5.2 Sustainable Supply Chain Management

Material Topic

PharmaEssentia adheres to the PIC/S GDP (Good Distribution Practice) regulations to establish a legal and comprehensive global marketing management mechanism. There are over 4,000 quality and safety management procedures, standard operating procedures, and various plans and reports within the company to ensure compliance with operating procedures, accuracy and completeness of records, and to ensure the quality and safety of drugs from the production factory to patient use, safeguarding the medication safety of every patient.

GRI 3-3

Management Policy

Internal Policies

- Raw Material Management Policy, Storage and Distribution Policy and Product Packaging and Labeling Policy
- Supplier Management Policy (Supplier Management Standards Operating Procedures, Supplier Management Procedures, Procurement Management Standard Operating Procedures and Supplier Audit Procedures).
- Quality Management Policy, Risk Management Policy and Outsourced Activities Policy

External Guidelines

- WHO Good Storage and Distribution Practices for Medical Products
- Strict adherence to laws and related external GxP regulations at all stages of the product life cycle, from research and development to production and sales
- Practical Guidelines for Sustainable Development of Corporate

Management Commitment

- PharmaEssentia is committed to building a stable, safe and high-quality drug supply chain, and strives to improve the accessibility, affordability, and availability of drugs. We continuously strengthen the safety and stability of the overall supply chain and reduce the impact of COVID-19 on the supply chain.

Accountable Units

- The Supply Chain Management (SCM) department of PharmaEssentia Headquarters includes business units, procurement units, production units, logistics units, manufacturing units, QA units, and SCM units of each subsidiary
- ECCS - Product Quality and Patient Safety Taskforce

Input Resource

- Professional division of labor and task execution among responsible personnel, with continuous on-the-job training
- Regular quarterly assessments for commercial and clinical development needs
- Transportation planning: Establishment of large cold-chain spaces to increase product storage capacity and turnover flexibility
- Supplier management: Increased communication frequency to ensure stable supply sources in response to COVID-19, cross-departmental collaboration for stocking, signing of supply or quality contracts, and completion of audits for commissioned transporters/storage facilities
- Outsourcing partner management: Establishment of communication channels to review quality management, provide demand estimation plans, and update them in a timely manner
- Tracking actions: Drug traceability management software, self-established drug complaint system, drug safety notification system, and supply shortage notification system for regulatory authorities in various countries
- System implementation, enterprise resource planning system (ERP), business process management system (BPM)

Targets

Short-term Targets for 2023

- Continuously expanding emerging markets and fields for BESREMi®: Launching in Japan in 2023
- Continuously expanding and strategically allocating production capacity: Construction of manufacturing center
- Upgrading and implementing ERP system to accurately plan raw materials and product inventory and production control
- Establishing good working relationships with suppliers: Mastering upstream original factory supply and rapid response stocking strategies
- Continuously developing and implementing secondary source of raw materials
- Continuously developing Supplier Behavior Code of conduct
- Managing long-term demand and other requirements requested by customers

Medium-term Targets for 2024-2026

- Continuously expanding emerging markets and fields for BESREMi®: Launching in new markets and regions, or clinical research projects for different indications
- Continuously expanding and strategically allocating production capacity: Optimizing the connection between front-end and back-end processes
- Establishing good working relationships with suppliers: Improving delivery reliability and flexibility
- Improving customer satisfaction: Planning for potential market demands to create maximum benefits for both the group and patients
- Forecasting demand from various countries: Planning and preparing production lines and raw materials to ensure timely and stable supply to potential markets
- Continuously optimizing internal operational processes and communication: Benefiting multiple parties and effectively reducing costs
- Optimizing internal processes within the group: Integrating the demands of various subsidiaries/countries and managing and allocating resources in a rational manner
- Integrating various country regulations and market requirements: Coordinating the launch of drugs in different countries to make the best use of group resources

Long-term Targets (2026 and beyond)

- Optimizing internal processes within the group: Integrating the demands of various subsidiaries/countries and managing and allocating resources in a rational manner
- Integrating various country regulations and market requirements: Coordinating the launch of drugs in different countries to make the best use of group resources

Evaluation of Management Policy

Management Evaluation Mechanism

- Establishment of supplier evaluation mechanism
- Implementation of internal audit and control guidelines at PharmaEssentia
- National drug safety reporting systems in different countries
- National drug supply shortage reporting systems in different countries
- Establishment of a drug complaint system at PharmaEssentia
- Regular management meetings and product quality reviews at PharmaEssentia
- SAP-related document operations

2022 Evaluation Results

- BESREMi® has been supplied to patients at a steady paceafter being approved for marketing in various countries
- COVID-19 still had a significant impact on the supply chain in 2022, but the introduction of a second source of materials and the search for alternative materials in the market ensured the supply of goods and reduced costs
- No complaints were received from hospitals or patients
- Sufficient stock was ensured based on the number of users
- No products were found to be ineffective or unsafe due to transportation and storage activities

Establishing a Stable and Reliable Supply Chain

SASB HC-BP-260a.1

Building a robust cross-border supply chain to provide high-quality and safe medicines that meet the urgent needs of patients with rare diseases worldwide is an important mission that PharmaEssentia and its upstream and downstream supply chain partners are committed to.

Integrated planning and management of drug demand

- **Cross-departmental coordination of production and sales:**
  Integration of clinical and external pharmaceutical business demands between headquarters and subsidiary companies
- **Manufacturing and production scheduling:**
  Confirming requirements coordination and supply with supply and production sides

PharmaEssentia

- Taiwan Headquarters
- US
- Malaysia
- Japan
- Singapore
- Hong Kong
- Korea
- Macau
- China
- Vietnam

Responsible procurement and supplier management

- **Supplier management:**
  Screening, evaluating, and approving suppliers in strict procedures, with priority given to local vendors as cooperative partners
- **Establishing safety stocks:**
  Timely grasp of raw material delivery times
- **Establishing alternative material sources:**
  Reducing the risk of material shortages
- **3 major supplier management points:**
  Conveying sustainable values to partners and jointly establishing a sustainable supply chain

- Procurement of raw materials, supplies, and equipment
- Supplier sustainability declaration

High-quality production and manufacturing

- **Complying with international normative standards:**
  Following Good Manufacturing Practices (GMP), ICH, EMA, FDA, and more than 4,000 internal standard operating procedures and other related regulations
- **Strict safety control:**
  Quality assurance and quality control departments managing and supervising quality safety and product release
- **Outsourcing filling and contract manufacturing:**
  Injection filling for the US market is done by qualified contractor Pyramid Laboratories Inc.

Biopharmaceutical manufacturing plant

PYRAMID Laboratories, Inc.

Fill and finish for injectable products

Drug storage and international logistics transportation

- **Stable marketing and distribution:**
  Strict control of packaging, transportation, and cold chain maintenance
- **Domestic marketing and distribution:**
  In-house sales and logistics teams responsible for supply and marketing
- **International marketing and distribution:**
  After injection filling is completed in the US, it is sent to a third-party logistics warehouse by contractor Pyramid Laboratories Inc., and ultimately delivered to patients through specialty distributors and pharmacies.

Warehouse and logistics center

CardinalHealth™
Third-party logistics

Specialty pharmacies and distributors

Effective Pharmacovigilance and Recall

- **Dedicated Pharmacovigilance team:**
  Composed of Pharmacovigilance personnel from headquarters and subsidiary companies and quality assurance personnel for Pharmacovigilance
- **Assistance from outsourcing research institutions:**
  Managing and maintaining safety data databases, collecting/exchanging drug safety information, and reporting to regulatory agencies
- **Safety monitoring reports:**
  Quarterly submission of regular safety reports and safety signal detection reports
- **Product traceability mechanism:**
  When quality problems arise, products can be recalled and related inventory can be processed within regulatory deadlines.

PharmaEssentia Headquarters Adverse Drug Reaction Reporting Email: Safety@pharmaessentia.com

Global Adverse Drug Reaction Reporting Email established by outsourcing research institutions:
PharmaEssentia.drugsafety@labcorp.com

Taiwan Adverse Drug Reaction Reporting Center Phone: 0800-818-886

PEC U.S. Call Center (800) 999-2449, a reporting management center specializing in serving the U.S. market. (800) 999-2449

Strengthening Sustainable Supplier Management with 3 Key Points

Adhering to the belief of mutual benefit and sustainable practices with suppliers and contractors remain a top priority for PharmaEssentia in the face of the global impact of COVID-19 on upstream supply chains. Together with our partners, we will continue to work towards these three key points to create long-term and sustainable value for the biopharmaceutical industry and patients.

Sustainability Declaration and Supplier Partnership

We strive for mutual benefits and sustainable development with our supplier partners. Our plan is as follows:

- **Declaration:** Communicate PharmaEssentia's sustainable philosophy and practices to our stakeholders.
- **Action 1:** Promote the Supplier Code of Conduct.
- **Action 2:** Sign the Supplier Code of Conduct.

Enhancement of Management Capabilities

To cope with the ever-changing world, our strategies for enhancing management and contingency capabilities are:

- Acquisition of information
- Strengthening supplier management capabilities
- Enhancing interaction with suppliers

Establishment of Alternative Material Sources

To ensure a stable supply, we take the following steps:

- Identify critical materials
- Screen candidate raw materials
- Confirm quality and conduct experiments
- Produce trial batches
- Monitor quality assurance to ensure compliance with regulations

Sustainability Declaration: Building Sustainable Supply Chain

We continuously communicate with our supply partners through formal and informal sustainability declarations to create positive and long-lasting impact. Our procurement and other related units have initiated the development of a Supplier Code of conduct and will roll out its promotion and signing in phases. In 2022, we promoted our PEC Corporate Sustainability Report to 177 suppliers. Currently, we are working on revising the Supplier Code of conduct and the Supplier Management Operation Guidelines, and plan to complete the signing by the suppliers in the third quarter of 2023. We hope to work together with each of our supply partners to grow, prosper, and prioritize corporate sustainability responsibilities.

Establishing Alternative Sources of Materials

To prevent interruptions in the supply of critical raw materials due to various factors such as suppliers not passing evaluations or the COVID-19 pandemic, we have conducted a comprehensive investigation of raw materials and established an internal standard operating procedure to determine the priority for introducing alternative sources for these materials.

Inventory of raw materials that require alternative sources to be established

The following criteria are used to determine whether alternative sources are needed:

- Notification from the supplier that they will stop production
- Regulatory agency requirements
- Key Material Assessment program to evaluate material risks

Quality confirmation

For materials with an immediate risk of shortage, quality confirmation will be carried out.

Process development and testing

Trial production will be carried out to test the quality of the materials. Qualified raw materials will then be entered into the GMP control process (supplier evaluation, specification inspection, and method establishment, etc.). After completing the relevant procedures, they will be added to the backup list.

Continuous monitoring of quality assurance

The quality assurance department will continuously monitor the test data and documents at each stage of material development to ensure that the entire process fully complies with regulatory standards.

Supply Chain Management and Resilience Enhancement

To mitigate the impact of the COVID-19 pandemic on the supply chain, PharmaEssentia is continuously enhancing its supply chain management and resilience. This includes maintaining safe inventory levels, establishing alternative sources of materials, balancing cost and long-term stockpiling, and actively reducing the risk of stockouts that could result in delayed or unstable supply.

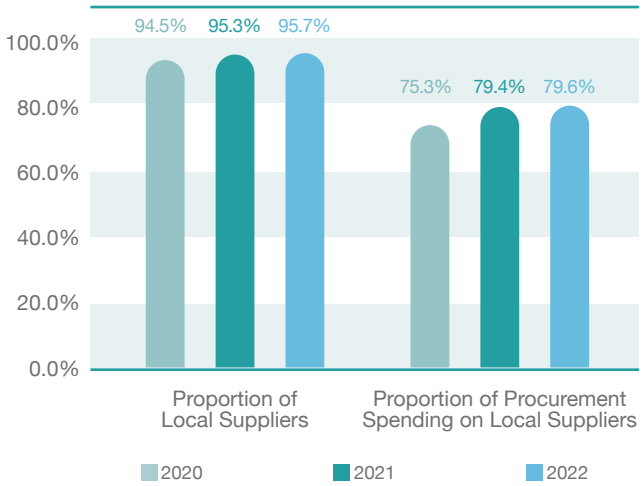
- Real-time monitoring of potential factors that may affect the supply chain, such as diseases, climate change, natural disasters, etc.
- Strengthening supplier management, adjustment, and contingency capabilities.
- Deepening communication with suppliers, monitoring the transportation and logistics status of materials in real-time, and obtaining complete information on transportation and logistics.
- Updating the lead time for the arrival of purchased materials from suppliers.
- Improving safety stock and monitoring changes in demand from healthcare institutions and patients.
- Paying attention to the epidemic situation in countries where raw materials are produced, evaluating the risk of material shortages, and proactively preparing for such risks.
- Actively establishing alternative sources of materials to reduce the risk of material shortages.

Management Process of Suppliers/Contractors

GRI 2-6 / 204-1 SASB HC-BP-430a.1

To ensure that the raw materials and equipment provided by our suppliers meet our company's standards for quality and delivery as well as Good Manufacturing Practice (GMP) regulations, our Quality Assurance department has formulated the Supplier Management Standards Operating Procedures and the Supplier Management Procedures as its approval procedures and operating standards for suppliers and contract service providers. We strictly monitor the screening, evaluation, and approval of raw material, material, and instrument/equipment suppliers. We also require suppliers to sign a Quality Agreement to ensure that both parties have a shared understanding of product and quality requirements. All vendors who should have signed the Quality Agreement have done so, with the proportion of local suppliers increasing to 95.7% in 2022, and the procurement amount from local suppliers increasing by 79.6%.

Proportion of Local Suppliers and Procurement Spending on Local Suppliers



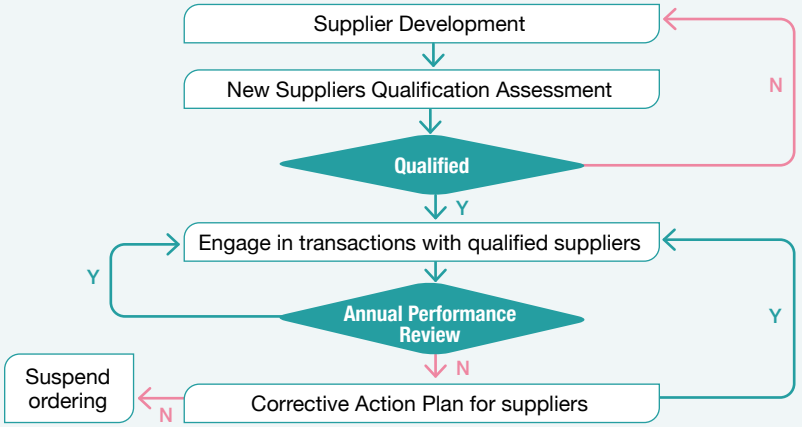
95.7%

Over 90% of local procurement suppliers for 3 consecutive years

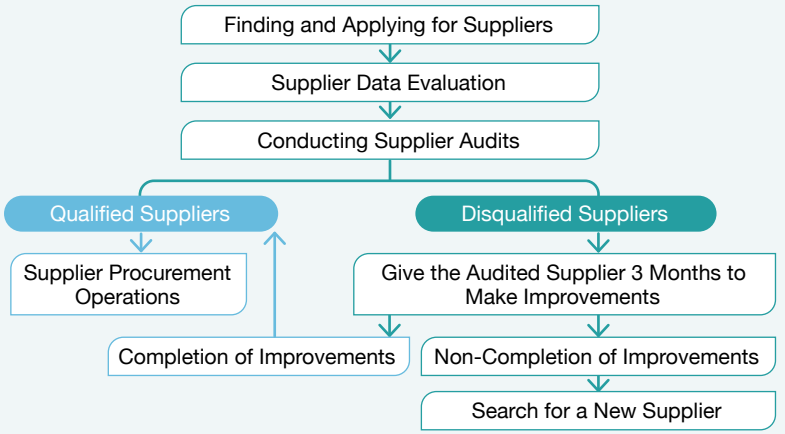
Note 1: The data range includes figures for both PharmaEssentia Headquarters and Panco Healthcare; the supplier number for 2021 and 2022, as well as the local procurement amount for 2021 are shown.

Note 2: Local suppliers refer to manufacturers, producers, and agents that provide products and services domestically. This includes those based in Taiwan.

Supplier Management Process at PharmaEssentia Headquarters



Supplier Management Process at Panco Healthcare

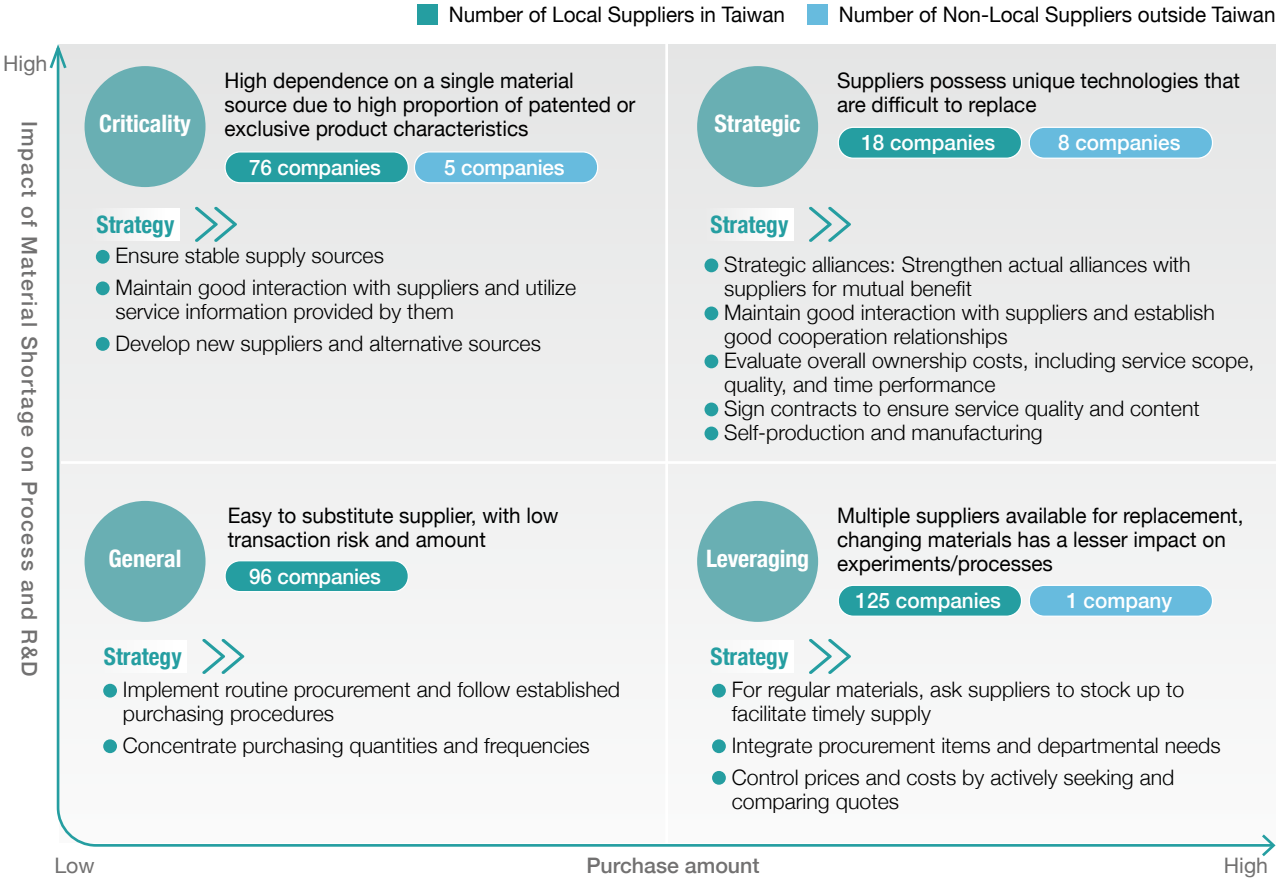


Suppliers/Contractors Management Strategy

Both PharmaEssentia and Panco Healthcare divide suppliers into four categories based on risk and procurement amount: strategic, critical, leverage, and general. Corresponding supplier management strategies are then formulated based on market characteristics and the attributes of each category's materials or services.

PharmaEssentia's US subsidiary categorizes suppliers into two categories, critical and non-critical, and conducts rigorous supplier risk assessments for critical-level suppliers, with a safe amount of stock as a main KPI to ensure the reliability of supplier delivery.

Supplier Management Process at PharmaEssentia Headquarters and Panco Healthcare



Supplier Management Process at PharmaEssentia's US subsidiary

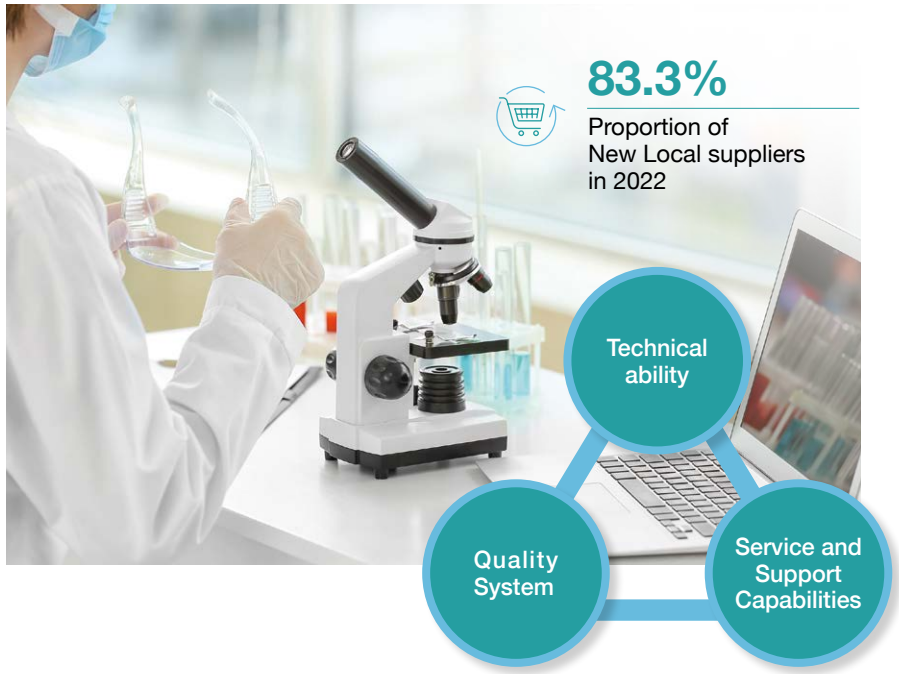
Level 1 Critical Suppliers

Suppliers that must pass GMP certification, are supervised by US quality management processes, and are difficult to replace

6 suppliers

Strategy

- Supplier risk assessment: Suppliers must comply with regulations and GMP requirements, and safety inventory levels will be evaluated as a key KPI
- Evaluation of 5 key points: Ensuring supply continuity, regulatory compliance, quality requirements, delivery time, and cost price



3 Key Indicators for Evaluating New Suppliers/Contractors

Screening and Evaluation of New Suppliers/Contractors

GRI 308-1 / 308-2 / 414-1 / 414-2

In the screening and evaluation of new suppliers/contractors by PharmaEssentia, there are three main indicators: quality system, technical capability, and service and support capability, covering aspects such as quality, cost, delivery, service, and management. The evaluation is carried out in accordance with the Procurement Management Standard Operating Procedures and the Supplier Management Operation Procedure Manual before transactions take place by the User department, Quality Assurance department, and Procurement department. The company attaches great importance to the impact of the supply chain on the environment and society. Currently, it plans to evaluate and introduce environmental and social standards into the supplier screening mechanism in the third quarter of 2023 and regularly conduct supplier performance assessments. In 2022, a total of 12 new suppliers/contractors were added, of which 10 were local suppliers, accounting for 83.3% of the total.

Annual Assessment of Suppliers/Contractors

100%
Completion of supplier internal assessments for 4 consecutive years

175
Suppliers/contractors completed internal assessments and reviews

72%
on-site audit rate

47
Suppliers/contractors conducted on-site audits

Each year, we conduct supplier/contractor assessments in accordance with our Supplier Audit Procedures, which includes both internal assessments and on-site audits. In the case of high-risk suppliers, we will shorten the reassessment frequency and take corrective action. If there are significant deficiencies, we will immediately cease procurement activities. In 2022, all 175 suppliers who were due for internal assessment had their assessments completed. Due to the impact of the COVID-19 pandemic, on-site audits were unable to be completed for 18 suppliers. One local supplier and two foreign suppliers had completed on-site audits by the end of February 2023, and they passed all items in the audit checklist. The remaining suppliers have scheduled their audits for 2023. We will evaluate whether to use alternative solutions, such as the Rx-360 audit report, to replace on-site audits to ensure the completion of our supply chain management even during the pandemic.

Assessment List of Suppliers/Contractors for PharmaEssentia and Panco Healthcare in 2022

	Internal assessment review (Note1)		On-site audit	
	Number of suppliers/contract		Number of suppliers/contract	
Value chain stages	to be assessed	actually assessed	to be audited on-site	actually audited on-site
New Drug Development	65	65	41	41
Clinical Trials	0	0	0	0
Production Manufacturing	126	126	24	6
Pharmaceutical Application	0	0	0	0
Marketing and Sales	5	5	0	0
Total (Note2)	175	175	65	47

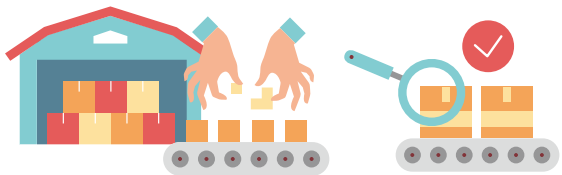
Note 1: The suppliers assessed are those who have transactions from July 1, 2021 to June 30, 2022. If the internal assessment reaches grades A and B in the previous year, it will be exempted from assessment in the current year.
Note 2: There are 21 manufacturers that span both the new drug development and production manufacturing stages. Therefore, the total number is deducted to avoid double counting.
Note 3: For the suppliers in the production manufacturing stage, due to the impact of the epidemic, 2 are local suppliers and 16 are foreign suppliers who have not yet completed on-site audits in 2022.

Safe and Stable Cross-Border Logistics and Transportation

Inventory transportation and sales operation system

We have established the Storage and Distribution Policy and established storage and transportation procedures to ensure that all raw materials, intermediate products and products can be stored and managed well. We have also established a Product Distribution Management Procedure Manual to establish a distribution procedure and tracking mechanism that meets the PIC/S Good Distribution Practice (GDP) requirements. We have established an Import and Export and Transportation Management Procedure Manual to establish import/export and transportation procedures to ensure that all transported goods are delivered to the designated destination in accordance with regulations, quickly and safely, and to maintain the safety of the medication. In response to the immediate risk of climate change-induced disasters in the United States, we maintain a safe level of stock of more than 4 months in the United States to ensure that patients there can obtain their medication in a timely manner.

Panco Healthcare Logistics Center also complies with Taiwan's Good Distribution Practice (GDP) for pharmaceuticals, and assists in the supply of the group's listed products and clinical drugs. From logistics management, warehouse management, processing and labeling to quality management in various operational processes, we have established an Emergency Response Handling Procedure to prevent or reduce the negative impact of natural disasters on our transportation processes.



Warehouse Management

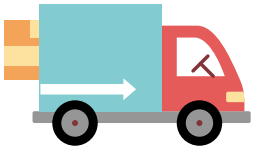
We have established the Standard Operating Procedure for Product Storage Management and the Storage and Distribution Policy to ensure that the quality of products is not affected by any activity or location. Panco Healthcare's Logistics Center has also established the Temperature Verification Plan for Storage Areas, and conducts temperature verification twice every three years to ensure the quality of the storage environment.

Product receiving and storage process

Receiving Application	Physical Verification	Compliance Confirmation	Confirmation of Receipt	Drug Storage
Submit the "Product Receiving Application Form" to the warehouse management personnel for product storage.	Warehouse management personnel, together with quality assurance personnel, confirm and perform physical verification based on the information in the application form.	The product name, code, batch number, required temperature, quantity, and container information on the product label must match the information in the application form.	Confirm that the product is properly sealed and packaged, and store it in the appropriate location according to the storage conditions.	Monitor the storage environment during storage to ensure optimal drug storage.

Quality monitoring of shipping and transportation

We have a Product Shipping Operations Standard to ensure that products from the Taichung Plant are shipped to contract manufacturing plants and storage facilities through a comprehensive transportation procedure before shipment to ensure the effectiveness of transportation. Medicines are transported in designated temperatures, ensuring the safety of our products as they are being transported worldwide.



Quality monitoring

Packing operation

- Check the cleanliness and temperature of the transport box, and place a temperature recorder inside the box for temperature monitoring
- Taking Ropeginterferon alfa-2b (P1101) as an example, it is necessary to ensure that the product is stored between 2°C and 8°C.

Transportation process

- Establish appropriate storage and transportation procedures based on the "Storage and Transportation Policy" as the quality objective.
- Pre-scenario analysis: Confirm that the cold storage status and equipment specifications meet the requirements.
- Regular verification: Ensure that raw materials, intermediate products, and products can be stored properly.