

Society

Quality management

Sawai Pharmaceutical

By conducting unannounced audits each year, Sawai Pharmaceutical confirms that its factories can pass inspections by government authorities whenever they may occur. Similarly, Trust Pharmatech's manufacturing locations, where operations were newly launched in fiscal 2022, are managed at the same level as Sawai Pharmaceutical factories, and similar audits have been started.

In terms of the quality of APIs, we rigorously check whether each manufacturing factory complies with Good Manufacturing Practices (GMP) stipulated by law using our own standards by conducting onsite verifications, etc. of API manufacturing sites for some 300 ingredients (a total of approximately 500 manufacturing sites), and only use APIs that have passed the verifications.



Quality audit

Quality management (Sawai Pharmaceutical)

<https://www.sawai.co.jp/medicine/sawaigenetics/quality/>
(Japanese language only)

Main items

- API quality
- Quality management system at factories
- Response to PIC/S
- Conduct drug use-results surveys

Video explaining quality-related initiatives (Sawai Pharmaceutical)

https://www.sawai.co.jp/medicine/sawaigenetics/quality_movies/
(Japanese language only)

Upsher-Smith

Upsher-Smith consistently manufactures products of permissible quality by undertaking production and quality management in line with the quality management system (QMS) required by U.S. government regulations.

For all raw materials and final products, the Company conducts testing in line with FDA approval standards. Furthermore, a comprehensive evaluation of final products is conducted using an annual product review.

The Company also makes comprehensive self-checks of equipment/systems regularly in line with the in-house procedure manual. At new factories, electronic batch records are being introduced to further increase quality.

Preventing counterfeit pharmaceuticals

Upsher-Smith

Upsher-Smith and its pharmaceutical supply chain are promoting initiatives required under the Drug Supply Chain Security Act (DSCSA). The requirements under the DSCSA establish a chain of custody for each saleable unit (primarily bottles/blisters) in accordance with the Act.

As the deadline for becoming serialization compliant is November 27, 2023, the Company is moving forward with related preparations. Furthermore, for all our bottles, the seal clearly indicates if it was improperly opened.

Communication with patients

Sawai Pharmaceutical

Patient Support Office

Sawai Pharmaceutical's Patient Support Office is the only in-house department permitted to directly communicate with patients. Because many inquiries by patients are due to vague concerns about treatment and medicine, the Patient Support Office first works to accept those concerns.

The goal is to alleviate the worries of patients, which helps them be more positive about their treatment and move forward with appropriate treatment.

Sawai Kenko Suishinka, Website for general population

Our corporate website offers knowledge and information that helps patients find peace of mind regarding drugs, and this information includes basic information on generic drugs and our quality initiatives. We also post a variety of healthcare-related information, including information on pre-disease and preventive measures, disease awareness, and health promotion through pages called Sawai Kenko Suishinka.

If using the PHR management application SaluDi to keep PHR, it is possible to easily access the Sawai Kenko Suishinka from within the app.



Top page of Sawai Kenko Suishinka (Japanese language only)
<https://kenko.sawai.co.jp/>

Human rights and human resources

The Sawai Group has established a Code of Conduct to define its approaches toward respect for human rights, consideration for the health and working environment of employees, and fair and appropriate treatment of employees. In line with the code, the Group is actively and proactively addressing these issues.

Details of policies and initiatives are reported on the website.

Human rights and human resources

<https://global.sawaigroup.holdings/sustainability/human/>

Main items

- Initiatives to respect human rights
- Fair and appropriate treatment
- Consideration for the health and the working environment of employees
- Enhancing diversity
- Consideration for employees' nursing care, childbirth and childcare
- Policy on human asset development
- Training system
- Policy on ensuring workplace diversity

Disclosed data

- Percentage of paid leave days used
- Percentage of female managers (Sawai pharmaceutical only)
- Turnover rate
- Percentage of employees with disabilities (Sawai pharmaceutical only)
- Number of employees taking nursing care leave, maternity leave, or childcare leave
- Number of participants in training

Policy on respect for human rights

As a healthcare corporate group closely related to life, our Group is committed to respecting the human rights of various stakeholders, including patients, employees in Japan and overseas, and business partners, and supports the International Bill of Human Rights and the International Labor Organization's Declaration on Fundamental Principles and Rights at Work, and promotes initiatives in accordance with the United Nations Guiding Principles on Business and Human Rights.

Sawai Pharmaceutical Group companies in Japan

In the Group companies in Japan, we recognize employees and labor unions as important stakeholders and maintain sound and good labor-management relations. In addition, we are striving to raise awareness of human rights by clearly stating in our Code of Conduct that we oppose any form of discrimination on the basis of race, gender, nationality, ethnicity, religion, ideology, political opinion, sexual orientation, disease, disability, and refuse any involvement in the infringement of human rights.

Upsher-Smith Overseas Group companies

Since our overseas Group companies are more racially diverse than the Group companies in Japan, they devote special efforts to respect for diversity, including racial diversity, which they recognize as an important social issue. At Upsher-Smith Laboratories (USL), a Group Company based in Minnesota, where the Black Lives Matter movement in 2020 originated, members of senior management have taken the initiative with the belief that the diversity of employees is a source of the Company's strengths and greater performance. In addition, the advisory council related to four minorities (Blacks, women, Southern Asians, and Hispanics) on four minority groups (Blacks, Women, South Asians, and Hispanics) meets regularly to identify the potential biases of employees and devise measures to increase mutual understanding between them, and the Employee Resource Group is working on women and LGBTQ+ issues.

Employee engagement survey

In 2022, the Group conducted an employee engagement survey, which is conducted every several years. The results confirmed not only that employees possess a stronger sense of identification with the Company and its management policies compared to the previous survey but also that we have maintained a high level of satisfaction as an employer. We consider this proof that even in the harsh business environment in recent years, employees are conducting their work with a sense of pride in and responsibility for providing generic drugs.

However, there were signs of a decline in collaboration between departments and sense of mutual help. Through this survey, we confirmed that there is engagement with the Company and work but also that there are issues, such as employees feeling stress regarding greater work volume and difficulty of their work and employees having a low desire to take on challenges because they are busy with the work in front of them.

These issues were reported to the Management Meeting and improvements were deliberated on. A summary of this is shared with employees via the in-house Intranet. We will continue to conduct this survey because it leads to a stronger sense of unity and engagement by delivering employee opinions to management and resolving problems.