

[Important Issues] Quality and Customer Safety

Policy and Basic Approach

The Nippon Kayaku Group has established a basic policy called the Declaration on Environment, Health and Safety, and Quality and has built a quality management system to continually deliver the best products that satisfy customers. We deploy various initiatives for quality across the entire company and work on quality assurance and quality improvement activities to increase customer satisfaction. We have also integrated the quality management systems of our Head Office and production bases for each of the business groups, aiming to prevent customer complaints and process abnormalities by further enhancing our quality improvement activities.

The Declaration on Environment, Health and Safety, and Quality

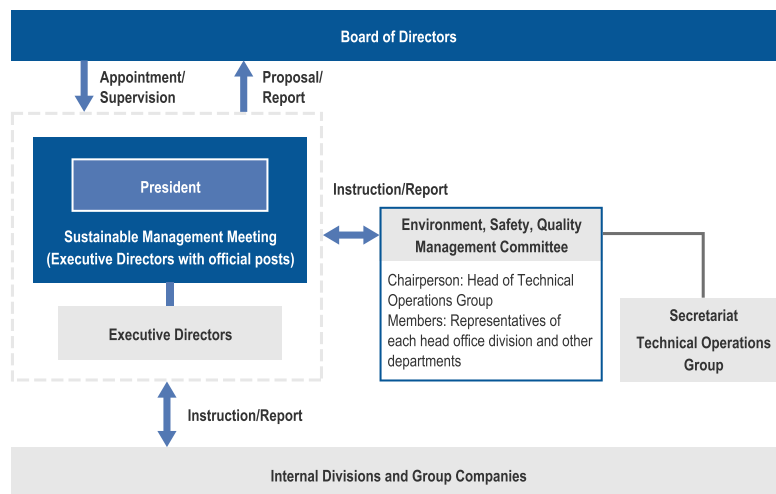
> [The Declaration on Environment, Health and Safety, and Quality](#)

System

Nippon Kayaku Group has established the "Environment, Safety, Quality Management Committee" as a specialized committee of the Sustainable Management Meeting to oversee quality assurance.

The committee is composed of the heads of the production or quality assurance department of each business group and the administrative departments at Head Office. It deliberates the issues related to the quality assurance policies and the status of quality improvement activities and countermeasures against them, reports the results to the Sustainable Management Meeting and strives to enhance the entire Nippon Kayaku Group's quality improvement activities.

Furthermore, each business group has established its own in-house quality assurance department as a cornerstone organization for the enhancement of its quality assurance system.



Acquisition of International Certification

The Nippon Kayaku Group has obtained international certification for its quality assurance systems in order to develop high-quality products and services that earn more trust and give more satisfaction to customers.

For the ISO 9001 international standard on quality management systems, we acquired certification for the Fukuyama, Asa, Tokyo and Kashima Plants in 1995. Subsequently, to further increase our customer satisfaction by conducting quality assurance activities in a comprehensive manner for our R&D, manufacturing, sales and service operations, we have acquired integrated ISO 9001 certification for the business groups and R&D department. Furthermore, we are striving to acquire the certification at our Group companies in Japan and abroad and enhancing our global quality assurance system in line with our business processes.

The members of the Functional Chemicals Group, including the Fukuyama, Asa and Tokyo Plants, the Head Office and laboratories, and Taiwan Nippon Kayaku Co., Ltd., started to operate their quality management systems in an integrated manner in October 2020 and acquired integrated ISO 9001 certification in July 2021.

The Pharmaceuticals Group, including the Takasaki Plant and the Pharmaceuticals Research Laboratories, acquired integrated certification for ISO 9001 and ISO 13485 (standard on quality management systems for medical equipment and in-vitro diagnostics) to enhance its quality assurance system. Moreover, the Takasaki Plant acquired a manufacturing license based on the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (GMP Ministerial Ordinance) and also acquired relevant certification in the United States and Europe (EU).

The Safety Systems Group, including the Himeji Plant and the Safety Systems Development Laboratories, has obtained certification for the IATF 16949 international standard on quality management systems set by the automobile industry's International Automotive Task Force (IATF). Outside Japan as well as in the country, Nippon Kayaku Group companies have obtained this certification in order to deliver products of even higher quality.

The Agrochemicals Division, including the Kashima Plant and the Agrochemicals Laboratories, started to operate its quality management systems in an integrated manner in March 2021 and obtained integrated ISO 9001 certification in August 2021 to further strengthen its quality assurance system.

List of the Nippon Kayaku Group's Business Sites with Certified Quality Management Systems

Business site	ISO9001	ISO13485	IATF16949
Fukuyama Plant	●		
Asa Plant	●		
Tokyo Plant	●		
Functional Chemicals Group (excluding the Polatechno Division)	●		
Functional Chemicals R&D Laboratories	●		
Taiwan Nippon Kayaku [Functional Chemicals Business]	●		
Polatechno Division	●		
Joetsu Plant	●		
WUXI POLATECHNO OPTICS	●		
Takasaki Plant	●	●	
Pharmaceuticals Group	●	●	
Pharmaceuticals Research Laboratories	●	●	
Himeji Plant			●
Safety Systems Group			●
Safety Systems Development Laboratories			●
Kashima Plant	●		
Agrochemicals Division	●		
Agrochemicals Laboratories	●		
NIPPON KAYAKU FOOD TECHNO	●		
MOXTEK	●		
Dejima Optical Films	●		
RaySpec	●		
KAYAKU Advanced Materials	●		
KAYAKU CHEMICAL (WUXI)	●		
WUXI ADVANCED KAYAKU CHEMICAL	●		
Kayaku Safety Systems Europe			●
Kayaku Safety Systems (Huzhou)			●
Kayaku Safety Systems de Mexico			●
Kayaku Safety Systems Malaysia			●

GMP-related Certification

The Takasaki Plant is licensed as a manufacturer under the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (GMP Ministerial Ordinance) and has also obtained relevant certification in the United States and Europe (EU).

◆ GMP Ministerial Ordinance*-related Certification

Business site	Major countries
Takasaki Plant	Japan, the United States and Europe

* The GMP Ministerial Ordinance was promulgated by the Ministry of Health and Welfare in 1980 and provides for the management procedures to be followed for the manufacture and supply of high-quality pharmaceuticals and medical equipment.

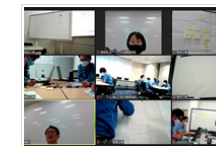
Promotion of Quality Assurance and Quality Improvement Activities

The Quality Management Division of the Technical Operations Group heads up the Nippon Kayaku Group's quality assurance and quality improvement activities.

We conduct quality assurance activities to enhance and improve employees' quality management skills to ensure stable quality through education and to reduce customer complaints and quality-related process abnormalities.

As a quality improvement activity, we are enhancing quality education by promoting in-house training for managers and practitioners of quality risk management and encouraging them to attend external quality training. To our laboratories we have introduced quality engineering and statistical methods to improve on-site design and development capabilities.

To verify that the Nippon Kayaku Group's quality management system is operating effectively, we conduct quality assessments of business sites in Japan and Group companies, including those outside Japan.



A photo of the "Why-Why Analysis Practical Training" online workshop, which connected all domestic business sites online. Participants learned some "why-why analysis" practice methods, doing exercises on examples from their own workplaces to deepen their understanding of analysis methods.

Quality Assurance and Quality Improvement Activities at Each Business Site

Each business site of the Nippon Kayaku Group deploys various types of quality assurance activities.

Also, we are building a database of quality process mishaps so that they can be shared across our business sites.

Quality Assurance Activities

- Quality patrol
- Trend management (visualization)
- Activities to prevent recurrences of quality troubles (why-why analysis, etc.)
- Enhancement of quality management technologies

Quality Improvement Activities

- Quality risk assessments
- Improvement of design and development capabilities
- Statistical analysis method ("Field Data Analysis—Learning Through Experience")
- Activities to prevent recurrences of quality troubles (why-why analysis, etc.)

Quality Risk Assessments

Whenever changes are made to a production process, such as an existing worker handing over to a new person or the installation of a new machine (that is, whenever so-called “4M” changes are made), we conduct a quality risk assessment to prevent quality issues before they occur. (The 4M changes means changes to “man,” “machine,” “material” or “method.”)

Educational Activities for Quality Assurance and Quality Improvement

As educational activities for quality assurance, we offer the “Field Data Analysis - Learning Through Experience” program geared toward researchers and developers for practical training on statistical analysis methods. We also send employees to take part in outside quality training and provide outreach teaching at plants as internal auditor training. Group training could not take place in person at the Hisho Training Center in FY2020 and FY2021 due to the pandemic but with the help of online videoconferencing we were able to connect all domestic business sites to hold training on measures against human error and practical training on “why-why analysis.” Given the advantages of holding the events online without the need for travel or accommodation, many people were able to join, making the training a big success.

At each of our plants, we utilize quality control (QC) methods such as using management diagrams and carry out quality patrols as part of our daily quality control activities to reduce customer complaints and quality process abnormalities.

Activities to Prevent Recurrence of Customer Complaints and Quality Process Abnormalities

In order to prevent the reoccurrence of similar customer complaints and quality process abnormalities, we encourage the use of Nippon Kayaku’s “why-why analysis” manual and the execution of the analysis at each of our workplaces. We have also built a database of quality process abnormalities on a companywide basis. In addition, we have published English and Chinese versions of the manual and are promoting “why-why analysis” also at Nippon Kayaku Group companies outside Japan.

Published the “why-why analysis” manual of the Nippon Kayaku Group

The Quality Management Division analyzed the quality abnormalities that had occurred in the past and found out that there were many similar cases due to a lack of ability to investigate the root cause of problems. We have therefore introduced “why-why analysis” with the aim of accurately understanding the relationship between cause and effect, identifying the underlying root cause and preventing the reoccurrence of similar cases. The first edition of the “why-why analysis” manual was created in Japanese by members selected from each plant, and the manual was subsequently translated into English and Chinese for use by Nippon Kayaku Group companies outside Japan.



History of our quality improvement activities

Nippon Kayaku’s initiatives for improving quality began with the voluntary introduction of statistical approaches to QC activities by plant engineers in 1948.

After receiving the Deming Prize in 1963, Nippon Kayaku organized its very first In-house QC Circle Conference in 1966 as an opportunity for employees to present the results of their QC activities. Since then, we have expanded the scope of these activities and changed the name of the event, first to the “Small Group Activity Meeting” open to all employees and then to the “Meeting of the Movement for Tomorrow,” inviting participants to make presentations on a wider range of themes, including not only quality improvement but also operational reforms, cost reductions, 5S activities, next-generation development, energy conservation, health and safety improvement, and environmental conservation. Nippon Kayaku Group companies outside Japan also now participate in the Meeting of the Movement for Tomorrow, as the event provides them with an opportunity to present their activities and interact with other Group bases. Since 2014, the QC activities have been revamped into small-group activities that focus not only on improvement but also on human resource development and sustainability.

Global quality control within the Safety Systems Group

The Safety Systems Group supplies automotive safety components to customers around the world, for which it needs to provide and guarantee a consistent standard of quality. The Safety Systems Group has production facilities worldwide, and the Quality Assurance Division at the Head Office and the Himeji Plant, the mother factory for the Safety Systems Business, provide each of the bases engaged in the business with quality management-related support. The Himeji Plant cooperates with other bases to grasp technological changes occurring in the industry and support them in adapting to those changes.

The Quality Assurance Division leads the bases in conducting quality improvement activities to build a global quality assurance system for the Group and increase and enhance its quality sensitivity.



Technical interns from Malaysia and members of the Himeji Plant's Quality Assurance Department

Initiatives

Pharmaceuticals Business

In the Pharmaceuticals Business, we have a website to provide patients and their families with useful information.

◆ Medical Information Service Center and Securing Customer Trust

The Medical Information Service Center accepts toll-free calls from patients and medical professionals with various questions relating to our pharmaceuticals and medical devices, such as anti-cancer drugs, treatments for autoimmune diseases and intravascular embolic materials. Staff at the Medical Information Service Center work diligently to provide accurate responses to each inquiry to ensure that all of the products supplied by Nippon Kayaku will perform at highest possible level. We also conduct surveys to check whether our responses meet the expectations of customers as part of our continual improvement initiatives.



Medical Information Service Center

Additionally, staff work with medical representatives (MRs) that visit medical facilities to ensure they can provide information that is beneficial to patients, while customer requests and opinions are communicated and reported to each relevant department in charge within the Company. The Medical Information Service Center is committed to improving medical care under the slogan, “Provide proper usage information and improve customer satisfaction in all situations.”

◆ Information Website

“IBD-INFO”

This is an information site for IBD patients.

IBD stands for inflammatory bowel disease. Generally, IBD refers to ulcerative colitis and Crohn’s disease. The IBD-INFO microsite provides easy-to-understand commentaries from healthcare professionals about the symptoms of ulcerative colitis and Crohn’s disease as well as about testing, diagnosis, treatment and daily care, among other topics.



The microsite features a host of different content about causes and symptoms, treatment methods, daily care, and public subsidies for defraying healthcare costs, so as to provide patients with an extensive resource of need-to-know information. Additionally, articles on the latest IBD treatment and care featuring interviews with specialist physicians are regularly published on the microsite as well.

The goal of this microsite is to broaden patient understanding and empower patients with the correct knowledge so that they will be more motivated during the treatment process.

> [IBD-INFO \(Japanese\)](#)

“RHEUMATISM RA-RA-RA”

The microsite “RHEUMATISM RA-RA-RA” was launched in February 2015 to educate people living with rheumatoid arthritis. This site was created with a commitment to serving as a close, everyday partner for people with rheumatoid arthritis by providing them with a place to turn to as a source of support.

The site, which is also compatible with smartphones, offers an easy-to-use platform that is user-friendly, including oversized icons that are easy to touch. The site offers various content covering the topics that patients want to know about, including the causes of rheumatoid arthritis, symptoms and treatment options, along with the medical costs involved and care services.

Additionally, the site provides information about Japan’s high-cost medical care benefit system accessible for the treatment of rheumatoid arthritis and also a medical cost reimbursement calculator. The video collection of exercises for rheumatoid arthritis patients selected by the editorial supervisor, who is a specialist in rheumatology, can be watched at home, allowing patients to try them out at their convenience.

The phrase “Feeling Happy” and the four-leaf clover mark form the logo used by Nippon Kayaku’s immunology business. We hope to play an integral role in patients’ lives, not least by providing them with emotional support. Offering new approaches, we support them in the treatment process and in improving their quality of life, hoping to help each patient live their life while “Feeling Happy”

> [RHEUMATISM RA-RA-RA \(Japanese\)](#)



“Breast Cancer Info Navi”

Breast Cancer Info Navi was launched in October 2006 as an informative website for breast cancer patients.

Containing information provided by specialist physicians and pharmacists, this website is designed to share such information with all women, not just breast cancer patients and their families.

The website is designed to help all women live the life they want.

> [Breast Cancer Info Navi \(Japanese\)](#)



Agrochemicals Business

◆ Contributing to Agricultural Production with Our New Insecticide (FINESAVE®)

Launched in June 2018, FINESAVE® is a new type of insecticide that is highly effective in killing thrips, silverleaf whiteflies, rust mites, cabbage moths and other pests that plague leeks, onions, tomatoes, strawberries, white radishes, cabbage and other types of produce.

Because FINESAVE® is a new kind of agent that does minimal harm to useful insects and the natural enemies of these pests, it can be used during the growing season, when the use of agricultural chemicals has traditionally been restricted. We are holding discussions with local instructional organizations regarding crop systems, the use of agrochemicals, etc. so that we can suggest ways to use this product efficiently and effectively while taking maximum advantage of its attributes. We are working hard to ensure that this agent can contribute to actual agricultural production in the future.



◆ Initiatives for Improving Crop Quality

For higher-quality crops and the production of safer crops, the Agrochemicals Division is proposing ways to use our existing products Leaf Guard® and Fumon® in combination with our new product FINESAVE®, which went on the market in June 2018 and is effective in killing such pests as thrips, rust mites and cabbage moths.

We are conducting marketing and sales promotion activities in which we propose the use of FINESAVE® and Leaf Guard® (which is effective on a broad range of eggs, larvae and adult insects) on major cabbage and Chinese cabbage pests like cabbage moths, which have thus far been fairly resistant to existing agrochemicals. In the activities, we also propose the use of FINESAVE® and Fumon® (which has the capabilities of a spiracle-blocking agent plus a spreading agent and is safe enough to use over and over until harvest time) on strawberries and the like.

We will continue our untiring efforts to improve the quality of future crops.



> [Website of the Agrochemicals Division \(Japanese\)](#)