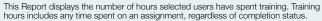
Risk Prevention

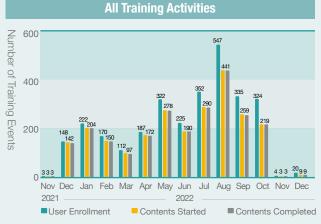
- The KnowBe4 system has an alert function. If an employee detects any abnormality, they can report it
  through the system and block potential phishing emails. If an employee feels that their account is at risk
  of information security, they can immediately seek IT support.
- Entrusted a third-party information security monitoring company to conduct IT audit management to
  prevent hackers or phishing attacks and collaborate to gradually improve management, including the
  establishment of more comprehensive policy and management processes, such as Bring Your Own
  Device (BYOD) Policy, Acceptable Use Policy, Asset Management, Security and Privacy Management
  Policy, IT Change Management Workflow, etc.
- No information security or network attacks have occurred to date.



- Management Procedures: There
  is currently an internal operating
  procedure (SOP-IT-001) that not
  only manages information security
  risks but also provides management
  instructions for other events that
  may pose risks to the company's
  continuous operation.
- Education and Training: All employees receive policy and management procedure instructions to promote the importance of information security. Regarding the use of the KnowBe4 system, all employees are required to complete relevant training courses regularly.
   A total of 599 training hours were







This report displays a count of training events, grouped by month.