3.2 Drug Quality and Product Safety GRI 3-3

Material Topics

Drug Quality and Safety Management

Description of Impacts

PharmaEssentia implements risk management on manufacturing processes, environmental controls, and material supplies. We have formulated case-specific "Monitoring Plans" and "Audit Plans" as part of our quality assurance and quality management procedures, and established the "Quality Risk Management Procedure" in accordance with the Taiwan ICH Q9 Quality Risk Management guidelines to serve as a risk management strategy for production and manufacturing. We also use the risk aspects recommended by ICH Q9 (probability, severity, and detectability) to assess risk levels. We established the Equipment Risk Assessment Procedure in accordance with the United States Pharmacopeia, and manage risk categories based on "GMP impacts" and "systemic complexities," thereby reducing quality hazards and risks from equipment operators.

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 qualification

Transportation: We rigorously adhere to GDP regulations, meet local standards for marketing authorization, and strictly control all packaging and transportation processes

Responsible Unit

- Production, transportation, quality management, and auditing departments at headquarters
- Quality control department, quality assurance department, clinical trial quality assurance and drug safety monitoring teams at headquarters: Maintain and monitor the quality of marketed and clinical drugs
- Executive Center for Corporate Sustainability Product Ethics and Safety Team: Responsible for compiling and managing material sustainability issues

Response Measures and Management Actions

- Introduced Trackwise electronic system to perform deviation management, corrective actions and preventive actions, supplier management, laboratory surveys, and other procedures under our quality system
- Production and manufacturing quality management and risk management: Hosted 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

Evaluation Mechanisms

- Official periodic GMP inspections (such as those conducted by the US FDA, EU EMA, and Taiwan TFDA)
- All departments need to undergo at least 1 internal quality audit every year
- Invite external experts to conduct quality audits as necessary
- External evaluation mechanisms for clinical trials adhere to inspections conducted by health authorities, and audits are conducted regularly by third parties (such as the institutional review boards at hospitals where trials are being conducted). Internal evaluations are conducted by the Clinical Trial Quality Assurance Unit (established in 2025)
- Established a Data and Safety Monitoring Board (DSMB) for human trials to perform reviews and assessments
- 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

Targets and Achievements in 2024

- Good Manufacturing Practice (GMP) plant certificates were updated or extended/maintained according to schedule
- Regularly implemented and passeed internal and external audits
- Completed GMP/GDP education and training
- Factory inspections conducted by EU and Brazilian supervisory authorities confirmed that there were no major deficiencies
- Completed incorporation of Blue Mountain electronic system for hardware management of GMP equipment, including calibrations, verifications, qualification determinations, and label generation
- Completed a total of 12 internal audits and 6 external audits on suppliers; all audited units completed corrections and passed re-inspections after being informed of deficiencies
- Organized a total of 750 GMP/GDP education and training sessions, with total training hours amounting to 14,797 hours
- Received a total of 208 customer complaints, none related to product safety, and achieved customer complaint rate of 0.12%
- PharmaEssentia hosted 32 global interdepartmental risk assessment team meetings for a total of 196 attendees to jointly review risk issues in factories

Targets

Short-Term Targets (1-2 Years):

- 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 and validation processes of new Zhubei Plant and obtain GMP certifications from various countries
- Complete construction of Taipei Bioinnovation Park site and commence production of Phase 1 and Phase 2 clinical APIs
- Continue to maintain drug quality and zero recall record

Mid-Term Targets (3-5 Years):

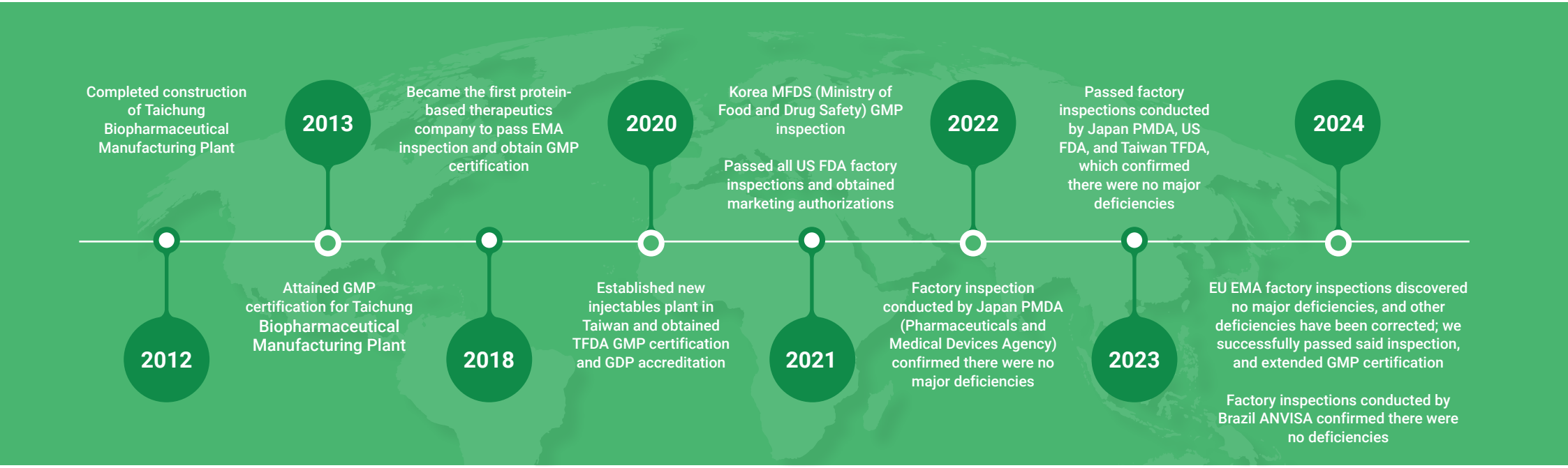
- Commence production of APIs that comply with the regulations of various countries at Zhubei Plant, and also begin production of GTP (Good Tissue Practice) cell therapies
- Support Houli Plant in passing international GMP inspections and commencing production of GMP-compliant PEG intermediates
- Continue to maintain drug quality and zero recall record

Long-Term Goals (More Than 5 Years):

- Establish production plants in Europe and the US to enable local production and make strides toward net zero targets
- Continue to maintain drug quality and zero recall record

PharmaEssentia Global Certification Landscape

We use practical actions to achieve vertical integration within our supply chain, gradually building our global market from production, quality control, filling, to delivery, actively demonstrating our vision to become a world-class pharmaceutical company.



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, reduce supply chain risks, and improve supply stability.

Process Optimization

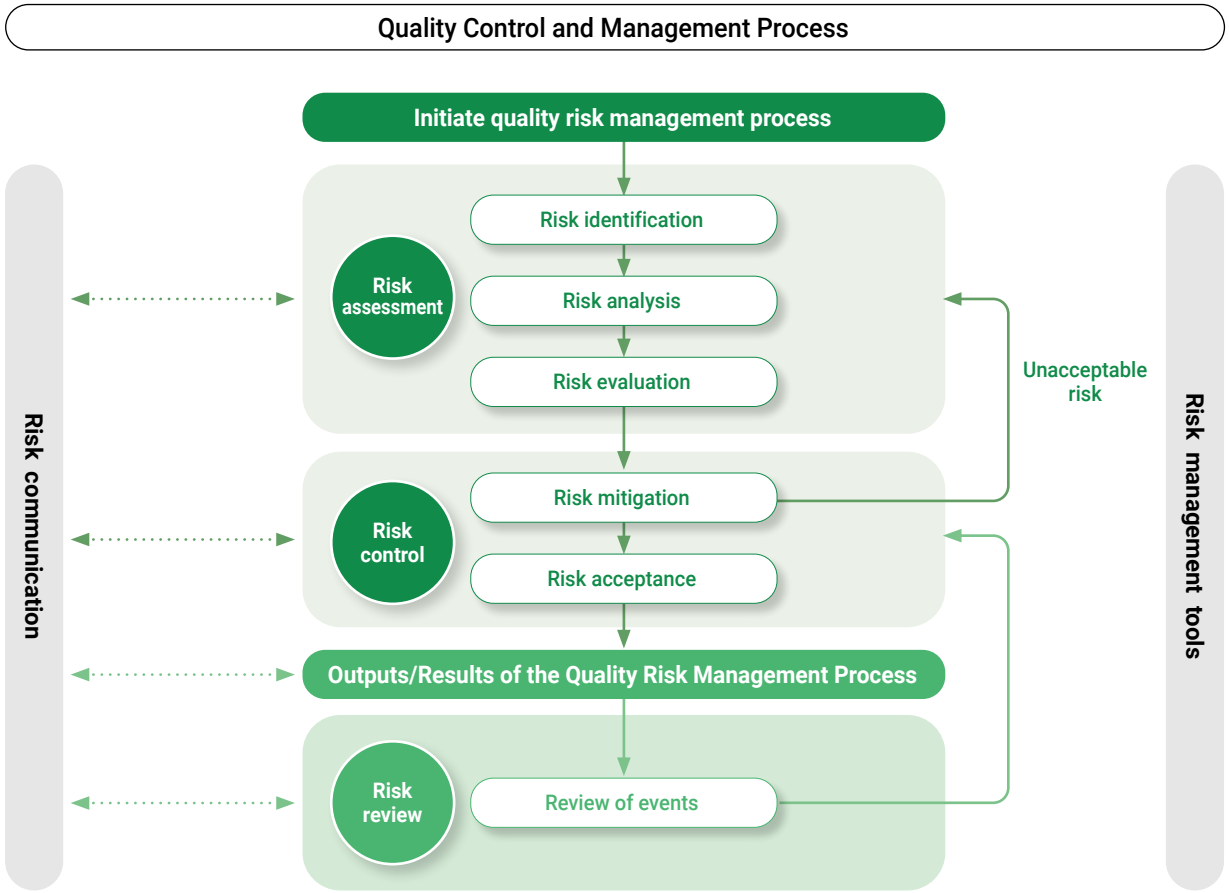
Enhancing Production Capacity

	Introduce second and third material sources	Establish second purification production line	Scale up PEG production line
Objective			
Goals and Results	To stabilize material supply, we completed 3 second-material source projects in 2024 and 3 more projects are in the testing phase. 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 2024, increasing production capacity by 100%.	Completed scaling up of PEG production line in 2024, increasing production capacity by 4-8 times.

Quality Control and Risk Management in Manufacturing Processes

PharmaEssentia's Taichung Plant emphasizes product quality and safety management. Each year, our colleagues at the plant have to undergo education and training related to product safety and GMP regulations so they can update their knowledge and incorporate quality management concepts in daily tasks. The Taichung Plant has developed work procedures and organizational operational procedures for factories in different countries that produce GMP-compliant APIs and drug formulations, which are detailed below. In 2024, we continued to implement, monitor, and report trends associated with production environments (HVAC systems), water systems, compressed air systems, and biosafety cabinets, requiring all systems to comply with design specifications and legal regulations. The Taichung Plant has also formulated the "Plant and Facility Emergency Response Management Standard" to establish emergency response mechanisms for natural disasters, equipment abnormalities, and other emergency hazards, thereby ensuring that all equipment can operate normally and all personnel can work in safe environments.

The Ropeg product sold by our Japanese subsidiary is manufactured and produced at headquarters, where we ensure that production processes adhere to procedures that have been verified by the Japanese government. If there are any deviations during the manufacturing processes, the quality control department at our Japanese subsidiary will work with quality control personnel at headquarters to conduct appropriate assessments that guarantee product quality. Additionally, we also commissioned a Japanese testing agency to conduct relevant tests (such as product purity tests) on products imported from Taiwan and also outsourced product packaging to a Japanese pharmaceutical company to comply with Japanese regulatory requirements.



Education and Training	GMP/GDP regulations	**750** sessions and **14,797** hours
Established relevant work procedures for factories in many countries that produce GMP-compliant APIs and drug formulations	Quality manual, quality policies, master validation plans	**29**
	SOP guidelines	**100**
	Operational SOPs	**>900**
	Record forms	**>1,000**

GMP Certification and Quality Audits

PharmaEssentia's Taichung Plant is 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 Panco Healthcare Logistics Center conducted internal quality audits in 2023 and found no major deficiencies that deviated from our quality system.

Frequency of internal audits

- At least 1 internal audit each month (each department undergoes at least 1 random audit each year)
- If audits identify deficiencies, CAPA plans should be submitted within specified time limits based on deficiency levels, and related procedures should be completed

Frequency of external audits

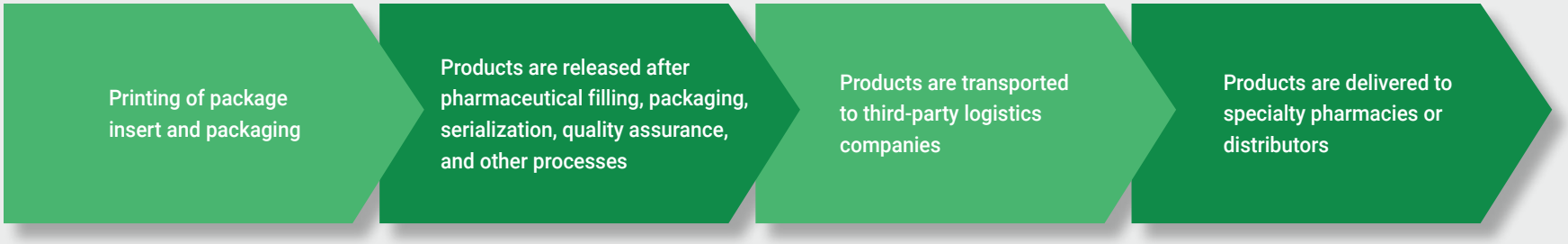
- Regular official GMP inspections every 2-3 years

CRO and CMO Management

In addition to filling and packaging operations conducted at our sterile formulation filling plant in Taichung, 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.

Secure Distribution Processes and Stable International Logistics & Transportation

Our secure distribution processes strictly adhere to GDP regulations and ensure proper management of pharmaceuticals throughout the transportation process. PharmaEssentia's GDP-compliant Panco Healthcare Logistics Center in Taichung supplies clinical drugs and marketed products, and also implements quality management regarding logistics management, warehousing management, and labeling processes.



PharmaEssentia has formulated the following strategies to maintain safe and stable international transportation:

1. "Storage and Distribution Policy" to regulate storage and distribution procedures that ensure appropriate storage conditions and management for raw materials, intermediates, and products
2. "Product Distribution Management Procedure," which stipulates that distribution procedures and tracking mechanisms at all operational sites around the globe must adhere to PIC/S Good Distribution Practice (GDP) requirements
3. "Import and Export Transportation Management Procedure" regulates import, export, and transportation procedures, and ensures regulation-compliant, fast, and safe delivery of all transported goods to designated destinations to effective safeguard patient medication safety
4. "Emergency Response and Handling Procedure" to prevent or mitigate negative impacts on distribution at Taichung Plant due to natural disasters
5. In 2024, we added a new air carrier to provide transportation services. PharmaEssentia verified transportation quality, ensured that appropriate temperatures were maintained during the transportation process, and confirmed there were no factors that could cause negative impacts on transported goods. This new transportation vendor helped to build another layer of transportation efficiency and additional protection for product transportation and logistics
6. We maintain at least 4 months of safety stock in the US in case of acute disaster risks within US borders caused by climate change to ensure that patients in the US can received their medications in a timely manner
7. Our Japanese subsidiary has formulated distribution procedures applicable for Japan and requires all Japanese logistics companies to comply with international and Japanese GDP regulations

Warehouse Management

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

Product Entry and Storage Process

Storage Application	Physical Verification	Conformity Confirmation	Confirmation of Storage	Medicine Storage
Storage of products requires submission of a "Product Storage Application" to warehouse management personnel	Warehouse management personnel, along with quality assurance personnel, confirm and verify the physical product based on the information provided in the application	The product labeling, including product name, code, batch number, required temperature, quantity, and container information, must match the details on the application form	Ensure the product is properly sealed and packaged. Once the storage conditions are met, the product is stored accordingly	During the storage period, the storage environment is monitored to ensure optimal conditions for medicine storage

Quality Control in Shipping and Transportation

PharmaEssentia has established the "Product Shipping Operations Standards" to ensure that distribution processes for products manufactured at the Taichung Plant and by CMOs, as well as packaging and transportation processes at storage warehouses, are appropriately managed and all pharmaceuticals are transported under prescribed and suitable temperature conditions to uphold global drug transportation safety.

Packaging operations

- 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

Transportation process

- Comply with the "Storage and Distribution Policy" in executing appropriate storage and distribution procedures
- Conduct scenario simulations for pre-analysis to confirm that cooling statuses and equipment specifications meet specification needs
- Regularly check raw materials, intermediates, and products to ensure that they are stored and managed appropriately