

Sawai Group's strengths



Research and development

R&D expenses
¥12.2 billion
 Sawai Pharmaceutical

Number of patents held
53
 Sawai Pharmaceutical

Strength 1 **Formulation technology capabilities based on human assets with expertise in API properties and formulation technology**

One of our Group's major strengths is our formulation technology capabilities, one aspect of which is collecting the latest information related to APIs and formulation from throughout the world, and this makes it possible to conduct development in line with ICH Guidelines. Furthermore, we actively take on research that will lead to future development themes and work to accumulate and expand our formulation technology. We also strive to provide drugs that meet the needs of healthcare professionals and patients using SAWAI HARMOTECH®, a series of formulation technologies born from this research.

Strength 2 **Ability to research and analyze patents of original drugs**

By utilizing both human assets with extensive experience in patent invalidation trials and proceedings and internal and external patent databases, we implement an extremely advanced patent strategy. We develop the best patent strategy for new issues in collaboration with attorneys who specialize in intellectual property.

In recent years, we have also been keeping an eye on intellectual property trends in the U.S. and Europe and leveraging those trends for our intellectual property strategy in Japan.

Initiatives

- Apply SAWAI HARMOTECH® technology to newly developed products
- Conduct joint research on bioequivalence prediction technology with independent research institutes
- Use digital technology to increase operational efficiency
- Increase quality of evaluation technology and test-method development



Procurement

Suppliers
 Procure a wide range of raw materials from around
500 companies in 30 countries
 throughout the world

Strength 1 **Strong new product API research and procurement abilities**

As for APIs used in new development, we undertake various activities such as searching for APIs throughout the world and examining production facilities and quality. We also conduct analysis and trial production of pharmaceuticals using samples of these APIs. We use APIs that meet our own standards, which are even higher than those of the Ministry of Health, Labour and Welfare. The API Sourcing Group, whose members have experience at new drug manufacturers and API trading companies as well as knowledge of formulation, provides support for research and procurement as specialists in purchasing.

Strength 2 **Selection and procurement of raw materials with primary emphasis on quality and safety**

We confirm that quality management systems meet Sawai standards by inspecting API manufacturer factories and checking that manufacturing is carried out in an appropriate environment and there is appropriate analysis of quality controls. We also release information on the country and factory where APIs are manufactured to provide healthcare professionals with peace of mind. In addition, we actively undertake multisourcing of API in order to ensure stable procurement.

Initiatives

- Expand application and screening processes and undertake multisourcing for new application items
- Continue to work to reduce costs in response to rising prices of raw materials, other materials, etc.
- Conduct GMP audits of API manufacturers and manufacturing subcontractors



Production and reliability assurance

Production capacity
18.5 billion tablets
 Sawai Pharmaceutical

Number of products approved to manufacture
Approx. 710
 Sawai Pharmaceutical

Strength 1 **Manufacturing know-how for high-mix, low-volume production**

To produce various types of generic drugs using the same machinery, it is vital to possess the know-how to prevent the mixing of principal ingredients. For tablet presses that form granules into tablets, it takes almost an entire day to switch between products, and Sawai ensures quality by validating each cleaning procedure. This know-how related to specifically validating generic drug production processes and managing production makes it possible to conduct high-mix, low-volume production while ensuring consistent quality.

Strength 2 **Working to become a trusted company**

We are working to foster a culture that values legal compliance and quality by designating the third week of each month legal compliance week and providing all employees, including officers of the various Sawai Group companies, with opportunities to continue their study of such topics as the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act), GQP/GMP ministerial ordinances, production controls, and quality controls.

We are aiming to become a trusted company by realizing an open, honest organizational culture through compliance education and similar activities.

Initiatives

- Increase production to eliminate limits on shipments
- Ensure the construction of new facilities and launch and transfer of production
- Work to improve yields through by scaling up
- Strengthen quality control through systems
- Improve retention rate through aggressive recruiting and expanded education and training



Sales and marketing

Number of MRs
Approx. 370
 Sawai Pharmaceutical

Number of products on sale
Approx. 770
 Sawai Pharmaceutical

Strength 1 **Provision of accurate information**

We provide information to patients and healthcare professionals through the following channels; approximately 370 medical representatives (MRs); the Medical Information Center, an inquiry desk open 24 hours a day, 365 days a year; and a website. As well as providing accurate information to all healthcare professionals, MRs are also responsible for collecting information on the side-effects and safety of drugs and providing feedback to the medical community.

Strength 2 **Extensive product lineup**

The lineup of products offered by our Group companies extends to about 770 products. Our ability to not only collect and provide information on various diseases, and in a wide range of fields, but also to broadly meet the treatment policies and needs of healthcare professionals, which is possible because we market numerous products, is another strength of the Sawai Group.

Because of our continuing training for MRs that covers various products, MRs acquire extensive knowledge. Furthermore, it is precisely because of our wide lineup of products that we can propose multiple drugs to treat the same diseases and more concomitant drugs.

Initiatives

- Improve the efficiency of visits by promoting area marketing
- Conduct promotion activities for healthcare professionals using a wide range of information provision tools
- Restore and improve trust through sincere, meticulous sales activities
- Build a foundation for stable supply by maintaining product value

Message from responsible officers

We are implementing numerous ingenious mechanisms to deliver high-quality generic drugs to patients through collaboration among various departments and divisions, including those involved in R&D, intellectual property, reliability assurance, manufacturing, and sales/marketing. Through these initiatives, we will contribute to a stable supply of generic drugs, part of the social infrastructure for an aging society.



Research & Development Division

Aiming to develop high value-added formulations selected by patients and healthcare professionals

In the R&D Division, we are moving forward with creating proprietary formulation and analysis technologies based on the latest science and technology knowledge, with the aim of developing high value-added formulations that are selected by patients and healthcare professionals. Along with reducing development costs through various measures, such as creating formulation evaluation technologies in collaboration with independent research institutes both in Japan and overseas and increasing research efficiency through digitalization, we are promoting the development of formulations suited for stable production with an eye on product life cycle.

The new knowledge and technology obtained from product development leads to more patents. It is also linked to the growth of both researchers themselves and the Company through proactive endeavors such as presenting reports at academic conferences and obtaining academic degrees, as well as through the increased recognition of Sawai's proprietary technology achieved by bringing SAWAI HARMOTECH® and other technologies under one brand.



Shoji Yokota, Ph.D.
Director,
Senior Managing
Executive Officer,
Group Chief Research
& Development Officer



Intellectual Property Division

Adding new technology to Sawai's proprietary formulation technology SAWAI HARMOTECH®

Some time ago, most of the formulation methods for particular GE drugs were patented in line with the management strategy of that time. In recent years, however, there has been a substantial increase in patents for general purpose formulation technology that can be applied to various drugs. We are moving forward with branding this general purpose formulation technology as SAWAI HARMOTECH®, and in fiscal 2023, new tablet printing technology, OD tablet evaluation methods, and other technologies were added to the brand. We are also developing proprietary technology for nitrosamines, a recent hot topic, and have already applied for several patents.

This technology is cutting edge for the times, and we are not only making use of it within our company but also considering collaboration with other companies. I would like to maximize the value of Sawai's intangible assets in this way. Therefore, there is an urgent need to develop human resources who can move these measures forward, and we are working with other divisions to address this issue.



Nobuko Sugimoto
Senior Executive Officer,
Group Chief Intellectual
Property Officer



Reliability Assurance Division

Working to retrain employees in response to inappropriate testing

Taking the inappropriate testing at the Kyushu Factory seriously, the Reliability Assurance Division is working to provide training on the PMD Act, drug production controls, and quality controls throughout the Company in order to once again raise awareness of laws, ordinances, and the GMP compliance spirit. Furthermore, head office staff discuss the sharing of issues at workplaces and countermeasures during their monthly visits to factories in order to reinforce collaboration between the head office Quality Assurance Department and factories.

At the same time, we are revising our audit methods, such as adding independent GMP/GQP experts to auditors to regain and improve trust in Sawai's overall production process, including API and formulation subcontractors. In addition, we are introducing a system of such activities as event controls, including ones related to deviations and recurrence prevention, and responding to inquiries from healthcare professionals.



Toshiomi Nakate, Ph.D.
Executive Officer
Group Chief Quality
& Safety Officer



Manufacturing Division

Expanding and reinforcing facilities to achieve a production capacity of 25.0 billion tablets or more

We are working to reinforce facilities, particularly at the Sawai Pharmaceutical's Daini Kyushu Factory and Trust Pharmatech, in order to achieve the production capacity of at least 25.0 billion tablets stated in our long-term vision. To operate the expanded production facilities under proper quality management, we plan to add more than 100 new workers in fiscal 2024 through new graduate and mid-career hires. We will lower costs and increase production efficiency through such initiatives as introducing quality and production-related systems, improving quality in collaboration with other divisions, and introducing multisourcing for main raw materials.

Through these initiatives, we will construct a system to eliminate generic drug instability and achieve a stable supply of high-quality products, which is one of our major social missions.



Toshiya Hasuo
Senior Executive Officer
Group Chief
Production Officer



Marketing Division

Working to regain the trust of medical facilities, wholesalers, and retailers

In light of the announcement of inappropriate testing and related administrative sanctions in fiscal 2023, the Sales Division worked to regain trust by apologizing to medical institutions and sincerely explaining our countermeasures.

At the current time when the drug supply remains unstable, there are high expectations for the Company, and we will not only properly communicate our various initiatives to offer a stable supply while maintaining product value but also aim to win high praise as the generic drug manufacturer that makes the greatest contributions to healthcare. To win the trust of medical facilities, wholesalers, and retailers, we will reinforce meticulous sales activities and area marketing and continue to evolve as both a generic drug manufacturer that can make contributions that meet diverse needs and the manufacturer with the top supply of prescription drugs.



Seiji Nishimura
Senior Executive Officer
Group Chief
Marketing Officer