

Society

Providing Responsible Products, Services, and Solutions

Pursuit of Quality and Trust

Quality Management

Group Quality Management System

At Sysmex, under the supervision and management of the President, the Quality Assurance Department leads our quality management efforts. More specifically, we hold a monthly quality meeting where the managers of our Development, Production, Marketing, and Service Departments explore what we can do to monitor the quality, effectiveness, and safety of our products and services, along with improvement measures. We also hold Quality System Committee meetings regularly to review quality targets, responses to inspections by regulatory bodies, and a management review of instructions for output. This is part of our efforts to maintain the Group's quality management system and promote activities for improvement.

All our production facilities for final products* have obtained ISO 9001 or ISO 13485 certification. Of the 84 companies in the Sysmex Group, 34 have been ISO 9001 certified, and 21 have been ISO 13485 certified. In fiscal 2022, two cases of nonconformity were identified in an internal quality audit, and five cases during an external quality audit. Remedial action is being taken. In addition, we have been making efforts to improve quality by setting the numbers of recalls and FDA warning letters as indicators for monitoring the progress of sustainability targets.

* Wholly owned subsidiaries

► Status of Sustainability Targets Status of Sustainability Targets



For details, refer to ID 0910589004 on www.tuv.com/
(The applicable scope of activities and websites vary in accordance with the standard.)

► <https://www.tuv.com/japan/en/>

► [Quality Policy](#)

► [Product Security Policy](#)

Sustainable Improvement Programs

Compliance with Related Laws and Regulations in Each Country

Used in laboratory testing, Sysmex's products play a vital role in protecting human life and health. Sysmex has created a system that allows us to thoroughly comply with regulations worldwide, including the Japanese Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the In Vitro Diagnostic Medical Devices Regulation in the EU, the U.S. FDA's Quality System Regulation, and the Regulations on the Supervision and Administration of Medical Devices in China, as well as maintaining and improving the safety and quality of our products.

► [Chemical Substance Management of Products](#)

Reinforcing Structures for Maintaining and Enhancing Quality

In the product development process leading up to market launch, Sysmex verifies product quality by setting up five "quality gates."^{*1} We also conduct quality- and safety-related risk assessments during a new product's design and development phases, as well as when changes are made to the design of an existing product. If a high-risk event is noted, we act to eliminate it. Also, when marketing products manufactured by other companies, we verify their quality by conducting audits of the manufacturers and meticulously inspecting their products. In addition to these efforts, in the unlikely event of a product defect, we have systems in place to quickly identify and respond to any problems.

At factory sites, each month we monitor manufacturing processes and the status of supplier conformity. We instruct suppliers with high nonconformity rates to improve quality as needed, and we have a system to ensure quality through regular quality audits. In addition, our global quality complaint processing system allows us to gather quality information in a timely manner from markets around the world. When we receive information about a problem or malfunction, we immediately investigate the cause and cease distributing the product in question. If we need to take any corrective or preventive actions regarding a problem or malfunction, we promptly plan such actions in accordance with the Group's regulations, carry out the plan, and later verify the validity and effectiveness of the actions taken.

In 2021, in order to ensure the quality and traceability of our products, we started to utilize the Global Positioning System (GPS) and temperature data loggers^{*2} for the transportation of some reagents used in testing. In the future, we will sequentially expand the use of these methods to diagnostic reagents that require high quality assurance.

* 1 Product design assessment, process design assessment, evaluation by Product Quality Control Department, quality management system (QMS) checks during the manufacturing process, and inspections for mass-produced items

* 2 A measurement device equipped with a thermometer and a data logger

► [Product Quality and Vigilance Control System](#)

► [Project for Promoting Digitalization: Product Quality Improvement Activities Based on Reforming Services and Support](#)

Providing High Quality Products and Services through Third-Party Certification

To enhance its credibility, Sysmex is strengthening its quality assurance system regarding product inspection results.

Our Ono Factory is ISO 17034 certified. This international standard relates to the competence of reference material producers. This was the first such certification granted in the hematology field in Japan. It recognizes a manufacturer's ability to provide reference materials of the proper quality. This certification strengthens our credibility concerning the quality of data of our products and services, enabling our customers in global clinical laboratories to verify their own competence to provide proper test data.

Employee Training

Focusing on Specialized Quality and Safety Training

In addition to Quality Policy training, Sysmex provides regular quality management training for related departments, as well as specialized training on laws and regulations for employees in specific departments or job categories. In fiscal 2022, we provided quality training to a total of about 2,800 employees across Japan in the Group companies' various development, production, and marketing and service departments, as well as in ISO-certified business offices. We also held quality training at all production facilities for final products and ISO-certified business offices managed by our Group companies overseas.

Quality and Safety Information

Sharing Customer Feedback within the Group

Sysmex established the Quality Assurance Department, which controls information regarding the quality and safety of our products. Its function is to handle inquiries it receives from outside the Company, as well as to investigate and analyze the information it receives; to share this information with the Design, Manufacturing, and other divisions, and to improve quality. In addition, we have established a structure for incorporating this information in the next generation of products.



Product Recall and Repair Information Posted on Our Website

Sysmex posts information about product recalls and repairs on its website under "Important Product Notices."

Working Aggressively to Stamp Out Counterfeit Reagents

To assure accurate testing results, Sysmex asks its customers to use Sysmex-branded instruments and reagents together. In recent years, however, counterfeit Sysmex reagents have been found in circulation in some areas. The use of such reagents endangers the reliability of testing results and, in some cases, can be harmful to patients' health. For this reason, Sysmex continuously monitors markets for counterfeit reagents. When they are discovered, we work with local government institutions and judicial bodies to ensure the swift and thorough enforcement of our intellectual property rights.

▶ Intellectual-Property-related Activities to Protect Business Models (Japanese)

Enhancing Customer Satisfaction

Conducting Customer Satisfaction Surveys in Japan and Overseas

Sysmex conducts customer satisfaction surveys in various countries and regions, including China and Japan as well as major countries in the Americas, EMEA, * and the Asia Pacific region. These surveys use indices customized for each country and region in accordance with the products and services offered in them.

Sysmex America has received the Best Customer Satisfaction award for 16 consecutive years, as well as the Best System Performance and the Best Service awards in the hematology system manufacturer category, among the IMV ServiceTrak Awards organized by IMV, a specialist provider of market research to the medical imaging processing and the laboratory diagnostic industries. In addition, it has received a Supplier Legacy Award from its business partner Premier Inc. for its long-term contribution to the provision of products and services that help improve operational efficiencies in clinical settings at low cost.

Sysmex Shanghai won several awards for excellence at the Chinese Medical Device Industry Conference in recognition of superior product quality and after-sales service.

* Europe, the Middle East, and Africa



2022 BEST CUSTOMER SATISFACTION WINNER:
Sysmex America, Inc.

Customer satisfaction rating in the United States

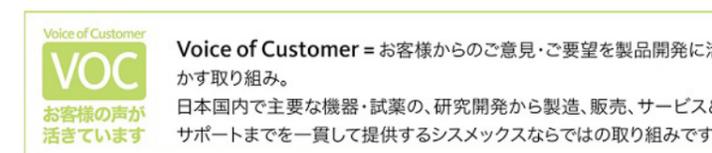
(On a scale of 1 to 10)

Fiscal 2020	Fiscal 2021	Fiscal 2022
9.28	9.27	9.4

* Research by IMV ServiceTrak

Efforts to Incorporate Customer Feedback in Our Products and Services

Requests and comments from customers are gathered by Sysmex's Voice of the Customer (VOC) Team. After analyzing this information from various perspectives, the results are provided as feedback to related divisions to utilize them in new product development and operational improvements. In fiscal 2022, we gathered feedback from some 13,600 customers in the Japanese market, and from many customers in foreign markets. We have received a positive response to instruments with new functions and equipment that we have added as a result of customer input, which is indicated by the VOC mark in our product catalog.



Providing Highly Satisfying User Training

Systemex provides training on instrument operation and maintenance for customers in each region as part of customer support. In response to the “new normal”, we have provided an online training system in various parts of the world in recent years, by which training can be live-streamed or attended on demand.

In addition, we have globally integrated, and begun providing, user training programs offered by Systemex America and Systemex Europe in a single training program under the brand name “Caresphere™ Academy”.



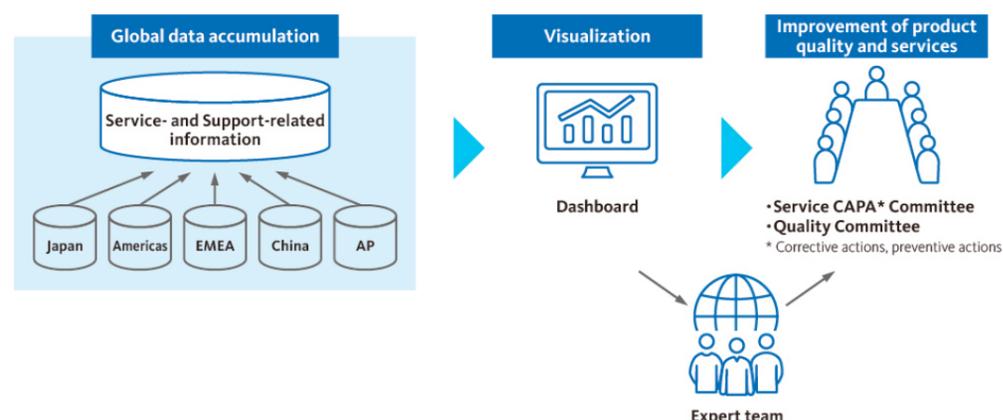
Online Training

Project for Promoting Digitalization

- Product Quality Improvement Activities Based on Reforming Services and Support -

Systemex supplies its products to over 190 countries and regions around the world. However, in the past, it has been difficult to obtain accurate information on instrument failures and service status. To address this issue, in 2019, people involved in services and support at different regional headquarters came together and started a project for restructuring these business areas.

In this project, we began accumulating global data on instrument failures and service status through common global codes created for service- and support-related information in each region. At the same time, we formed a team of experts to monitor data, speed up the quality and service improvement process, and proactively detect defects, reducing instrument failure rates.



Activities to Improve the Quality of Technical Services and Scientific Support Based on Training Reforms

As part of its training reform, Systemex introduced a virtual training space to train its technical service engineers and scientific support personnel across the world. This virtual training space enables them to participate in training and to experience and learn, through their avatars, about new software products from anywhere in the world. As they can share the operation of the software in a virtual space, all the participants can learn how to operate the software irrespective of where they are, even without physical terminals. We will continuously offer training in which the participants can effectively learn to provide high-quality technical services and scientific support across the world.



Disseminating Useful Information

Systemex disseminates valuable information to its customers in the Support Information section of its website in Japan. Systemex continually expands the functionalities of the website to ensure that customers can use the website to a greater extent, such as by adding an email magazine distribution service, which communicates the latest information, and “My Page” functionality, which enables users to manage content and their browsing history.



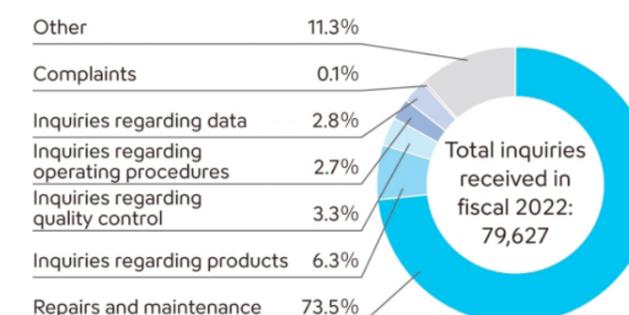
Support Information website (Japan)

Responding to Inquiries Rapidly and Responsibly

The Systemex Group has established regional customer support centers to reply quickly and carefully to inquiries, as well as to respond promptly to customer requests.

In Japan, we have established a Customer Support Center, where experienced staff members with expert knowledge respond to customer inquiries 24 hours a day, 365 days a year (separate agreement required for use). By creating a database containing maintenance histories and the details of past inquiries from customers for quick reference, the center responds to inquiries and requests rapidly and carefully.

Responding to Inquiries at the Customer Support Center



Scientific Activities

Systemex holds scientific seminars to impart the latest information about clinical testing in various countries and regions across the world. In Asia, we work with government agencies, including national health ministries and major academic societies, to conduct scientific activities designed to help improve the quality of clinical testing.

Holding Scientific Seminars for Medical Professionals

Systemex has held annual Scientific Seminars since 1978 to discuss topics selected from a range of medical research areas and to provide opportunities to share the latest information and knowledge. In 2022, a seminar on the theme of hematologic diseases was held in hybrid form, with both online and onsite participation, and around 3,500 people from all over the world attended. We globally distributed videos of the lectures after the seminar. We also conduct participant surveys in each country in order to determine medical issues and interests specific to countries and regions. This information is utilized to determine themes for future seminars or Group initiatives.

In addition, we have held many other seminars globally, in which a wide range of people participated. Through these initiatives, we aim to build trust-based relationships with medical professionals and help improve the quality of healthcare.

► Scientific Support Activities to Standardize and Increase the Quality of Clinical Testing

Activities for Patients and the General Public

Systemex set up the online scientific information website “Medical meets Technology” to provide information on the varied roles of technology in healthcare from a scientific viewpoint in an easy-to-understand format.

In addition, from the viewpoint of informed consent, product information for the NCC Oncopanel™, a testing system for cancer genome profiling, has been newly developed with easy-to-understand explanations for patients and their families. Such information was previously only available to medical professionals. In response to issues related to antimicrobial resistance (AMR), we are conducting a variety of initiatives, which include the global implementation of “#AMRfighter”, an awareness-raising activity, and widely distribute a scientific booklet titled “Proper Use of Antibiotics” directed at patients and the general public.

► Medical meets Technology (Japanese)

► Things You Should Know about Testing Using the NCC Oncopanel System (Japanese)

► What Is Antimicrobial Resistance? (AMR)?



Systemex Scientific Seminar 2022



Scientific Information Website: “Medicine meets Technology”

Society

Strengthening supply chain management

Supply Chain Management

Stable Supply of Products

In Japan, Systemex has developed an efficient production system for instruments by utilizing ICT to overcome global cost competition and ensure high quality for our products. The production of reagents, which are essential for daily testing carried out by medical institutions, has been expanded globally.

In order to ensure a stable supply of our products, we procure key raw materials from multiple sources and select production locations in accordance with the concept of “local production for local consumption”, thereby spreading out any risks. In addition, for emergencies, we have created mutual supply systems among factories and secured alternative transportation routes.

The resurgence of novel coronavirus infections has affected our business in many ways in recent years. In a tight supply situation for various raw materials, we obtained the cooperation of suppliers in prioritizing materials intended for healthcare. As a result, we could secure the purchase quantities of materials and increase inventories, enabling us to maintain a stable supply of our products. We also managed to maintain stable supplies during the prolonged disruption of global distribution by such measures as using new sea routes. In addition, in Japan, we’ve promoted initiatives for business continuity in an emergency. For example, January 2023 we started operations of new warehouses with a base-isolated structure resistant to various disasters.

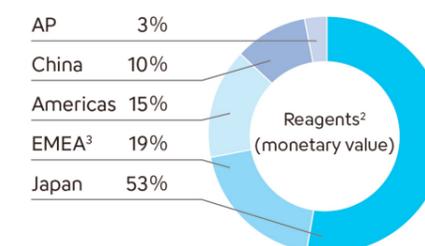
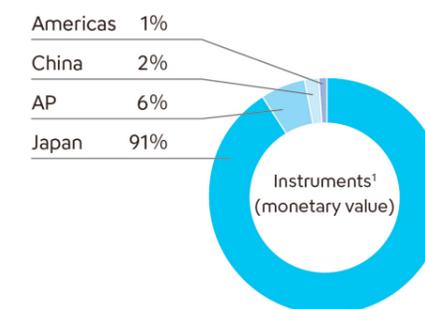
► Establishment of a Business Continuity Plan (BCP)

Conducting CSR Surveys

Systemex conducts CSR surveys of its business partners. For surveys of existing business partners, we use the CSR/Sustainable Procurement Self-Assessment Tool Set developed by Global Compact Network Japan, which covers a wide range of issues such as human rights, labor practices (including health and safety of employees), corruption, and the environment. We do not conduct business with new partners with inadequate CSR initiatives. In addition to CSR surveys, we hold management interviews with new business partners. We undertake the same sort of initiatives for overseas partners. In particular, personnel in charge of procurement make local visits to determine the status of child labor and workplace environments in order to confirm that no problems exist.

Each Group company also conducts regular surveys of its business partners. Systemex Europe conducts CSR surveys of all new business partners regarding such aspects as human rights and green procurement. Jinan Systemex Medical Electronics also holds quarterly meetings with its business partners to conduct risk assessments, in addition to carrying out environmental and occupational health and safety surveys. Systemex Wuxi encourages its business partners to strengthen environmental and safety management when carrying out periodic risk assessments of them.

Procurement Region Analysis (Fiscal 2022)



1 Analysis of procurement regions for parts

2 Regional analysis of Group companies that purchase raw materials (excluding purchased products)

3 Europe, the Middle East, and Africa

Fiscal 2022 Results

The response rate for surveys of primary raw material suppliers conducted in fiscal 2022 was 90%, maintaining the previous fiscal year's high response. Based on the results of the CSR surveys in the previous fiscal year, we identified items with low scores or high risks and followed up with our business partners with suggestions for improvement.

We are also considering measures to strengthen suppliers' risk management. In FY2022, we conducted on-site verification of three primary suppliers on a trial basis, in addition to the CSR surveys. Continuing from the prior year, we expanded the CSR surveys of secondary suppliers, conducting CSR surveys of 69 secondary suppliers jointly with 13 primary suppliers.

- ▶ [Global Compact Network Japan Common version of CSR survey form "CSRProcurement Self-Assessment Toolset"](#)
- ▶ [Status of Sustainability Targets](#)

Improving the Quality of Supplied Parts and Raw Materials

Systemex provides a quality assurance agreement that clearly states our requirements for the quality of goods, and concludes agreements with business partners after confirming their understanding of our procurement policy. We perform quality assessments of supplied goods and audits of business partners regularly to ensure that proper quality control is being carried out.

Relations in the Supply Chain

At Systemex, we strive to strengthen our relationships with trading partners by holding annual briefing sessions for our suppliers to ensure their understanding of our business and procurement policies.

In fiscal 2022, we held BCP training for our primary suppliers, as well as explanatory meetings on the promotion of sustainability and green procurement, in which 431 business partners in total participated.

We also hold regular meetings with overseas business partners to strengthen collaboration. Systemex Europe periodically holds meetings with all of its business partners, checking their compliance with Systemex's environmental and social responsibilities, as well as details of business activities. Systemex Malaysia holds monthly meetings with local distributors to discuss customers' needs and issues, aiming to improve product quality and customer satisfaction.

Conducting Internal Awareness Activities to Ensure Compliance with Legislation

Systemex uses an electronic procurement system to prevent undue reduction in payments and return of products. In addition, all members of Systemex Corporation's Procurement Department and relevant members of Systemex's domestic Group companies undergo training on the Subcontract Act. For people newly assigned, we also provide training on our procurement policy, CSR, and procurement risks.

- ▶ [Procurement Policy](#)
- ▶ [Green Procurement Standards](#)
- ▶ [Anti-Slavery and Human Trafficking Policy](#)