Toward an era where Sawai is preferred for its quality and supply capabilities

**The introduction of the Generic Drug Provider Evaluation System focused on quality and supply capabilities is expected to accelerate consolidation in the generic drug industry, a crowded field of approximately 190 companies.
The Sawai Group views this change as an opportunity and aims for sustainable growth through one of the industry's largest-scale supply systems.**

Continued on next page

1 Current situation An industry structure in which multiple companies market products containing the same active ingredient

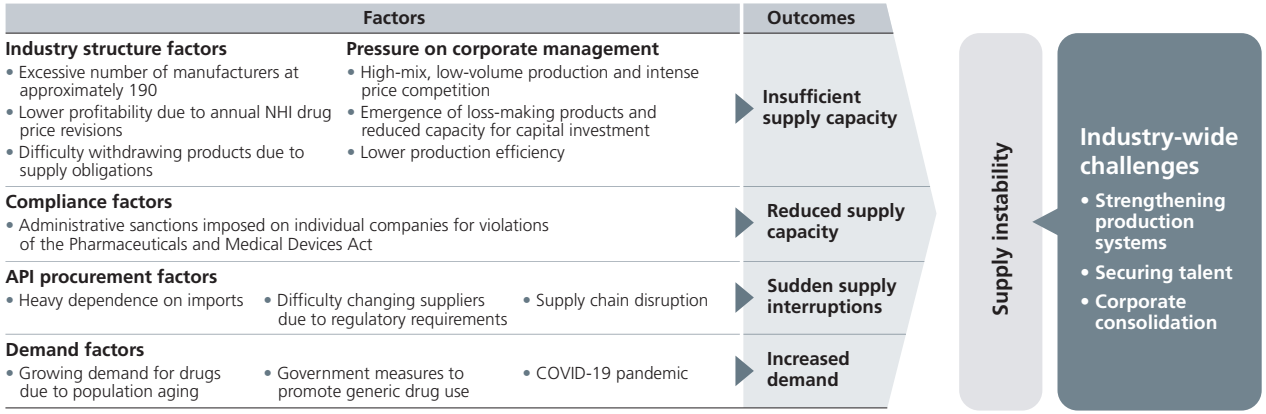
Supported by government measures to promote their use under the 2004 Basic Policy on Economic and Fiscal Management and Reform, generic drugs in Japan increased their volume share from just over 16% in 2004 to approximately 90% in 2025, becoming essential infrastructure underpinning the nation's healthcare system. However, ongoing reductions in NHI drug prices have kept the market virtually flat on a value basis over the past five years, putting pressure on the profitability of generic drug manufacturers.

The industry's rapid growth has also led to an accumulation of structural challenges. Low barriers to entry have resulted in a fragmented market of approximately 190 companies. Even though we are one of Japan's largest generic drug manufacturers, the Sawai Group held only around 16% of the generic drug market in 2025, according to our estimates.

Amid intense competition, manufacturers repeatedly launched new products as a survival strategy, making high-mix, low-volume production the norm and leading to lower production efficiency and weaker quality control systems.

Against this backdrop of structural challenges, manufacturing and quality control violations have been uncovered at several companies since 2020, and supply disruptions resulting from government orders to suspend operations have become more widespread. Compounded by supply chain disruption caused by the COVID-19 pandemic, concerns over drug supply have grown more serious and prolonged. As of September 2025, 14% of all drugs, or 2,224 products, were still subject to limited shipment or supply suspension, continuing to affect medical institutions.

Factors behind supply instability



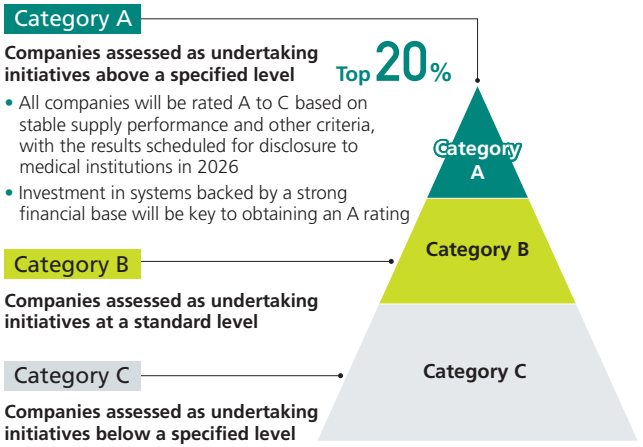
Reference: Japan Generic Medicines Association, Report of the Study Group on Ideal Industrial Structure for a Stable Supply of Generic Drugs
https://www.jga.gr.jp/assets/uploads/2026/2683ec6909b711c72406e774af863408a37d936c.pdf

2 Drivers of change Introduction of the government's

In response to these challenges, the government has recently embarked in earnest on reforming the industry's structure. A report issued in May 2024 by the Study Group on Ideal Industrial Structure for a Stable Supply of Generic Drugs, etc. designated the next five years or so as an intensive reform period and set out three objectives: ensuring appropriate manufacturing and quality control systems, securing stable supply capabilities, and establishing a sustainable industry structure.

The Generic Drug Provider Evaluation System is central to these reforms. It assesses generic drug manufacturers against 17 indicators in four areas: disclosure of stable supply information, contingency capacity, supply performance, and deviation between NHI drug prices and actual selling prices. Manufacturers are classified into three categories: the top

Generic Drug Provider Evaluation System



Generic Drug Provider Evaluation System

20% as Category A, those scoring below zero points as Category C, and all others as Category B.

The key feature of this system is that evaluation results are directly linked to the NHI drug pricing system. Relatively high NHI drug prices are maintained for products supplied by Category A companies, while Category C companies receive no preferential pricing treatment. Moreover, disclosure of company names and evaluation categories to medical institutions is expected to encourage medical institutions and pharmacies to prioritize products from Category A companies. This represents a shift to a system that rewards companies contributing to stable supply through both NHI drug prices and market selection, and could fundamentally transform an industry structure previously centered on price competition.

In addition, the 2025 amendments to the Pharmaceuticals and Medical Devices Act introduced legal requirements to report supply suspensions and appoint managers responsible for stable supply systems. The government also established the Fund for Generic Drug Manufacturing Infrastructure Development, totaling ¥84.4 billion, to support product consolidation and capital investment, thereby addressing high-mix, low-volume production through both institutional and financial measures.

3 Future outlook Consolidation around highly reliable companies

Through these reforms, the generic drug industry is expected to consolidate around companies with strong quality control and stable supply systems. According to estimates by the Japan Generic Medicines Association, industry-wide supply and demand will be nearly balanced in fiscal 2026, while supply is projected to exceed demand by approximately 4% in fiscal 2029, the final year of the intensive reform period. Product consolidation and intercompany collaboration are also beginning to take concrete shape, and steady progress is being made in addressing high-mix, low-volume production.

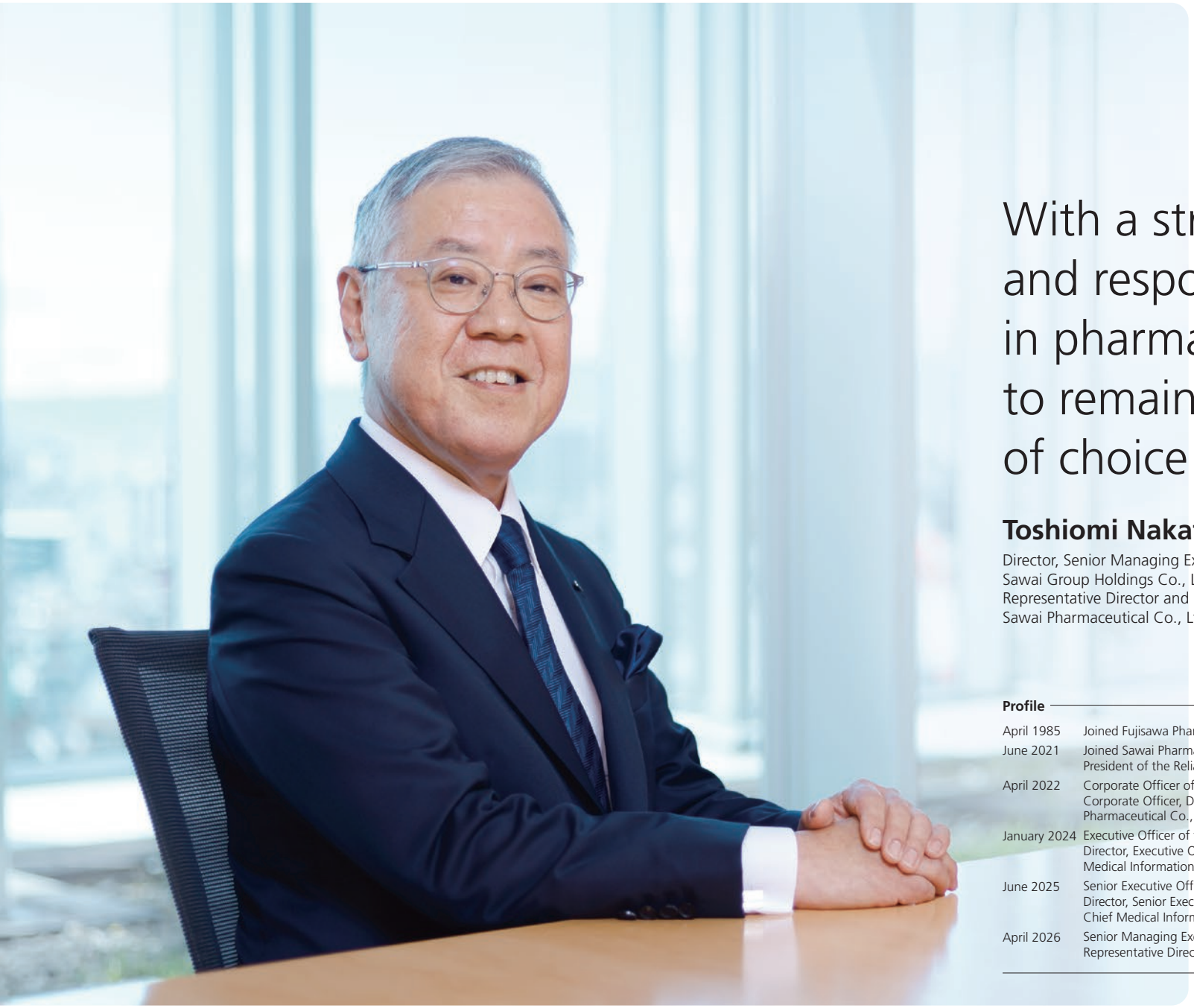
The Sawai Group views these changes in the business environment as a growth opportunity. To enhance its quality management systems, the Group has assigned on-site QA personnel* reporting directly to the pharmaceutical manufacturing supervisor at its factories. It is also diversifying its API suppliers and taking all necessary steps to achieve a Category A rating under the Generic Drug Provider Evaluation System.

The Group is also expanding production capacity, including through construction of a new building at the Daini Kyushu Factory, and expects to have an industry-leading annual production capacity of 25 billion tablets by the end of fiscal 2030. Since fiscal 2023, it has also shifted to a sales strategy emphasizing appropriate pricing, seeking to achieve both stable supply and profitability.

* On-site personnel verify that GMP activities at factories are conducted in accordance with prescribed procedures, among other matters.

Sawai Group initiatives

	Key initiatives	Related page
Increasing production facility utilization and output	Accelerating product transfers to the new building at the Daini Kyushu Factory and to Trust Pharmatech Reducing equipment downtime associated with production changeovers	▶ p. 25
Continuously expanding production capacity	Continuing to consider additional investments, including building its own factories and forming partnerships with other companies, toward achieving in-house production capacity of 25 billion tablets in fiscal 2030	▶ p. 25
Strengthening product quality assurance systems	Building close collaboration with manufacturing sites and promoting a two-way mechanism for rapidly sharing and assessing the status of manufacturing control and quality control at those sites	▶ p. 41
Recruiting and developing talent	Using diverse recruitment channels, successfully recruited approximately 200 new graduates scheduled to join in April 2026 and approximately 200 mid-career hires in fiscal 2025	▶ p. 36
Rebuilding corporate governance	Holding monthly meetings of the Group Compliance Committee and drawing on external experts' knowledge to verify, from a legal compliance perspective, the appropriateness of decisions made regarding deviations	▶ p. 48



With a strong awareness of and responsibility for our role in pharmaceuticals, we aim to remain the company of choice for society.

Toshiomi Nakate
Director, Senior Managing Executive Officer
Sawai Group Holdings Co., Ltd.
Representative Director and President
Sawai Pharmaceutical Co., Ltd.

Profile

April 1985	Joined Fujisawa Pharmaceutical Co., Ltd. (Astellas Pharma Inc.)
June 2021	Joined Sawai Pharmaceutical Co., Ltd., Corporate Officer, Assigned to the Senior Vice President of the Reliability Assurance Division
April 2022	Corporate Officer of the Company, Deputy Group Chief Quality & Safety Officer Corporate Officer, Deputy Senior Vice President of Reliability Assurance Division of Sawai Pharmaceutical Co., Ltd.
January 2024	Executive Officer of the Company, Group Chief Quality & Safety Officer Director, Executive Officer and Senior Vice President of Reliability Assurance Division, Chief Medical Information Service Management Officer of Sawai Pharmaceutical Co., Ltd.
June 2025	Senior Executive Officer of the Company, Group Chief Quality & Safety Officer Director, Senior Executive Officer and Senior Vice President of Reliability Assurance Division, Chief Medical Information Service Management Officer of Sawai Pharmaceutical Co., Ltd.
April 2026	Senior Managing Executive Officer of the Company Representative Director and President of Sawai Pharmaceutical Co., Ltd. (incumbent)

We deliver medicines with awareness and responsibility, always mindful of the people whose lives our work touches

I am Toshiomi Nakate, and I became Representative Director and President of Sawai Pharmaceutical Co., Ltd. in April 2026. My involvement in pharmaceutical sciences and the pharmaceutical industry began in 1985, when I joined Fujisawa Pharmaceutical Co., Ltd. (currently Astellas Pharma Inc.) after graduating from university. I spent more than 20 years there in formulation development, including formulation design and development at the company's formulation research laboratories and technology transfer to factories. I subsequently served as plant manager at three plants and spent three years as representative director of a manufacturing subsidiary. Since joining Sawai Pharmaceutical, I have drawn on these experiences in overseeing quality assurance and reliability assurance.

I chose to pursue a career in the pharmaceutical industry because of my own experience with childhood asthma. When I was in elementary school, an inhaler that opened the airways became available; it was amazingly effective and I was deeply grateful for it. This experience not only prompted my choice of major at university but also became the starting point for my approach to corporate management. In my previous career, I was posted overseas in Germany, the United States, and Ireland. The insights I gained there into global pharmaceutical industry trends, from development and production to technology transfer, have also been invaluable assets in my role as a business leader.

As Senior Vice President of the Reliability Assurance Division, I was personally responsible for executing the initiatives undertaken under my predecessor to strengthen the foundations of quality and reliability assurance. Now, as President, my principal mission is to further embed the systems introduced to date in our workplaces and make them an integral part of Sawai's culture. We aim to establish annual production capacity of 22 billion tablets at our own factories in fiscal 2026 and are moving forward with plans to expand this to 25 billion tablets by fiscal 2030. I will also take responsibility for steadily implementing the capacity enhancements at the Daini Kyushu Factory and Trust Pharmatech approved under my predecessor, further strengthening our supply capabilities.

Alongside expanding production capacity, it is important to develop the talent who support actual production and establish a system capable of producing medicines of reliable quality. The most important aspect of our quality initiatives is for every employee to recognize and take responsibility for the fact that what we manufacture and deliver are medicines. Without this awareness, they may take ambiguous actions or choose easy solutions that could deviate from established rules. We must not distance ourselves from the patients we serve; if we remember that we or a loved one could be in their position tomorrow, it should become clear how we must approach our work. Ensuring that every employee firmly embraces this awareness is the foundation of our quality.

To improve quality, it is also essential to understand the rules correctly and follow them without fail. Understanding the technology and science behind those rules is equally vital to reducing the risk of quality issues. I want those joining Sawai to begin with a strong awareness that they are handling medicines, acquire skills while following procedures, and maintain a commitment to supporting quality.

In addition to these initiatives, we place importance on increasing employee engagement. This requires transparency in management and the workplace, together with two-way communication. Regular small-group discussions between management and employees and the strengthening

SWOT analysis

Strengths
- Brand strength as top manufacturer
- Stable financial base
- Strengthened production capacity following quick investments
- Development capabilities that enable us to launch products first
- Formulation technologies that enable high-value-added products

Weaknesses
- Securing and developing talent that can handle growing production capacity
- Constraints on productivity due to high-mix, low-volume production

Opportunities
- Momentum toward restructuring of the generic drug industry
- Growing demand driven by population aging
- Growing healthcare and medical needs
- Generic drugs as social infrastructure
- Generic Drug Provider Evaluation System that promotes sales at reasonable prices
- Revision of the NHI drug pricing system for authorized generics (AGs)

Threats
- Rising geopolitical risks
- Lower reliability due to generic drug supply instability
- Growing raw material and utility costs
- Lower NHI drug prices due to annual drug price revisions
- Changes in various systems

of our whistleblowing channel, the Corporate Ethics Helpline, are part of this effort. Creating an environment in which employees feel comfortable speaking up enables us to identify organizational issues early and fosters a healthy culture of autonomous improvement.

We will continue efforts such as these to strengthen relationships of trust with our employees.

My policy as President for this fiscal year is "Making sincerity the power behind progress." Here, sincerity means maintaining compliance awareness, preventing harassment, collaborating across organizations, communicating openly, and remaining mindful of the patients and healthcare professionals whose lives our work touches. To translate this sincerity into the growth of both the Company and its people, I emphasize three concepts: challenge, thoughtful action, and compliance. The principles that will guide management decisions going forward are to make ethical awareness the foundation of everything we do, maintain a willingness to take on challenges by anticipating and addressing change rather than being satisfied with the status quo, and think and act autonomously.

Growing production capacity while appropriately managing inventories to meet market demand

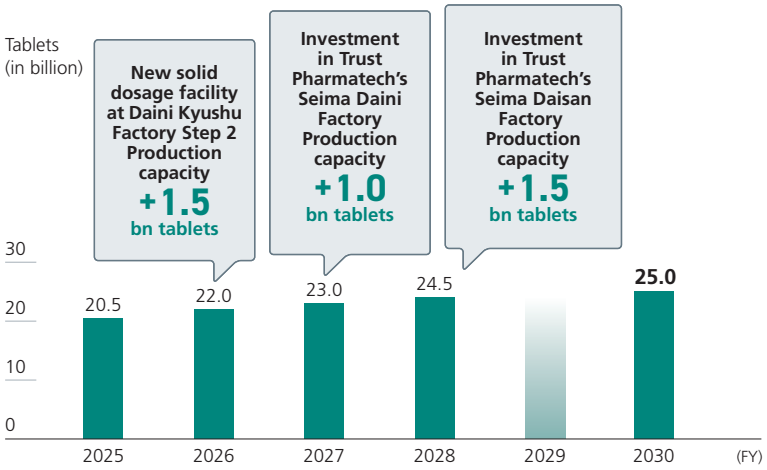
A major issue affecting our fiscal 2025 performance was the gap between production and sales volumes. Although we planned to produce 18.3 billion tablets, actual production was limited to 16.6 billion tablets, falling short of our projection. Meanwhile, sales volume was 17.1 billion tablets, meaning that we drew down inventories by 0.5 billion tablets. In response, we have set the fiscal 2026 production plan at 18.0 billion tablets and plan to increase sales volume by 2.9% year on year to 17.6 billion tablets. We will increase production capacity while maintaining appropriate inventory levels to meet market demand.

As part of our efforts to ensure stable supply and improve production efficiency, in September 2025 we reached an agreement with Nichi-Iko Pharmaceutical Co., Ltd. to collaborate on consolidating generic drug manufacturing and integrating product lineups. In June 2026, as the first outcome of this collaboration, we obtained approval through the expedited review process for specified manufacturing process changes related to consolidating the manufacturing sites for Atorvastatin Tablets and are optimizing production resources. Consolidating some of the products manufactured by the two companies will have great significance for us, improving production efficiency and reducing costs while also allowing the resulting manufacturing capacity to be allocated to other products.

Pursuing a range of measures to strengthen our stable supply system

I believe the primary reason fiscal 2025 production volume fell short of the plan was that it took longer than expected for newly hired talent to demonstrate their capabilities in the workplace and work independently. Although we increased staffing through recruitment and provided training, employee development required time and also placed a considerable burden on those providing instruction, affecting production growth. In response, we reviewed our training system. We now clearly separate the roles of mentors, who provide emotional support, and technical instructors, while also providing workplace readiness training, particularly for new employees joining directly after high school. As a result, employees are steadily developing their skills, giving me confidence that we can achieve future production capacity expansion. Therefore, I believe we now have a structure capable of achieving this fiscal year's production target of 18 billion tablets,

Expanding in-house production capacity towards FY2030



Note: Assumptions for production capacity: For the current number of items, it is assumed that the machines are kept running in two shifts per day on weekdays. The number of items produced under contract manufacturing is not included.

centered on employees hired through the previous fiscal year who have developed solid capabilities under the revised training system. We also welcomed more than 150 new graduates to the Manufacturing Division this fiscal year. We expect them to become a reliable force in further strengthening production capacity in the future.

We are systematically introducing robotics and automation and improving production efficiency. We are introducing the Laboratory Information Management System (LIMS), which supports laboratory testing, at all factories to further improve the efficiency of testing and quality control. We also view AI as a tool that can significantly improve how we use data on deviations and problems at factories and share knowledge. The Quality Event Management System launched last year stores cases from each factory as digital information. Using AI to rapidly search for and analyze similar past cases and responses should enable us to use this information as training material and improve the accuracy of investigations and decisions when problems occur.

One area we intend to pursue further is lifecycle management for individual products. When launching a new product, we use a range of indicators to assess the value it will deliver to society and its viability as a business, carefully determining whether it can be supplied sustainably. Medicines carry an extremely high level of social responsibility. If patients need a product and we are its sole supplier, we must take responsibility for continuing to deliver it to them.



At the same time, fulfilling our responsibility to ensure stable supply requires us to remain sustainable as a company. Through proactive investment in growth areas and appropriate earnings from other product groups, we must achieve a high-level balance between contributing to healthcare and maintaining a robust management foundation. Going forward, we will carefully assess the value of each product and maximize its role while further strengthening our stable supply system as social infrastructure.

We aim to remain a trusted company by translating each employee's growth into organizational growth.

The top priority for management going forward is to strengthen our system for the stable delivery of medicines of reliable quality. We also intend to focus closely on providing the information needed for the proper use of medicines. Medicines can fully deliver their value only when correct information is provided on matters such as administration, handling, and interactions with other drugs. Our Medical Communications Department, medical representatives, and Medical Information Department work in close coordination to provide healthcare institutions and patients with the information they need.

I tell employees that I want them to recognize their role as professionals in "creating" medicines. Here, "creating" encompasses not only manufacturing but every process involved in delivering medicines to patients, from research and development to quality control and information provision. When each employee considers what they must do as a professional and continues to grow, this drives the growth of the entire organization. By promoting individual growth and close collaboration across organizations, we will enable our quality assurance systems to function at a higher level and achieve the stable supply of medicines of reliable quality.

By steadily building on and continuing these initiatives, we aim to remain the company of choice for patients and healthcare professionals and to earn the lasting trust of society at large. We will also enhance corporate value and contribute to healthy lives for all our stakeholders.



Toshiomi Nakate
Director, Senior Managing Executive Officer
Representative Director and President of
Sawai Pharmaceutical Co., Ltd.

Further enhancing corporate value through continued investment in growth while maintaining strict financial discipline

Taku Nakaoka Director, Senior Executive Officer, Group Chief Financial Officer
Sawai Group Holdings Co., Ltd.



Business performance for fiscal 2025

The Sawai Group identified improving capital efficiency as a key theme for strengthening its management foundation in its medium-term business plan, Beyond 2027. The Group's key performance targets are ROE of at least 10% and ROIC of at least 8%. These targets were set at levels that exceed the Group's cost of capital, reflecting our belief that management has a responsibility to generate returns that surpass the cost of the capital entrusted to us by our shareholders and creditors. The Group is making a concerted effort to improve capital efficiency by actively investing in the necessary areas and strongly emphasizing the prompt generation of returns on investment.

I must begin by acknowledging that our financial performance in fiscal 2025, the second year of Beyond 2027, fell short of plan. Revenue remained solid, increasing 6.7% year on year to ¥201.7 billion, driven by the impact of the Elective Care Scheme and contributions from new products. Profit, however, fell short of plan.

The first major factor affecting our results was settlement costs related to an intellectual property lawsuit involving teriparatide at the Group's core operating company, Sawai Pharmaceutical. Settlement costs of approximately ¥4.0 billion were recorded in the second quarter of fiscal 2025. This was a one-time expense and will not affect our financial performance from fiscal 2026 onward. The Group is strengthening its business viability assessments and litigation risk management while taking steps to prevent similar issues from occurring in the future.

The second factor was a shortfall in the Group's production volume. Production totaled 16.6 billion tablets, 1.7 billion tablets below the planned 18.3 billion tablets. As a result, the gross profit margin did not improve as planned.

The third factor was increased investment for future growth. Expanding the manufacturing workforce increased labor costs as an upfront investment to support future growth. Selling, general and administrative expenses also increased as we strengthened the stability of our supply system and made upfront investments in new businesses. The Group considers these investments essential to expanding earnings over the long term.

Core operating profit decreased 3.6% year on year to ¥24.8 billion. Weighing on earnings were, as mentioned above, labor costs and selling, general and administrative expenses that exceeded the increase in gross profit, and the revisions to National Health Insurance drug prices, which lowered our profit margins. The Group views these higher costs as investments necessary to lay the groundwork for expanding production capacity and improving profitability from fiscal 2026 onward. We recognize that we have a responsibility to ensure these investments deliver tangible numerical results.

The Group positions fiscal 2026 as the year to overcome these challenges and return our business performance to a growth trajectory. In fiscal 2026, we plan to increase revenue 3.3% year on year to ¥208.4 billion, core operating profit 19.5% to ¥29.6 billion, operating profit 71.1% to ¥27.2 billion, and profit attributable to owners of the parent 78.2% to ¥18.6 billion. Improved profitability from new product sales and higher production volume is expected to increase the gross profit margin from 29.2% to 31.4%, and we expect ROE to return to the 10% level.

We expect the October 2026 revisions to the NHI drug pricing system for Authorized Generics (AGs) to reduce the risk of disposal losses on new products, and provide further opportunities to expand our market share. We will continue improving profitability and capital efficiency throughout the Group to achieve the ROE target of at least 13% set in our long-term vision for fiscal 2030.

Cash allocation plan

The Group's basic policy for cash allocation is to fund growth investments and shareholder returns primarily through operating cash flow generated by the business, while supplementing those funds with borrowings and corporate bonds when appropriate. In fiscal 2025, we raised ¥20.5 billion through long-term borrowings and ¥7.4 billion through corporate bonds to fund capital investments in the new solid dosage form building at the Daini Kyushu Factory and at Trust Pharmatech.

The highest priority for cash allocation is growth investment to expand production capacity for our Japan generic drug business. The next priorities are providing shareholder returns, primarily by delivering stable dividends, and upfront investments in new businesses, including digital healthcare, that will form the foundation for future growth. We also recognize the importance of balancing operating cash flow and investing cash flow while maintaining an appropriate net debt-to-equity ratio.

Three growth investments are particularly important. The first is investment in Step 2 of the new solid dosage form building at the Daini Kyushu Factory. The facility, which will increase the Group's production capacity by 1.5 billion tablets, is scheduled to begin operations in December 2026. Demand is strong, and we fully expect the expanded capacity to translate directly to increased sales opportunities. We are aiming for this investment to begin generating returns in fiscal 2027 as increased sales volume boosts both revenue and profit.

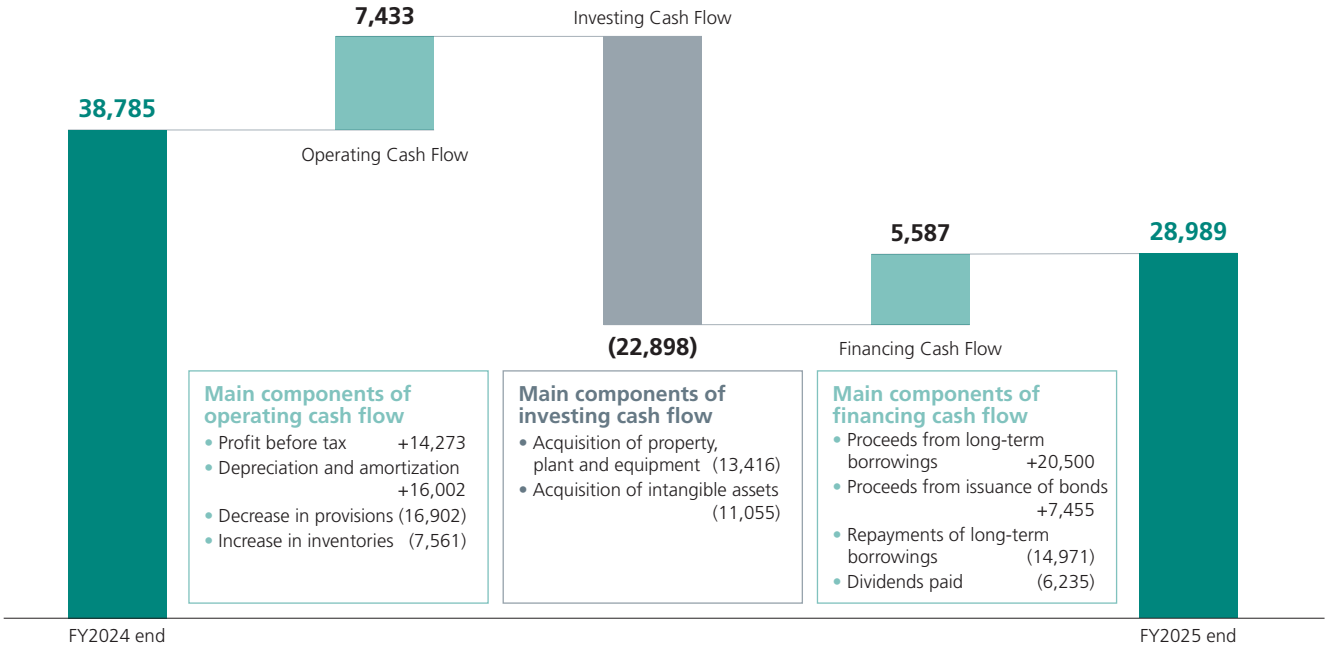
The second growth investment is our investment in Trust Pharmatech. This investment will expand production capacity by a total of 2.5 billion tablets and will be a cornerstone of our long-term plan to increase the Group's total production capacity to 25 billion tablets by fiscal 2030.

The third is our upfront investment in the digital healthcare and medical device business. While revisions to official drug prices effectively set limits on our main drug business, the digital business has no such constraints and can build sales steadily over time. We also see a significant opportunity in the digital business because there is not yet a dominant player in the market. We plan to build the digital business into a meaningful source of medium- and long-term earnings.

The cash allocation plan has progressed largely as expected, with capital expenditures tracking closely to the plan. However, litigation-related payments and higher inventories caused operating cash flow to decline sharply from ¥27.8 billion in fiscal 2024 to ¥7.4 billion in fiscal 2025, resulting in negative free cash flow. We expect operating cash flow to improve in fiscal 2026 as business performance recovers. We will continue to maintain strict financial discipline while executing a capital allocation strategy that balances growth investments with shareholder returns.

Cash flow

(Unit: million yen)



Shareholder return policy

Sawai Group Holdings' basic policy on shareholder returns is to provide stable and sustainable dividends while taking a comprehensive view of our medium- to long-term earnings level and maintaining a dividend on equity (DOE) attributable to owners of the parent of at least 3.0%.

We increased the annual dividend from ¥43.33 per share (adjusted for the stock split) in fiscal 2022 and fiscal 2023 to ¥53 in fiscal 2024. We will maintain a stable dividend and plan to distribute annual dividends of ¥55 in fiscal 2025 and ¥56 in fiscal 2026. DOE in fiscal 2025 was 3.6%, exceeding our target of 3.0%.

Share repurchase programs are conducted with the primary objective of enhancing the Group's capital efficiency. From July 2024 through February 2025, we repurchased approximately 16.01 million shares, representing 12.2% of our total shares outstanding, for a total of ¥33.0 billion. All of the repurchased shares were retired in April 2025.

We will continue to flexibly consider repurchasing shares, while taking into account free cash flow, market trends, and other factors. The medium-term business plan commits to distributing at least ¥19.0 billion in total dividends over the three years of fiscal 2024 through fiscal 2026. We aim to continue enhancing shareholder value by expanding our business to increase profits and earnings per share (EPS), while maintaining stable dividends with a focus on DOE.

We will continue working toward our long-term vision for fiscal 2030 as a comprehensive healthcare group committed to sustainable growth alongside society. We thank our shareholders and investors for their continued support.

Reliably delivering assured quality

Three production leaders discuss their mission and challenges

The Sawai Group is working to resolve the supply shortages affecting the generic drug industry as a whole. In this section, factory managers and the executive responsible for production discussed the progress made and the challenges ahead.



Teruo Araki
Factory Manager
Daini Kyushu Factory
Sawai Pharmaceutical Co., Ltd.

Toshihiro Yanagi
Factory Manager
Trust Pharmatech Co., Ltd.

Toshiya Hasuo
Senior Executive Officer,
Group Chief Production Officer (Group CPO),
Sawai Group Holdings Co., Ltd.

The Manufacturing Division's Operating Environment and Our Roles

Hasuo Supply shortages arose for numerous generic drug products following manufacturing and quality control issues at several generic drug manufacturers that came to light from 2020 onward. Sawai Pharmaceutical and other companies have been working to increase production, but the shortages have yet to be completely resolved. As the executive responsible for overseeing the Group's Manufacturing Division, I am working to eliminate uncertainty surrounding the supply of generic drugs.

Yanagi As Factory Manager at Trust Pharmatech, I see my mission as contributing to a stable supply and expanded production capacity across the Group. Production volume was just over 1 billion tablets in fiscal 2025 and is expected to reach around 1.5 times that level, or 1.65 billion tablets, in fiscal 2026. Our factory production capacity is approximately 3 billion tablets, and installation of new equipment will be completed at Seima Factory No. 2 and Seima Factory No. 3 in 2027, leaving ample scope to increase production. Looking ahead, we will continue accepting products transferred from Sawai Pharmaceutical and supporting the expansion of the Group's supply capacity.

Araki At Sawai Pharmaceutical's Daini Kyushu Factory, where I serve as Factory Manager, we are expanding production capacity in line with the Company's policy of increasing the Group's annual production capacity to 25 billion tablets by fiscal 2030. A new building was completed at the Daini Kyushu Factory in July 2024. In the first phase, equipment with production capacity of 2 billion tablets was installed, and shipments began in December of that year. As further production expansion is required, we are now installing additional equipment with capacity of 1.5 billion tablets as the second phase. I see my role as securing and developing the talent needed to accommodate increased production and

establishing systems that strengthen quality assurance, in preparation for all equipment becoming operational as scheduled in December 2026.

Hasuo Once the second phase of capital investment at the Daini Kyushu Factory is complete, the factory will have total production capacity of 6.0 billion tablets, including 2.5 billion tablets at the existing building. This will give it the Group's largest production capacity for solid dosage forms, a major product category for Sawai Pharmaceutical. In terms of quality, the new building is equipped with a Manufacturing Execution System (MES) and Laboratory Information Management System (LIMS), establishing a framework that enables manufacturing and quality testing to be performed more easily and reliably.

Production volume outlook

(Unit: tablets)

	FY2024 results	FY2025 results	FY2026 plan
Trust Pharmatech	0.88 billion	1.06 billion	1.65 billion
New solid dosage facility of Daini Kyushu Factory	0.07 billion	0.83 billion	1.20 billion
Other existing factories (excluding contract manufacturing)	13.70 billion	12.56 billion	12.70 billion
Total (including contract manufacturing)	16.6 billion	16.6 billion	18.0 billion

Investing in people to support stable supply

Yanagi Trust Pharmatech was established with 403 employees, including 243 production staff, transferred (along with facilities) from the former Kobayashi Kako. At the time of launch, we provided thorough GMP training and devoted considerable time to preparing operating procedures. We also dispatched more than 130 employees to Sawai Pharmaceutical factories, where they spent up to three years learning the standards established by the Group. Those employees have now returned to their respective workplaces and are taking the lead in sharing what they learned. I also feel that employees at production sites are increasingly drawing on their experience to determine what they need to do and act autonomously.



In July 2023, one year and three months after the company was established, we made our first shipment of a product manufactured through an integrated process from weighing to packaging. Former Kobayashi Kako employees were deeply emotional when they realized they could ship products from their factory again.

Hasuo Trust Pharmatech invested considerable time and effort in production preparations. After receiving technology transfers from Sawai Pharmaceutical, it rebuilt all manufacturing and testing documentation in accordance with Group standards, thereby establishing a robust production system. When the new solid dosage facility at the Daini Kyushu Factory was being constructed, rapidly rising demand created expectations that production would begin earlier and ramp up faster than initially planned. Under this pressure, approximately 40 project members worked hard on everything from construction and equipment installation to preparations for launch, overcoming schedule extensions caused by extreme heat and heavy rain as well as rising prices. In parallel, they prepared the documentation needed to manufacture and test products using the new equipment and systematically recruited and trained the employees who would handle actual production. Securing and developing talent is the highest-priority issue for both factories. I am grateful that past talent development efforts have enabled steady progress in this way.

Yanagi Our immediate challenge is developing mid-level personnel involved in manufacturing. We are applying Sawai Pharmaceutical's training programs at Trust Pharmatech and are also introducing a mentoring system. Cultivating talent inevitably takes time. It is important to instill an awareness of compliance, maintain and improve each employee's motivation, and further strengthen their sense of responsibility for handling pharmaceuticals that affect patients' health.

Araki At the Daini Kyushu Factory, recruitment has progressed smoothly since 2020, ahead of construction of the new building, with the cooperation of Iizuka City in Fukuoka Prefecture, where the factory is located. However, we face the same talent development challenge as Trust Pharmatech. From a quality assurance perspective, we must rapidly provide training that raises individual awareness and practical capabilities and revise operating procedures to meet increasingly stringent GMP requirements. We will continue using e-learning and other tools while focusing on training employees to obtain operator certification. I believe that expanding our training framework from a long-term perspective will enhance instructors' teaching capabilities and accelerate the development of new employees.

Fostering a Quality Culture

Araki The Manufacturing Execution System (MES) and Laboratory Information Management System (LIMS) introduced at the Daini Kyushu Factory's new building play a major role in reducing human error and dramatically improving the precision of quality control and assurance. They also improve production efficiency, for example by enabling one person, with support from the systems, to perform checks that previously required two people. When the systems were first introduced, some employees at the production site expressed concerns about the time required for implementation, a shortage of personnel capable of operating them, and a decline in work efficiency until employees became accustomed to them. However, by carefully explaining the benefits, including improved work efficiency and stronger quality assurance, we gained their understanding. The systems are now operating smoothly.

Hasuo The number of Group employees has grown rapidly, more than doubling over ten years from 1,490 in March 2016 to 3,630 in March 2026. Of these, approximately one-quarter joined within the past two or three years. The development of mid-level personnel capable of leading production sites has not yet kept pace with this rapid organizational expansion. As highly proficient mid-level personnel are essential to ensuring quality, I have held repeated discussions on skills enhancement and talent development measures with Mr. Araki, Mr. Yanagi, and the other factory managers.

Yanagi At Trust Pharmatech, many of our employees have experienced manufacturing control issues faced by the former Kobayashi Kako, so I feel that the importance of compliance as the foundation supporting the business is deeply rooted in each employee's awareness. At the same time, we must remain alert to the risk that this awareness may fade as the number of mid-career hires increases and time passes. Training that merely presents technical terms will not communicate the message effectively. We therefore do not assume that participants already understand the material, but focus on presenting it in a way that they can accept and view as personally relevant. For example, we use videos to make the content easier to understand and provide training that enhances the skills of all employees, including new hires.

Araki As Factory Manager, my foremost priority is operating the factory with safety first. On that basis, I emphasize maintaining a balance between ensuring quality and stable supply, while creating an open workplace environment that supports both.

Sawai Pharmaceutical and Trust Pharmatech production personnel structure

	Personnel at the end of FY2025		End of FY2026 initial plan
	Initial plan	Results	
Sawai Pharmaceutical	2,593	2,559 (increase of 172)	2,776
Trust Pharmatech	451	439 (increase of 72)	563
Total	3,044	2,998 (increase of 244)	3,339

Figures in parentheses show changes from the end of the previous fiscal year. Personnel figures are for factories only and include contract and temporary employees.

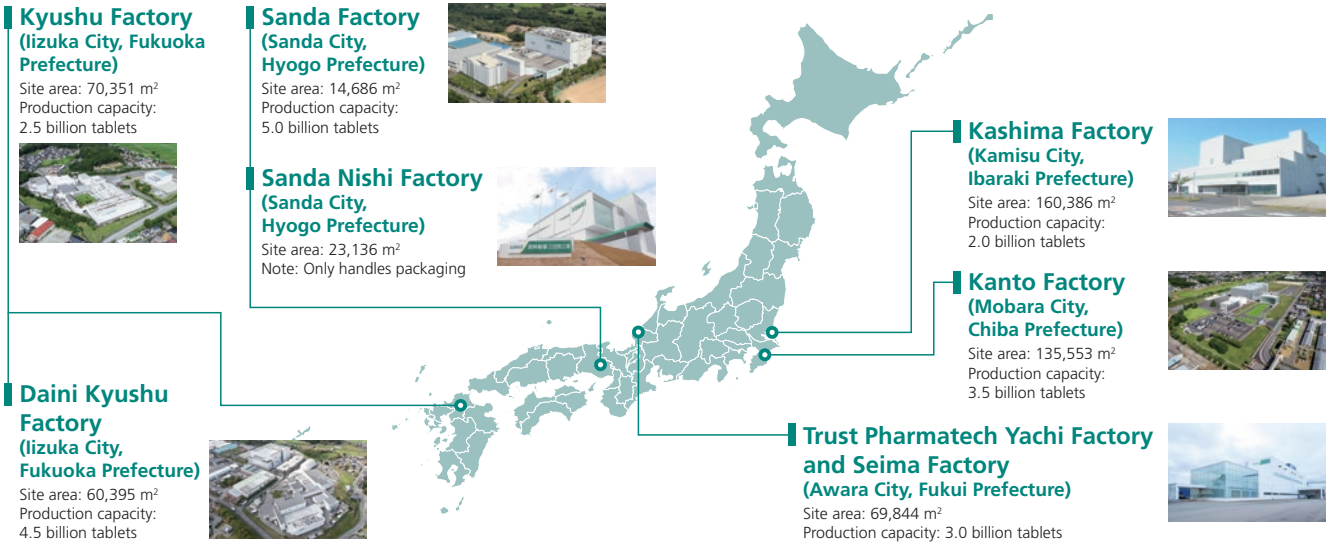


Hasuo Ensuring quality and stable supply are the two essential pillars of pharmaceutical manufacturing. However, quality issues often arise when this balance is lost and stable supply is given undue priority. Preventing problems requires active communication with supervisors and colleagues and an environment in which employees can speak candidly about difficulties or anything that does not seem right.

Araki To improve the workplace environment and operations, including quality, the Group has long conducted M1 Club Activities. "M1" means "everyone striving to be number one." Small groups spend approximately six months planning and carrying out improvement activities, then present the ideas they devised and the results achieved across the Company. Following Group-wide selection, the Daini Kyushu Factory won awards for two consecutive years in fiscal 2025 and fiscal 2026. From what I see at the production site, I feel that we are establishing a culture in which employees are conscious not only of safety and quality, but also identify issues themselves, exchange opinions candidly, and translate them into improvements.

Yanagi Trust Pharmatech's training programs also include active cross-departmental group discussions. Building internal relationships through training helps daily operations run more smoothly, so I tell participants to broaden their connections across departments to help create a more facilitative workplace. I have also built connections across departments through various opportunities over the years. The colleagues I met

Production facilities (Sawai Pharmaceutical 6 factories; Trust Pharmatech: 2 factories)



remain people I can rely on in difficult times. I believe this mutual support gives employees a sense that they are helping their colleagues and the company and contributing to society, ultimately fostering pride in never compromising on quality.

Hasuo Streamlining and optimizing operations while putting quality first is another important challenge for the Manufacturing Division. In response to the quality testing issue that resulted in administrative sanctions, the Group has spent the past several years reviewing and rebuilding its quality control framework, including compliance with GMP. At the same time, the increase in required checks and other factors has temporarily reduced productivity per employee. Our next major task is to improve productivity without compromising quality by combining various measures, including process automation, longer periods of unattended operation, systemization, and the use of AI. At the beginning of fiscal 2025, we also established an improvement proposal program and a framework for sharing improvements among factories to promote continuous improvement activities. I see these efforts as more than simply establishing programs and systems. They are intended to foster a corporate climate and culture rooted in each employee's awareness and actions. We will continue working steadily to foster a quality culture in which everyone embodies the Group's desire to "push ourselves to pursue higher quality in everything we do" as stated in our Code of Conduct.

Building a Manufacturing Division growing with mutual employee inspiration in pursuit of higher quality

Hasuo Guided by Sawai Pharmaceutical's corporate philosophy of "always putting patients first" and our Group's effort to "push ourselves to pursue higher quality in everything we do" as stated in our Code of Conduct, each factory is taking action toward four goals: become a team of highly committed employees; create a workplace with good communication; create a safe and secure workplace; and become a team of employees committed to talent development and personal growth. It is important to achieve all four of these in a balanced manner.

Yanagi People are the key to these initiatives. The more equipment we add, the more it can produce, but the same does not apply to people. Employees need training to become fully proficient, and their development takes time. At present, that training cannot be replaced by AI, nor can the issue be resolved simply by adding more people. That is why I believe our mission is to carefully develop the talent who will pursue stable supply and quality as two equally important priorities.

Araki As you say, it is important to maintain a balance among quality, stable supply, and talent development. Just as prioritizing stable supply alone can lead to quality being neglected, focusing too heavily on any one of these three will inevitably create distortions. As those ultimately responsible for our factories, we must continually assess this balance and steer operations accordingly. By doing so, we will fulfill our fundamental role of reliably delivering medicines of assured quality to society.

Hasuo I regularly tell factory managers and department heads such as yourselves that we must continue learning and improving ourselves if we are to lead our subordinates effectively. By communicating these messages repeatedly and passionately, I want to make continuous self-improvement part of the Manufacturing Division's culture and build a division whose members inspire one another and continue to grow.



Achieving first-to-market launches through advanced formulation technology and meticulous analysis and evaluation

Toyohiro Sawada Executive Officer, Group Chief Research & Development Officer (Group CRO)
Sawai Group Holdings Co., Ltd.



Strengths of our research and development strategy

The Sawai Group's strength lies in its formulation technology capabilities, supported by talent with both advanced expertise and broad perspectives. This strength has enabled us to launch several generic drugs which are the first or the sole item in their market category. In recent years, we have been working to improve the accuracy of bioequivalence (BE) predictions.

Specifically, based on the Decision Tree (DT), a proprietary set of criteria developed by Sawai Pharmaceutical, we identify and classify risks in demonstrating BE arising from API and formulation characteristics under fasting, fed, and low-gastric-acidity BE study conditions. Based on the risks identified, we then assign a BE Score Category that rates the level of difficulty on a five-point scale, thereby quantitatively visualizing the risks.

In addition, we have systematized the optimal formulation evaluation methods for each risk. By using risk-based, multifaceted analyses to clarify differences between our formulations and the reference products, we can minimize risks with a high degree of certainty. The resulting knowledge is centrally managed through our proprietary Bioequivalence Management System (BEAMS) and used for cross-product analysis, providing a robust foundation for improving the probability of BE success.

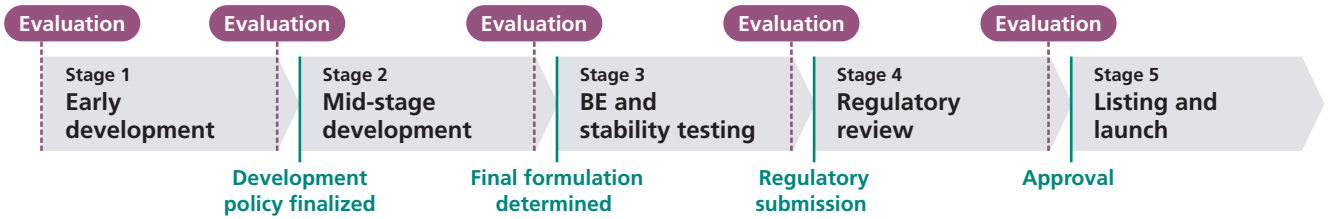
Optimizing the allocation of management resources and creating social value through the Portfolio Strategy Committee

For new product development, we have established the Portfolio Strategy Committee, chaired by the President of Sawai Pharmaceutical, to make rigorous decisions that both optimize investment efficiency and address social needs.

As a basis for these decisions, the R&D Division has introduced a stage-gate process for project management. In addition to quantitative indicators such as net present value (NPV) and internal rate of return (IRR), we conduct qualitative assessments through risk and opportunity analysis. This process integrates scientific evidence, regulatory requirements, intellectual property strategy, and financial perspectives to present the key issues and supporting rationale needed to determine whether a project should advance to the next stage.

In addition to managing individual projects, we take a comprehensive view of all products under development as a development portfolio, enabling us to optimally reallocate management resources based on the risks and opportunities across the pipeline. While balancing contributions to medical needs with investment discipline, we seek to maximize medium- to long-term corporate value, with final decisions made by top management.

Stage-gate process and business viability assessment



Intellectual property risks and response policy

The Sawai Group focuses on reducing infringement risk and strengthening its intellectual property foundation. We have established a system for assessing intellectual property risks by closely examining patents covering the active ingredients, indications, dosage and administration, API crystalline forms, formulations, and other aspects of original drugs. When considering patent avoidance strategies, multiple departments, including the Intellectual Property Department, Development Department, and Pharmaceutical Development Department, discuss strategies at the Patent Strategy Committee, including the possibility of patent invalidation trials. We also work with attorneys specializing in intellectual property to formulate patent strategies, enabling us to identify and mitigate in advance risks that could lead to disputes over infringement.

We continuously monitor the patent landscape from the development review stage onward to ensure reliable product launches, while actively filing patent applications for technologies developed in-house. In addition to applications covering formulations and designs related to products under development, we focus on developing manufacturing and analytical technologies, thereby expanding the intellectual property foundation that supports sustainable competitive advantage.

Research and development

Established competitive advantages

- Scientific knowledge, technologies, and experience accumulated through efforts to launch new products at the earliest opportunity and be first to market
- Swift and steady responses to increasingly rigorous quality regulations

Initiatives for stronger advantages

- Research and development of new products with consideration for product life cycles, and improvements to the quality and productivity of existing products
- Development of technologies for assessing the risk of nitrosamine contamination and establishment of a specialized analytical facility

Comment

Bringing together expertise from across the organization to deliver high-quality pharmaceuticals

My workplace has a deeply rooted shared understanding that achieving higher pharmaceutical quality is connected to "always putting patients first". We therefore bring together our accumulated scientific and technological knowledge and experience as organization-wide expertise and collaborate across organizational boundaries to address the challenges before us. We also actively use digital transformation technologies, including generative AI, to standardize and streamline operations. Through these efforts, we uphold high ethical standards and compliance in research activities while further enhancing our scientific and technological capabilities. In this environment, I will continue to view every change as an opportunity for growth and sincerely take on new challenges each day as a researcher helping to lead the generic drug industry, so that I can provide patients with genuine peace of mind.



Emiko Onishi
Analytical Research II
Analytical Research Department
Research & Development Division
Sawai Pharmaceutical Co., Ltd.

Manufacturing

Established competitive advantages

- More advanced operations through the introduction of highly effective systems aligned with on-site needs, including LIMS and MES
- Expertise passed down from one generation to the next
- An organizational culture that disseminates accumulated expertise throughout the factory

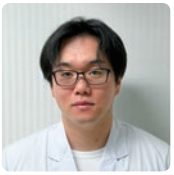
Initiatives for stronger advantages

- Education and training that convey on-site pharmaceutical manufacturing capabilities and mindsets to new employees
- Development of mid-level personnel who enhance teamwork by applying on-site awareness and expertise and drive initiatives under the medium-term business plan
- Establishment of mechanisms for sharing best practices with other workplaces and factories

Comment

Aiming to develop more user-friendly systems by listening to frontline employees

My workplace has long valued listening to the voices of those on the front lines. When introducing the Laboratory Information Management System (LIMS), an initiative under "establishing a trusted corporate foundation" in the medium-term business plan, we also work to improve operational efficiency by carefully listening to the requests of the analysts who will actually use the system. This project is led primarily by younger employees, and the team lacked sufficient frontline experience in the beginning. By actively consulting senior colleagues and learning from their past experience, the entire team is deepening its understanding of workplace operations as we seek to develop a user-friendly system. After its introduction, I hope to take the lead in ensuring stable operation and pursue improvements and training to increase the efficiency of testing operations. By continuing to listen closely to workplace feedback and passing this mindset on to the next generation of younger employees, we will enhance the ability of the entire Sanda site to respond to change.



Yuta Sugama
Quality Control Section
Quality Control Department
Manufacturing Division, Sanda Factory
Sawai Pharmaceutical Co., Ltd.

Reliability assurance

Established competitive advantages

- Close quality assurance collaboration with manufacturing sites within and outside the Group, supported by a team of 142 specialists in the Reliability Assurance Division, including 58 in the Quality Assurance Departments (headcounts as of April 1, 2026)
- Cultivation of compliance awareness and a quality culture through operational improvement initiatives
- Reestablishment and operation of an appropriate reporting system centered on management reviews for management issues relating to reliability assurance

Initiatives for stronger advantages

- A training framework designed to enhance the expertise required to properly perform quality, efficacy, and safety management duties
- Periodic reviews of the operation of the reliability assurance system through management reviews, followed by revisions and enhancements
- Deeper collaboration across the reliability assurance system, led by the marketing director, quality assurance manager, and safety control manager

Comment

Passing on a quality-first organizational culture to the next generation

My workplace is steadily fostering an organizational culture of rigorous compliance and seeing every task through to completion. As a foundation for this culture, we are enhancing education, training, and study sessions to raise compliance awareness and share and expand specialist knowledge. Personnel also visit the Sawai Group's drug product manufacturing sites each month, engaging in face-to-face dialogue and building strong relationships of trust. We value creating an environment that encourages proactive information sharing and allows everyone to offer opinions or seek advice without hesitation. We also review procedures against actual working practices and promote standardization to prevent dependence on specific individuals and avoid incidents before they occur. Going forward, I will pass on to junior colleagues the importance of quality assurance that fulfills our accountability to patients and all other stakeholders. Through attentive communication with both internal and external stakeholders, I will contribute to deeper relationships of trust and stronger collaboration.



Hiroki Kido
Quality Assurance 1 Department
Reliability Assurance Division
Sawai Pharmaceutical Co., Ltd.

Sales and marketing

Established competitive advantages

- Timely and appropriate provision of information through nine branches nationwide
- Strong collaboration with pharmaceutical wholesalers and sales companies
- An extensive range of drug information materials

Initiatives for stronger advantages

- Promotion of accurate information provision through collaboration between medical representatives (MRs) and supporting internal departments
- Strengthening of the stable supply system through collaboration with pharmaceutical wholesalers and sales companies nationwide
- Enhancement of materials promoting the proper use of the Company's products and providing patients with information on taking their medications

Comment

Providing accurate information as a bridge between Sawai's teams and the medical field

In my workplace, we strive to accurately understand the needs of patients and healthcare professionals through our daily sales activities and provide information promptly. To deliver accurate information, I thoroughly update my pharmaceutical knowledge and carefully verify information while actively learning from the outstanding work of colleagues and incorporating it into my own activities. When interacting with healthcare professionals, I always consider what to say and when from their perspective as I work to become a trusted medical representative. I reliably communicate the feedback obtained from healthcare settings to Sawai's teams, using it to further improve our products and materials. I believe my mission is to serve as a bridge between Sawai Pharmaceutical and the medical field by creating a two-way connection between frontline needs and internal initiatives.

I will continue passing on the knowledge and experience I have inherited to junior colleagues and boldly taking on new challenges without ever becoming complacent.



Aoi Mizumoto
Nagoya Branch
Sales Division
Sawai Pharmaceutical Co., Ltd.