3.3 Pharmaceutical Quality Management

2024 Important Performance

- The manufacturing site passed the API GMP and finished product GMP and GDP inspections by the Taiwan Food and Drug Administration.
- Oneness Biotech passed the Medical Devices Quality Management Systems (QMS) from the Ministry of Health and Welfare.
- No major violation of laws or regulations regarding medicinal products between 2020 and 2024.
- No product quality-related events that are required to be reported between 2020 and 2024.

Quality Policy

Continuous Quality Improvement for Excellence

- Put emphasis on talent cultivation, information analysis of new drug research and development and technological innovation.
- Focus on meeting customers' ongoing needs while conforming to all appropriate technical standards, regulatory requirements, and customer quality expectations. Commitment to product quality, safety and efficacy is the cornerstone of Oneness Biotech, and the staff comply with the most appropriate regulations and standards to implement international good practice.
- Quality is the responsibility of every employee in Oneness Biotech. From product research and development, regulatory inspection, material preparation, manufacture (including packaging), laboratory testing, product release, to supply chain management on the market side, Oneness Biotech takes the responsibility for checking every link. Oneness Biotech strengthens product quality through systematic methods and standardized procedures to comply with regulatory requirements in various markets. Use well-defined, standardized and documented operating procedures to scientifically manage the daily work system. Through the effective operation of the quality management system, including the process of continuous improvement in the system and the guarantee of compliance with the requirements of customers and applicable laws and regulations, Oneness Biotech ensures that the Company's products can meet the requirements of customers and applicable standards and regulations.

Quality Management Objectives

- The management representative plans and determines the quality objectives that can be quantified and meet the regulations and product requirements before the annual management review meeting.
- To implement quality management system and obtain third-party certification, including ISO 9001 for quality management system and ISO 13485 for medical device quality management system.
- To apply a risk-based approach to control the appropriate processes required by the quality management system and strengthen product quality through systematic methods and standardized steps to meet the regulatory requirements of various markets and customer expectations.

Quality Management Structure and Responsibilities

Management Commitment

- Through the implementation and operation of the quality management system, as well as various training programs and awareness programs, the Company aims to cultivate quality awareness among relevant personnel and enhance their understanding of the importance of meeting customer requirements and applicable regulatory obligations.
- The Company establishes the quality policy and quality objectives as the organization's overall intentions and direction related to quality, and as indicators for measuring the effectiveness of the quality management system.
- Management reviews of the quality management system are conducted to ensure the continuing suitability, adequacy, and effectiveness.
- The Company also ensures the effective management and allocation of resources.

The Company has established a Quality Assurance Center to coordinate the management and supervision of product quality and safety, to ensure that all products comply with applicable laws, regulations, and quality standards. The Quality Assurance Section (QA) and Quality Control Section (QC) within the QA Center have clearly defined responsibilities and work in a complementary manner, to enhance overall product quality and ensure production compliance.

QA Center Supervisor

- Ensure the implementation and maintenance of quality-related systems.
- Lead product quality-related risk assessments.
- Ensure that personnel have completed the required training and are assigned according to operational needs.

Quality Assurance Section (QA)

- Responsible for the establishment and maintenance of the quality management system, including internal audits, document management, change control, supplier review, and compliance assessment, in order to ensure that the production process and final products comply with GMP and other international standards.
- Responsible for investigating deviations or abnormal events, assessment of risks, and implementation of continuous improvement measures, to enhance overall quality management performance.

Quality Control Section (QC)

- Responsible for the quality inspection of raw materials, processes, and finished products through rigorous analysis and testing, to ensure that products meet the specified requirements for each production stage.
- Utilize advanced instruments for physical and chemical testing, microorganism testing, and stability testing, and continuously optimize testing technologies, to improve the accuracy and efficiency of quality inspection.

Note: Only the key tasks are summarized, and not all details are provided.

Through close collaboration between the QA Section and QC Section, the QA Center can systematically monitor quality risks, to ensure product safety and effectiveness, and to continuously improve quality management, thereby enhancing corporate competitiveness and customer trust.

Quality Education and Training

Professional training

In addition to key personnel being required to receive training from external organizations and obtain the required credits/certifications according to the regulatory requirements, all personnel must also complete education and training related to their respective positions and pass the corresponding exams before they are allowed to independently perform their assigned tasks.

General knowledge training

The Nanchou Plant has organized a series of courses on the "Pharmaceutical Good Manufacturing Practice (PIC/S GMP) Regulations," "Good Distribution Practice (GDP) Regulations," and the quality management system. All personnel at the Nanchou Plant are required to participate in the training and to pass an examination, to ensure that all colleagues of the Nanchou Plant possess and apply quality-related professional knowledge.

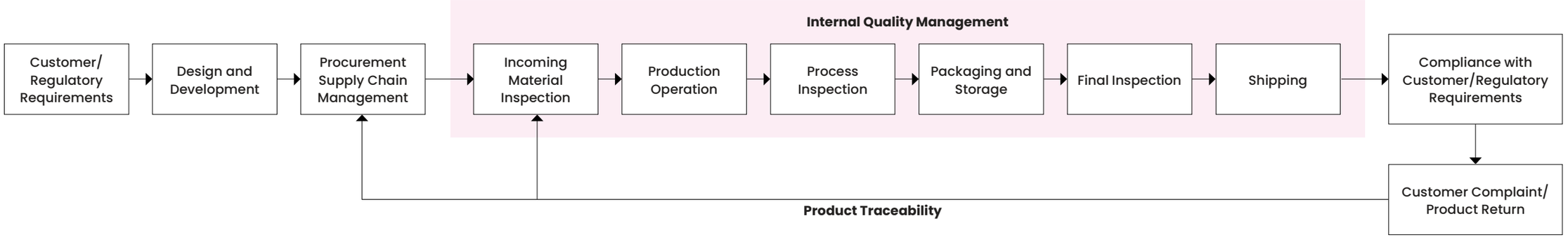
All training shall be evaluated through the examination methods of a written exam, an oral exam, and hands-on practical exam, and it is required that the score of evaluation shall be 90 points or above.

Implementation and Specific Actions of Quality Management

The Company has established a comprehensive quality management system (QMS) in accordance with international standards such as PIC/S GMP, ISO 9001, and ISO 13485. This system ensures that every stage of operations—from the receipt and inspection of active pharmaceutical ingredients (APIs), through manufacturing, finished product testing, and storage, to distribution—meets the highest standards of quality and safety.

By integrating PIC/S GMP, ISO 9001, and ISO 13485, the Company has established a rigorous and internationally competitive quality management system that ensures products comply with regulatory requirements and meet customer needs, thereby enhancing the Company's reputation and market competitiveness.

Good Manufacturing Practice PIC/S GMP	• Internationally recognized pharmaceutical production standards that regulate the entire process from raw material procurement, manufacturing, and quality control through to product release, to ensure product safety, consistency, and compliance with laws and regulations. • The Company strictly complies with the GMP standards and implements a risk management mechanism, to ensure a controlled production environment, and to reduce quality risks through internal audits and continuous improvement.
Quality Management System International Standards ISO 9001, ISO 13485	• Such standards provide a comprehensive quality management framework, and emphasize customer orientation, process management, and continuous improvement. • The Company has established a standard quality management process through the implementation of ISO 9001 and ISO 13485, to enhance the operational efficiency and ensure collaboration of all departments in terms of quality management.



Quality Safety Risk Assessment and Management Measures

The Company has established a quality risk assessment and management mechanism in accordance with the ICH Q9 (Pharmaceutical Quality Risk Management) principles. The SME team, consisting of R&D experts, technology transfer personnel, process engineers, engineering staff, QA, QC, and other specialists, applies scientific methodologies to identify, assess, and control risks that may affect product quality and safety, ensuring that products comply with PIC/S GMP, ISO 9001, ISO 13485, and other relevant regulatory requirements.

The quality risk assessment is conducted mainly based on the following steps:

- **Risk Identification:** Identify potential risk factors that may affect quality within the scope of raw materials, final products, support systems, manufacturing processes, equipment, and machinery, including personnel, machines, raw materials, methods, and environment.
- **Risk Analysis:** Evaluate the probability of occurrence, potential impact, and detectability of risks, and determine the overall risk level using qualitative and/or quantitative methods.
- **Risk Assessment:** Conduct a comprehensive analysis of the severity and acceptability of risks to determine whether further control measures are necessary.

If the assessed quality risks exceed the acceptable level, appropriate control measures are implemented to reduce the severity and likelihood of occurrence, and to improve the detectability of hazards and quality risks. Internal audits are conducted periodically, and the Company cooperates with reviews conducted by competent authorities and third-party organizations to ensure the quality management system continues to meet international standards.

Production Environment Quality Control

Our facilities are designed and managed in accordance with the most rigorous PIC/S GMP standards and standard operating procedures (SOPs), to produce safe, specification-compliant pharmaceuticals and medical devices. Each stage of the manufacturing process is automatically controlled to ensure operational consistency at every step and the stability of the final products.

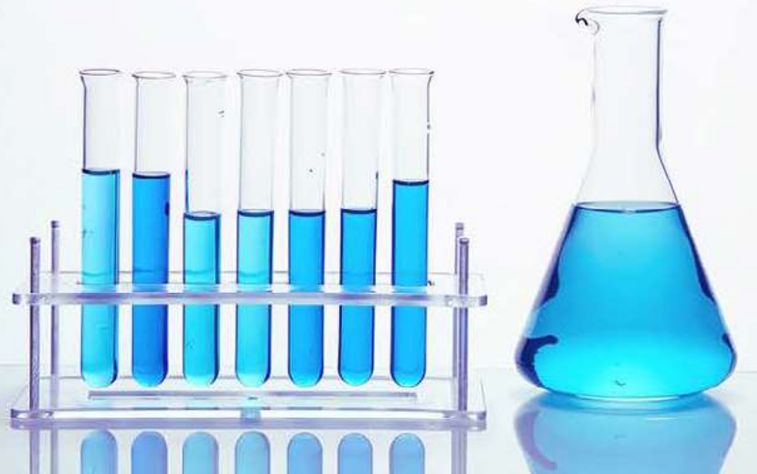
- The manufacturing area is implemented with the controls for preventing cross-contamination of active substances, and separate flows for personnel and logistics are also adopted
- The temperature, moisture, suspended particles, and pressure difference in the entire manufacturing area are strictly controlled to meet regulatory requirements, to prevent the risk of cross-contamination
- Nitrogen is used to replace and reduce the amount of oxygen in the equipment, to prevent static electricity or an overly high level of organic vapor from causing personal or property damage
- Organic solvent and oxygen content detectors are installed in the manufacturing process area for 24-hour monitoring
- The air conditioners of the grade-D clean room are provided with 99.97% HEPA filters, and the return air system is mounted with non-woven filters, and all filters are replaced periodically
- A mobile monitoring alert system has been set up to notify responsible personnel of abnormal occurrences via mobile phone text messages

Product Inspection and Release

The Company has established a QA Laboratory at the Nanchou Plant, responsible for quality inspection of raw materials, semi-finished products, and final products to ensure product quality complies with PIC/S GMP standards. All testing operations are performed in accordance with standard operating procedures (SOPs). Strict procedural controls ensure the accuracy, reproducibility, and scientific validity of testing methods.

The laboratory's analytical instruments are regularly calibrated, and performance verification is conducted according to a predefined schedule to ensure the validity and reliability of testing data. Each batch of products requires review and approval by the supervisor of the QA Center before release, implementing a multi-layered quality control mechanism that ensures product safety and compliance. This rigorous quality control ensures customers receive trustworthy pharmaceuticals and medical devices. Furthermore, the laboratory is accredited with TAF ISO/IEC 17025 certification and possesses the technical competence to conduct testing for heavy metals, pesticide residues, and microorganisms, verifying that testing quality meets international standards.

- **Incoming material inspection:** Inspection of raw materials, auxiliary materials, and packaging materials to ensure compliance with specifications and requirements
- **Semi-product inspection:** During the production process, key process stages are inspected (IPC) to ensure that product stability and consistency are maintained throughout the manufacturing process, and manufacturing parameters are adjusted timely
- **Final product inspection:** Final inspection is conducted before product shipment, including physical and chemical analysis, microbiological testing, and stability testing, etc., to ensure that product quality meets standards.



Product Storage and Transportation

The Supplies Section conducts receiving inspections upon unloading incoming goods. The inspection includes checking the logistics vehicle environment, verifying supplier qualification, verifying quantities, and inspecting the appearance of goods. Raw materials, supplies, and finished products are stored in the quarantine area or on designated inspection shelves (for dry materials and finished products) pending inspection. Items approved by QC inspection are labeled for conformity by QA personnel on their external packaging, and then transferred by Supplies Section personnel to the approved goods storage area in the warehouse.

Product transportation is entrusted to logistics companies compliant with GDP regulations. Transportation covers Taiwan's main island, remote areas, and outlying islands, with deliveries to the outlying islands handled by Kerry Pharma Logistics through subcontractors.

Drug Traceability and Recall

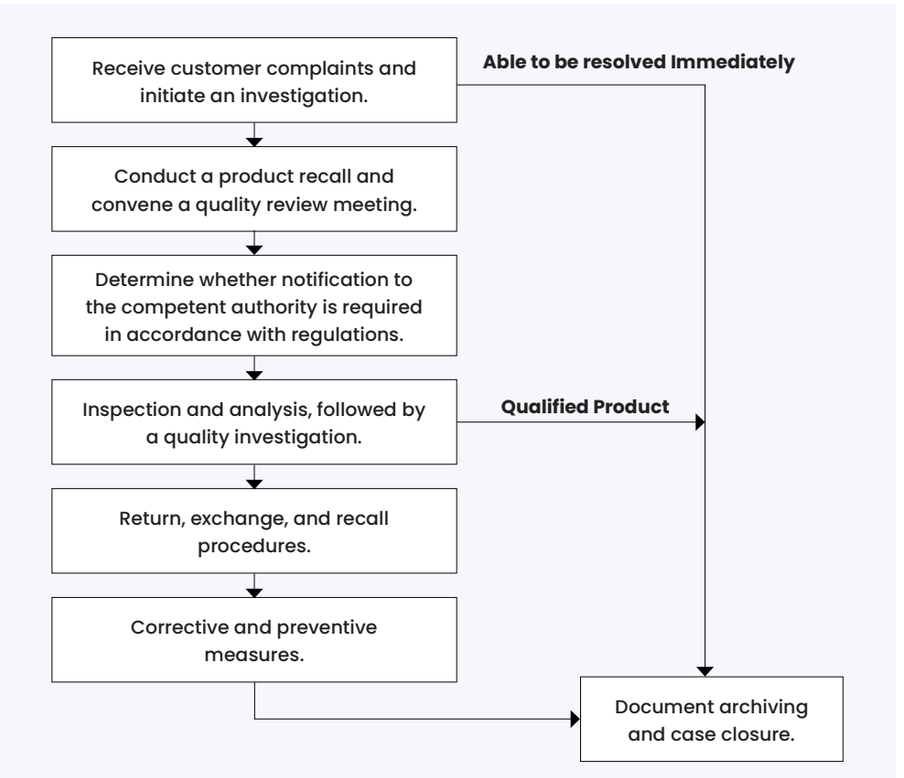
An effective drug traceability system helps ensure and safeguard patient medication safety. Each batch of products is assigned a batch number or product serial number, and records of receiving inspection, production, and quality control are maintained. In the event of a quality issue, the production and inspection history of the product can be traced using these records. These records provide essential information for customer complaint investigation and handling, as well as the development of corrective and preventive actions (CAPA).

Customer Complaint Handling

An effective drug traceability mechanism helps ensure and enhance patients' medication safety. Each batch of products is given a batch number or product serial number, and the corresponding records of receiving inspection (of components closely related to safety), production, and examination shall be preserved. In case of any quality issue, the production and inspection status of the product in question at that time can be traced through the corresponding records. These records also serve as reference information for use in customer complaint investigations and handling and in the formulation of corrective or preventive measures.

If a customer has a doubt about drug quality, and therefore complains, a cause analysis and liability identification shall be performed according to the corresponding reference sample in the Factory, in order to determine whether the customer complaint in question is a quality-related complaint or a non-quality-related complaint. If it is a quality-related customer complaint, a comprehensive investigation must be carried out, and corrective/preventive measures taken, in order to close the case.

If a suspected counterfeit or prohibited drug is identified, logistics providers and the Company's QA personnel must be notified within 24 hours. Sales and distribution of the suspected batch shall be halted immediately. The batch stock shall be quarantined and physically isolated to prevent unintended use. QA personnel will initiate a deviation or complaint investigation, verify packaging identification, and sample the stock for comprehensive chemical analysis at the laboratory to determine authenticity. If confirmed as counterfeit or prohibited, a drug recall shall be initiated immediately.



Recall Operation

The QA Center is responsible for drafting the drug recall plan. Once the highest-level responsible executives decide to approve the plan, the related sales unit shall work with the logistic companies to check the sale of the batch of products in question, communicate with the customer in regard to the recall of that batch of products, and manage the recalled products and the related sales and distribution documents. After the recall operation, relevant reports are then completed and submitted to the competent authority. During the recall operation, the QA personnel shall supervise and follow all the activities for the drug recall to be completed by the specified time limit. No product recalls occurred during the 2021–2024 reporting period.

Emergency Response Simulation

If no recall operation has taken place in the entire year, the Quality Assurance Center shall initiate at least one simulation audit and prepare the corresponding simulation audit plan to link the operations of the related departments of the Company to the market-end operations according to the plan.