Issue 2. Ensuring Pharmaceutical Safety

The safe management of medicine lies at the heart of national safety and health care and is the first step of Hanmi Pharm's sustainable management. We, as an R&D-centered pharmaceutical company, are leading the growth of the Korean pharmaceutical industry throughout the product lifecycle from the development of medicines to clinical trials and production and distribution. With our management principles of "Respect for Humanity" and "Value Creation" as our main goals, we are operating an advanced quality control system to continuously supply quality-certified finished drugs to the market. Also, because our products are directly related to life and death, we must deliver accurate information to healthcare workers. We make concerted efforts to deliver evidence-based information accurately and appropriately, while taking extra precautions so as not to exaggerate or distort any information.

Key Achievements in 2024

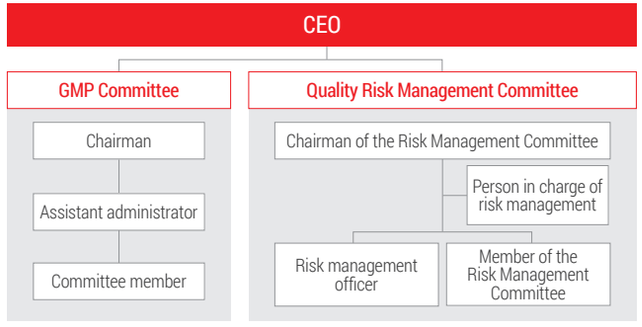
Inspection by customers/regulatory authorities

8 cases

I. Governance

Decision-making Structure

Hanmi Pharm consistently manufactures and manages all pharmaceuticals to enhance product quality and maintain a high level of Good Manufacturing Practice (GMP). To ensure proper guidance and oversight of GMP operations, we establish and operate GMP committees at each production facility. We also convene and operate quality risk management committees at necessary production sites to manage overall quality risks.



Pharmaceutical Safety Assurance Committee

Type	Time	Roles
GMP Committee	At least once per month or once per quarter	Supervising/guiding work related to GMP operations to maintain high GMP standards.
Quality Risk Management Committee	Periodic	Operating procedures designed to enable effective and consistent risk-based decision-making regarding pharmaceutical quality.

Roles of the Dedicated Organization

Type		Roles/Authority
CEO		Overall control over pharmaceutical safety assurance.
GMP Committee	Chairman	Chairman of the GMP Committee: Exercising overall control over business.
	Assistant administrator	Assisting the chairman and reporting to the top management on important matters.
	Committee member	Managers of each field and experts in each field: Making decisions on issues related to GMP.
Quality Risk Management Committee	Chairman of the Risk Management Committee	Overall responsibility for risk management; reporting to the corporate manager.
	Risk management officer	Convening the Risk Analysis Committee; compiling risk management data; taking responsibility for ensuring the adequacy of procedures.
	Risk management committee member	Selecting risk management tools and conducting analysis; proposing and evaluating measures for reducing potential risk factors; reviewing procedures for monitoring and reducing potential risk factors.
	Person in charge of risk management	Coordinating meetings of the Risk Analysis Committee meetings and managing documents, etc.

Training to Maintain Expertise in Pharmaceutical Safety Assurance

Hanmi Pharm consistently maintains our manufacturing managers' expertise and qualifications for pharmaceutical safety assurance by having them complete such training programs as are required by regulatory authorities.

Type	Target	Hours	Training content
Training for Manufacturing Managers	Managers Overseeing Manufacturing at Manufacturing Plants	16 hours/2 years	Manufacturing/quality control standards, latest technologies by field, and other related regulations such as the Pharmaceutical Affairs Act.

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Identifying Risks and Opportunities

Hanmi Pharm identifies key risks and opportunities that could have a significant impact on our stakeholders and sustainability in pharmaceutical safety assurance based on the IRO (Impacts, Risks, and Opportunities) analysis conducted by internal and external experts, and strives continuously to develop effective response strategies based on the findings.

RISK

Production Stoppage and Administrative Actions Taken due to Quality Risks

Characteristics of impact	Actual impact
Affected stakeholders	Customers
Severity of impact on society/environment	Scale ■■■■■ Scope ■■■■■ Recoverability ■■□□□
Expected financial impact	Possibility of occurrence ■■■□□ Scale ■■■■■
Impact on corporation	Pharmaceutical safety is a core value of the pharmaceutical industry and a social responsibility. Inadequate responses can lead to severe consequences for the sustainability of pharmaceutical companies.
Corporation's response	- Compliance with global manufacturing and quality control standards (GMP) and establishment of a quality management system in accordance with these standards. - Systematic quality assurance system. - Advanced quality management system.

OPPORTUNITY

Strengthening Pharmaceutical Safety based on Drug Monitoring Systems

Characteristics of impact	Potential impacts
Affected stakeholders	Employees
Severity of impact on society/environment	Scale ■■■■■ Scope ■■■■■
Expected financial impact	Possibility of occurrence ■■■■■ Scale ■■□□□
Impact on corporation	Pharmaceutical safety is ensured by detecting, evaluating, interpreting, and preventing safety-related issues throughout the entire pharmaceutical life cycle based on the pharmacovigilance system.

- Transparent disclosure of recalls and administrative actions.
- Voluntary recall (recall by business operator) in the event of risk detection.

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Compliance with International Good Manufacturing Practices (GMP)

5 Main Quality Policies for High Product Quality

To supply medicines with proven efficacy, safety, and quality, Hanmi Pharm has established and maintains a quality management system that satisfies the cGMP requirements, relevant laws, and conditions required by the regulatory authorities and ISO standards throughout the entire process of medicine production. In addition, based on know-how obtained from undergoing audits and cooperating with numerous domestic/foreign regulatory authorities and partners for many years, our quality management system is capable of satisfying not only domestic requirements but also the requirements of the Global Standard Quality System (US FDA's "six system" / EMA). To take a leap toward becoming a top-rank global pharmaceutical company based on production and distribution technologies at the global level and high-quality systems, we are doing our best based on these five virtues.

High Quality	Guarantee that medicines are manufactured, managed, and supplied according to an advanced, high level quality system.
Compliance	Systems and procedures are operated in compliance with the GMP regulations and guidelines distributed by international regulatory agencies.
Integrity	The accuracy and integrity of data generated from the manufacturing and management of medicines is guaranteed.
Innovation	Encouragement and support are provided to ensure constant innovation throughout the GMP area.
Partnership	Amicable partnerships are maintained with domestic/overseas partners to expand business areas.

Our Quality System

Under the management goal of providing safe and reliable medicines to our customers, Hanmi Pharm manages all finished drugs produced, stored and manufactured from the development stage to the warehousing of related raw materials, testing, shipping, manufacturing of semi-finished products/finished products, IPC (In-Process Control), product testing, labeling and packaging, storage, shipping, and distribution within our quality system. We manage the entire life cycle of distributed medicines strictly and thoroughly by continuously monitoring them for safety and effectiveness even after their distribution.

Manufacturing Preparation	Medicine Manufacturing	Quality Assurance	Storage Management & Distribution
· Warehouse all raw materials. · Test and check the quality of raw materials. · Prepare systems and procedures for manufacturing.	· Manufacturing and packaging. · Manage and monitor quality through intermediate process testing.	· Test products. · Check quality and approve shipping. · Monitor quality through product quality assessment.	· Manage the storage and distribution of products through the automation system.

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Compliance with International Good Manufacturing Practices (GMP)

Performance and Development Plan for Quality Management System

Hanmi Pharm's quality management system includes each element of a quality system and the responsibilities of top management, and requires the efficacy and safety of medicines, achievement and maintenance of the required quality control level, and continuous improvements. Accordingly, we have set our quality target based on the management objective and periodically report performance to top management via the board of directors. To continuously supply high-quality medicines, top management reviews and supports essential facility investments, employee recruitment, improvements to software, and the introduction of computing systems. By doing so, we are doing our best to maintain the production and supply of high-quality medicines. To guarantee the integrity of data generated from the efficient operation of the quality system, development, manufacturing, and quality control of medicines, we have introduced computing systems in various areas, such as ERP (Enterprise Resource Planning), EDMS (Electronic Document Management System), MES (Manufacturing Execution System), LIMS (Laboratory Information Management System), etc.

Additionally, we appoint data Integrity experts for each business division to ensure the integrity of data generated throughout the entire pharmaceutical manufacturing process, track related issues, and take prompt and timely actions to address areas that require improvement. We conduct regular risk assessments of each GMP area to enhance data integrity levels and, based on these evaluations, continue to advance our quality management system.

History of Regulatory Authorities and Partner Audits

Hanmi Pharm has been certified for the effectiveness and compliance of our quality management system in inspections conducted by regulatory authorities such as the MFDS (Korea), US FDA (U.S.), EMA (Europe), PMDA (Japan), and MITRF (Russia). We also undergo regular audits by our partners in various countries, thus ensuring that we operate a reliable GMP system. In 2024, we underwent a total of eight inspections by regulatory/certification bodies and partners at home and abroad, including the US FDA and Korea's MFDS. These inspections reaffirmed that we maintain robust manufacturing facilities and a solid quality system.

History of Audits by Major Regulatory Organizations in the Past 5 Years

No.	Period	Country / Regulatory organization	Details
1	Jul. 27- 31, 2020	Korea / MFDS	Korea / MFDS, SGS
2	Dec. 10, 2020	Korea / SGS	ISO 13485 surveillance audit
3	Oct. 18, 2021	Korea / SGS	ISO 13485 surveillance audit
4	Apr. 11-14, 2022	Russia / MITRF	Regular GMP inspection 1) Amlodipine + Losartan Tab. 2) Amlodipine + Losartan + Rosuvastatin Tab.
5	May. 9-13, 2022	Korea / MFDS	Regular GMP inspection (biological drugs)
6	Jun. 27-Jul. 05, 2022	U.S. / USFDA (CDER)	Pharmaceutical PLI audit: Rolvedon (pre-license inspection)
7	Jul.11-15, 2022	Korea / MFDS	Regular GMP inspection
8	Oct. 17-20, 2022	Europe / NSF Health Sciences Limited	QP inspection: HM43239 20mg & 80mg Tab. (EU CT number issued)
9	Sep. 26-28, 2022	Korea / SGS	ISO 13485 renewable audit
10	Apr. 11-14, 2023	Korea / MFDS	CMO suitability assessment inspection
11	Nov. 9, 2023	Korea / SGS	ISO 13485 surveillance audit
12	Jul. 25-Aug. 2, 2024	U.S. / USFDA	Regular inspection of the pharmaceutical manufactory (surveillance inspection)
13	Aug. 19-22, 2024	Europe / NSF	Regular EU qualified person audit
14	Sep. 10-12, 2024	Korea / MFDS	Pre-GMP inspection (Pyeongtaek Solid Pharmaceuticals Part)
15	Nov. 11-12, 2024	Korea / SGS	ISO 13485 surveillance audit

Status of Partner Company Due Diligence Inspection in 2024

No.	Period	Partner	Description
1	Apr. 24-25, 2024	Silanes	New audit of Mexican partner
2	Oct. 15-17, 2024	MSD	Regular MSD partner audit
3	Oct. 21-23, 2024	Parexel	Regular EU qualified person audit
4	Dec. 3-4, 2024	Assertio	Regular Assertio partner audit

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Systematic Quality Assurance System

Establishing a Quality Assurance System based on Risk Management

Hanmi Pharm applies risk management procedures across our entire product lifecycle, implementing a risk-based approach to GMP areas where necessary. Regarding pharmaceutical quality, we make effective and consistent decisions based on the results of risk assessments in order to prevent foreseeable risks. If risks must be accepted, appropriate measures are taken to minimize their impact.

Education and Training

Hanmi Pharm manages GMP training through our LMS (Learning Management System), an electronic education management system. All employees working at our business sites are only assigned duties after completing the appropriate training for each job, including on-the-job training. By periodically conducting basic training related to GMP, the system is operated so that employees can recognize the importance of the major concepts of the quality system and the quality control of medicines. Furthermore, we support employees in their efforts to complete external training operated by pharmaceutical organizations, universities, the Ministry of Food and Drug Safety, and overseas regulatory organizations according to the required subjects, in addition to in-house training. By conducting knowledge delivery training for required personnel, when necessary, we operate appropriate secondary training.

Classification	2022	2023	2024
Total no. of GMP training	5,987	6,777	7,482

Inspection for Pharmaceutical Safety

The Quality Assurance Department of Hanmi Pharm voluntarily inspects the entire manufacturing and quality control process, as well as the integrity of all data generated during these processes and voluntarily improves any deficiencies to ensure the supply of high-quality pharmaceuticals to patients.

Self- inspection	Hanmi Pharm conducts at least one inspection per year across all departments involved in pharmaceutical manufacturing and quality control activities. If factors that pose risks to manufacturing and quality control are identified, they are addressed through CAPA (Corrective and Preventive Actions).
Site inspection by quality department	On-site inspections are carried out separately from self-inspections. The Quality Department strengthens the inspection procedures across four key areas—manufacturing, quality, manufacturing infrastructure, and support centers—to proactively prevent potential issues and rigorously manage the overall operational status.
Review clinical trial data	The relevant department conducts a primary inspection of the clinical data generated during manufacturing and testing, including audit trails, for each batch. Additionally, dedicated personnel regularly review the data to ensure compliance with the related procedures and maintain data integrity.

Genotoxic Impurity Management

Hanmi Pharm has established and operates procedures that enable a swift and immediate response upon receiving official safety information and action directives from foreign authorities and the Korean Ministry of Food and Drug Safety (MFDS) regarding genotoxic impurities.

We identify affected products and all batches currently on the market, develop analytical methods of detecting impurities, and promptly assess impurity levels in distributed batches. For previously manufactured batches that exceed the regulatory limits, we take such actions as a suspension of sales or product recall based on the results of an MFDS review. For future production, various strategies are being explored to reduce genotoxic impurities, and quality testing is conducted at the time of batch release to ensure that only safe pharmaceuticals are delivered to patients.

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Enhanced Quality Control Systems

Hanmi Pharm's quality control group collects and analyzes samples of the raw materials used in manufacturing medicines, semi-finished products and final products in order to maintain the safety, stability, and overall quality of raw materials/final drugs manufactured and distributed, and assesses the overall development stage, including shipping and stability testing of medicines manufactured according to the product characteristic analysis required by the relevant authorities, the verified analysis method, and the approved specifications.

Quality Control Test

Hanmi Pharm conducts tests of all raw materials related to the manufactured medicines, IPC, medicine shipment tests, and stability tests to guarantee that the quality of all medicines due to be distributed is maintained throughout the product lifespan. In addition, the development and transfer of test methods is possible according to ICH Q2 (R1) guidelines. We also conduct the test method verifications required by domestic and overseas regulatory agencies. We have established a management system so that only finished drugs, whose quality is confirmed by shipment tests, are shipped and distributed, while the employees responsible for performing quality control are subject to periodic verification of their qualifications through job training and evaluation.

Physico-chemical Test
Property, moisture, pH, osmotic pressure check

Microbial Test
Sterility test, microbial limit test, bacterial identification, endotoxin, nonsoluble particles

Device Analysis
HPLC, UPLC, GC, GC-MS, FT-IR, UV, TOC

Stability Program

Hanmi Pharm guarantees that the quality of our medicines will be stable for the duration of their lifespan. Generally, we operate a stability room/chamber under long-term and acceleration conditions according to the product storage conditions, and we have prepared a facility in which stability tests can be conducted according to other specific requirements in order to collect physical/mechanical stability data on our medicines. The progressive stability data are monitored in real time, and if significant changes or non-conforming issues are detected in the quality of the medicine, the necessary corrective measures are taken immediately based on an impact assessment according to the related procedures, and the matter is reported to the relevant regulatory organizations.

Environment & Clean Utility Monitoring

Hanmi Pharm designs all the areas in which our medicines are manufactured, packaged, and stored to ensure that they are suitable for work, maintenance, and location. The walls are made of clean panels to facilitate cleaning and maintenance, while floor surfaces are coated with epoxy to prevent contamination in the manufacturing environment and facilitate cleaning. Furthermore, environmental monitoring is carried out by classifying areas by cleanliness. Samples of the water used for manufacturing or injection, and compressed air are periodically tested for quality. Tests are conducted for each cleanliness grade on falling bacteria, airborne bacteria, surface bacteria, and airborne particles when performing environmental monitoring. As regards the monitoring of water, we test its properties, total organic carbon content, electrical conductivity, nitrate content, pH value, and endotoxin content. All air compressors are oil-free compressors that supply air after passing compressed air through a 0.2 μm filter.

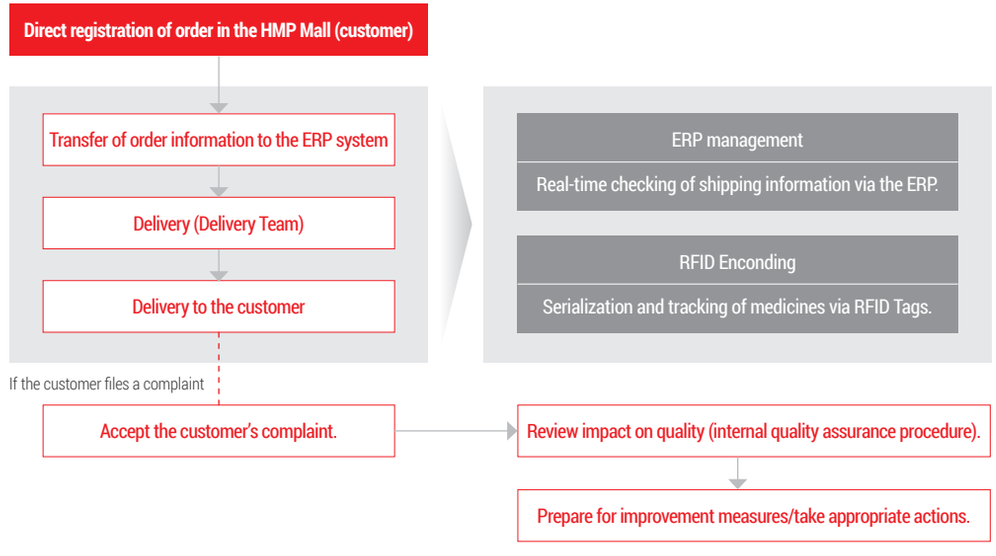
System for Ongoing Monitoring throughout the Lifecycle of Shipped Medicines

Medicine Theft and Counterfeit Monitoring System

Hanmi Pharm has established a system for preventing counterfeit medicines and managing safety from the manufacturing stage to the final distribution stage of finished drugs by using an ERP (Enterprise Resource Planning) system and our unique recognition device, RFID (Radio-Frequency Identification) Tags. If the head office sales representative enters the order information from a customer in the ERP system, the relevant information is automatically sent to the Delivery Team via the system, and the shipping information of the ordered product can be checked in real time.

All finished drugs manufactured and shipped from Hanmi Pharm support serialization using RFID Tags and tracking technology, which serve to strengthen supply chain security. We have established and are managing a system suitable for the distribution and management policy of the related countries to which our products are exported, including Korea. Detailed information (date of manufacture, batch number, date of shipment, customer information) on all finished drugs that are shipped and distributed is recorded in the in-company system, which makes it easy to track and take countermeasures promptly in the event of a report of counterfeit medicine.

In addition, upon receiving a customer complaint, we review whether the complaint could have an impact on product quality by promptly investigating the matter according to our internal quality guarantee procedure and then we prepare improvement measures and ensure that they are taken immediately.

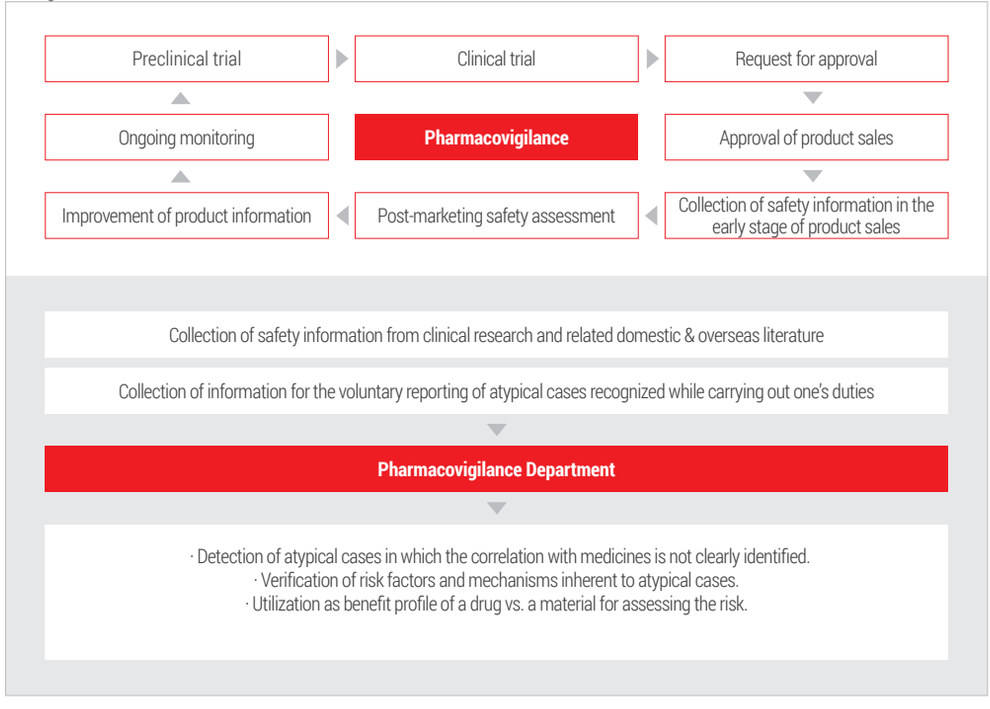


Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Pharmacovigilance System

Pharmacovigilance refers to the scientific activities involved in detecting, assessing, interpreting, and preventing adverse events or safety-related issues associated with pharmaceuticals. Pharmacovigilance activities span the entire pharmaceutical lifecycle, from collecting safety information to managing risks. In Korea, various measures such as the drug re-evaluation system, voluntary adverse event reporting system, risk management plan system, appropriate drug use recommendations, and pharmaceutical injury relief fund system have been introduced and strengthened to continuously improve and develop the pharmacovigilance framework. Hanmi Pharm has established and operates our own pharmacovigilance system, contributing to the enhancement of drug safety. We collect, analyze, and evaluate the safety information of our manufactured pharmaceuticals through various channels.



Pharmacovigilance Training

Hanmi Pharm provides all our employees with regular in-house pharmacovigilance training every year. This training emphasizes the necessity and importance of pharmacovigilance while providing guidelines to ensure that all employees are able to promptly report any adverse events they may encounter in their work to the Pharmacovigilance Department. With this training, we will strengthen our company-wide pharmacovigilance system and contribute to the improvement of pharmaceutical safety management.

Type	Unit	2021	2022	2023	2024
No. of target employees	persons	2,325	2,350	2,315	2,476
Training completion rate	%	99.4	99.7	98.9	91.1

Target employees: Includes those who have resigned and those who are on leave.

Issue 2. Ensuring Pharmaceutical Safety

II. Strategy_Risk and Opportunity Response Plan

Customer Health & Safety

Because all the products produced by Hanmi Pharm are directly related to human health and life, we are working hard to secure customer trust by constantly strengthening and monitoring our capability to ensure the safety of our products. We disclose product information transparently so that customers can rest assured when taking our products, and we take the health and safety of our customers into account from the development stage. In addition, we collect and manage customer suggestions related to our products according to the regulations of the Ministry of Food and Drug Safety (MFDS).

Status of Drug Recall Measures

As of Dec. 31, 2024

Type	2022		2023		2024	
	cases	Recall quantity (tons)	cases	Recall quantity (tons)	cases	Recall quantity (tons)
Total	**3**	**9.99**	**3**	**3.97**	**1**	**1.07**
Class Ⅰ	0	0	0	0	0	0
Class Ⅱ	1	9.99	2	2.77	1[1)]	1.07
Class Ⅲ	2		1	1.20	0	0

1) Ferromax Solution

Details of Administrative Measures Imposed in 2024

Product	Description	Measure
Ambrocol Syrup	Failure to thoroughly supervise and manage a subcontracted manufacturer	Fine of KRW 42.3 million imposed

Group Integrated Call Center

Hanmi Pharm set up the Group's integrated call center in 2014 and are doing our best to listen to the voices of our customers. We manage the collected issues and, based on this, eliminate the factors that cause customer inconvenience, with the focus on products for which we frequently receive questions about how they are used. This not only enhances customer convenience but is also a part of our efforts to practice customer satisfaction management.

Classification	2022	2023	2024
No. of customer interactions (cases)	73,181	66,890	62,906

Key Customer Feedback and Actions Taken in 2024

Product	Consumer opinions	Actions
Toramycin Eye Drops	Empty case	Reinforced the gap between equipment and defective boxes that are marked as underweight; and improved procedures for handling defective products.
Maxibupen Syrup	Color fading	Due to the characteristics of colorants derived from natural ingredients, the appearance of this product may lighten over time, but this does not affect product quality. To minimize this phenomenon, the amount of naturally derived, safe pigments has been increased, and the packaging has been improved.
Isotinone Soft Capsules	Empty packing	A perforation function has been applied to the PTP pack when sorting products using the vision system.
Duted Soft Capsules	Empty packing	Due to the inherent characteristics of soft capsules, they tend to stick together. Therefore, to prevent them from being inserted into the pocket while stuck together, the size of the pocket mold has been reduced.

Issue 2. Ensuring Pharmaceutical Safety

III. Risk Management

Hanmi Pharm has integrated the risk and opportunity management process related to pharmaceutical safety assurance into the company-wide Enterprise Risk Management (ERM) system in order to effectively manage corporate risks while maximizing potential opportunities, thereby promoting sustainable growth.

Risk and opportunity monitoring	Monitoring period	Monitoring target	Monitoring method	Management and supervision
Inspection by regulatory authority	Upon request	All approved domestic products, overseas export products	· Maintenance of a high GMP level at all times through a voluntary regular inspection system, such as an internal inspection, quality department on-site inspection, or clinical data inspection. · Reflection/maintenance of the mandatory requirements of each country's regulatory authorities through regular audits of partner companies.	QA Team
Risk assessment	When necessary	When an assessment within the QMS is required	· Risk assessment using the risk management tool suggested by the quality risk management procedure. · Identification of acceptable risks and implementation of actions to reduce such risks.	QA Team
Pharmacovigilance system	Always	Entire pharmaceutical lifecycle	· Hanmi Pharm continuously monitors and analyzes domestic and international academic literature, regulations, and reports on adverse drug events in order to collect the latest safety information. · Hanmi Pharm also identifies and addresses safety concerns by detecting potential adverse events and safety signals at an early stage, and by evaluating them based on the collected data.	PV Team

IV. Indicators and Goals

Indicator	2024 performance	Achievement status	2025 target	Mid-to-long term (2030) plan
Compliance with the global level GMP	· Monitored the number of critical and major issues pointed out during inspections conducted by regulatory authorities and partners.	-	· Reduce the number of identified critical issues to 0, and major issues pointed out to 2 or less.	· Maintain a constant on-site inspection system.
Advances in the quality system	· Selected about 30 quality indicators, including changes, deviations, complaints, and OOS, and managed the target settings.	-	· Select 30 quality indicators and continuously operate goal management.	· Check the operational status of the quality system and identify areas for improvement by continuously monitoring the quality indicators.