

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 certifications. Of the 79 companies in the Sysmex Group, 34 have been ISO 9001 certified and 21 have been ISO 13485 certified. In fiscal 2023, four 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



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 when designing and developing new products, as well as when changes are made to the designs of existing products. If a high-risk event is noted, we act to eliminate it. In addition, when marketing products manufactured by other companies, we verify their quality by conducting audits of the manufacturers and meticulously inspecting their products. Moreover, in the unlikely event that a product defect occurs, we have systems in place to quickly identify the details and respond to any problems.

At factory sites, we conduct regular quality audits and monthly monitoring of manufacturing processes and supplier conformity to ensure quality. We appropriately instruct and support suppliers with high nonconformity rates to improve their quality. Our global quality complaint processing system allows us to gather quality information from markets around the world in a timely manner. 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 began to utilize a Global Positioning System (GPS) and temperature data loggers² for the transportation of some reagents used in testing. In the future, we will sequentially expand the use of these methods to include the transportation of diagnostic reagents that require high-quality assurance.

*1 Product design assessment, process design assessment, evaluation by the 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

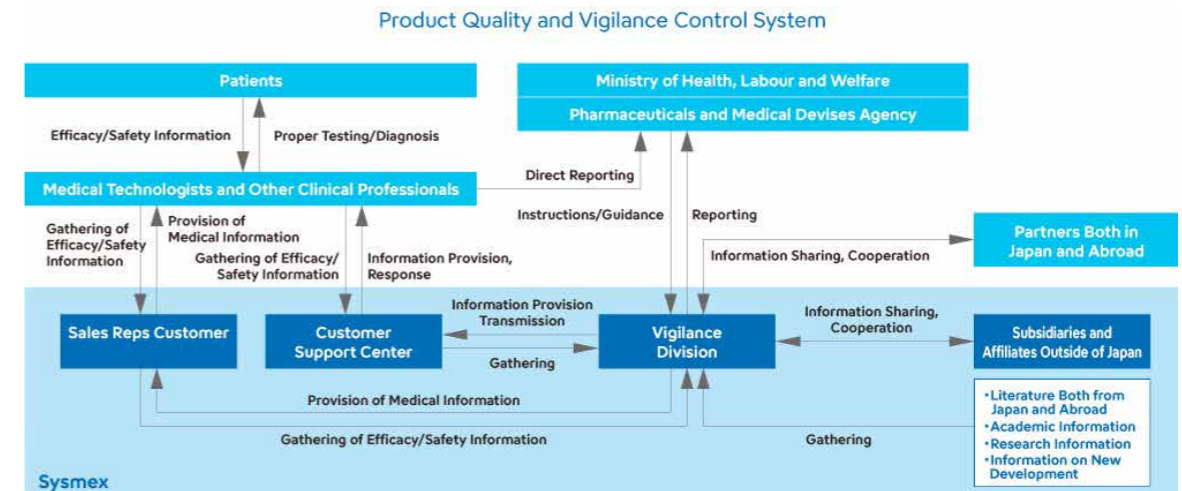
Focusing on Specialized Quality and Safety Training

In addition to Quality Policy training, Sysmex provides regular quality management training to the relevant departments, as well as specialized training on laws and regulations for employees in specific departments or job categories. In fiscal 2023, we provided training on the topic of quality 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 training regarding quality at all production facilities for final products and ISO-certified business offices managed by our Group companies overseas.

Management of Information Regarding Quality and Safety

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."

Response to the Circulation of 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 to be in circulation in some instances. The use of such counterfeit reagents endangers the reliability of testing results, and in some cases, they can be harmful to patients' health. For this reason, Sysmex continuously monitors markets for counterfeit reagents. When they are discovered, we exercise our intellectual property rights and work with local government institutions and judicial bodies to ensure swift and thorough responses.

► Intellectual-Property-Related Activities to Protect Business Models

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.

* Europe, the Middle East, and Africa

External Evaluation of Customer Satisfaction

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. These accolades are among the IMV ServiceTrak™ Awards organized by IMV, a specialist provider of market research to the medical imaging processing and the laboratory diagnostic fields. 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 received the highest excellence award in the 2024 China Medical Device Industrial Data Survey. The company received top honors in all five categories evaluated by the survey: market share, overall customer satisfaction, retention, NPS (a customer loyalty index), and training satisfaction. The company has received recognition as a result of this survey for three consecutive years.

Customer satisfaction rating in the United States

(On a scale of 1 to 10)

Fiscal 2021	Fiscal 2022	Fiscal 2023
9.27	9.4	9.42

* Research by IMV ServiceTrak



China Medical Device Industrial Data Survey Award

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 in order to utilize them in the development of new products and in operational improvements. In fiscal 2023, we gathered approximately 13,500 customer feedback responses from the Japanese market and many from Europe and other 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.

Voice of Customer
VOC
お客様の声が
生きています

Voice of Customer = お客様からのご意見・ご要望を製品開発に活かす取り組み。
日本国内で主要な機器・試薬の、研究開発から製造、販売、サービス&サポートまでを一貫して提供するシスメックスならではの取り組みです。

Providing Highly Satisfying User Training

Sysmex provides training for instrument operation and maintenance for customers in each region as part of our customer support. In recent years, to respond to a sustainable society, we have provided an online training system in different parts of the world by which training can be live-streamed or attended on demand.

We established a training center for technical services and application support in Brazil and Turkey to serve as a new base. In addition, the user training program provided is a globally integrated program under the name "Caresphere™ Academy."



Training Center in Brazil



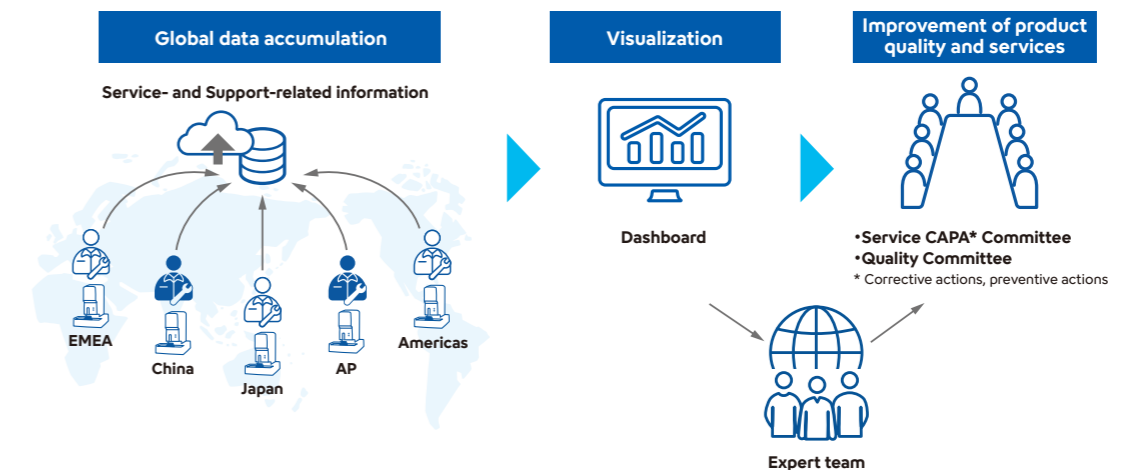
Turkey

Project for Promoting Digitalization

Product Quality Improvement Activities Based on the Restructuring of Technical Services and Application Support

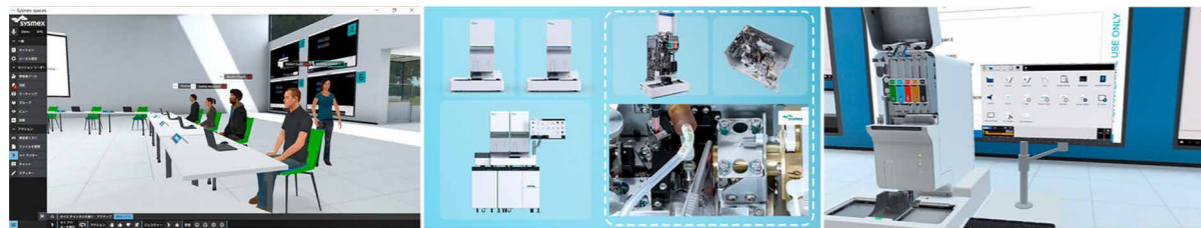
Sysmex supplies its products to over 190 countries and regions around the world. However, in the past, it has been difficult to obtain accurate information on instrument failures and service status. To address this issue, people involved in technical services and application support at different regional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

In addition to accumulating global data on instrument failures and service status through common global codes created for service-related information in each region, this project reformed the market support escalation system and promoted the digitalization of data. A global team of experts periodically monitors this data to speed up the quality and service improvement process while also proactively detecting defects and 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, Sysmex introduced a virtual training space to train its technical service engineers and application support personnel around 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 are able to operate the software together in a virtual space, all participants can learn how to use the software, irrespective of where they are—and even if they are without physical terminals. We will continuously offer training that enables the participants to effectively learn to provide high-quality technical services and application support around the world.



Disseminating Useful Information

Sysmex Corporation disseminates valuable information to its customers in Japan through the Support Information section of its website. Sysmex continually expands the functionalities of the website to ensure that customers have the ability to use the website to a greater extent. Examples include adding an email magazine distribution service, which communicates the latest information, and “My Page” functionality, which allows users to manage content and their browsing histories.



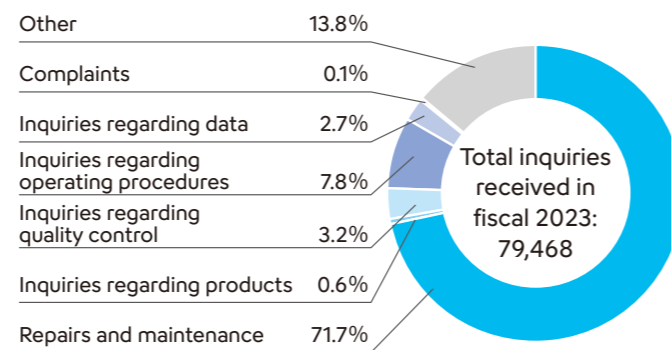
Support Information website (Japan)

Responding to Inquiries Rapidly and Responsibly

The Sysmex 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

Sysmex 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

Sysmex has held annual Scientific Seminars since 1978 to discuss topics selected from a wide range of medical research areas and to provide opportunities to share knowledge from the latest information and research. The topic in 2023 was clonal hematopoiesis, and the seminar was held in an onsite and an online hybrid format. The lectures in Kobe and Tokyo were streamed not only domestically but also internationally. The seminar was conducted primarily in English, with simultaneous interpretation offered in Chinese, Indonesian, Thai, and Vietnamese. We were pleased to be able to welcome participants from 21 countries worldwide. After the seminar, videos of the lectures were distributed globally. We also conducted country-specific participant surveys to identify medical issues and interests that differed depending on country and region. We utilize such information for future seminar theme setting and the Group’s initiatives.

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



Sysmex Scientific Seminar 2023

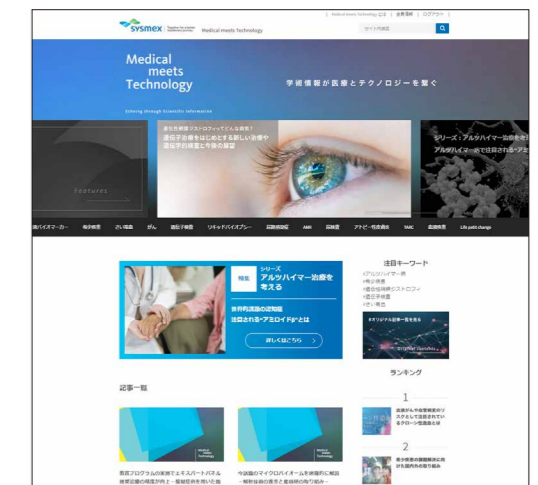
► Scientific Support Activities to Standardize and Increase the Quality of Clinical Testing

Activities for Patients and the General Public

Sysmex 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)?



Scientific Information Website: “Medicine meets Technology”

Society

Strengthening Supply Chain Management

Various Policies Regarding Supply Chain Management

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

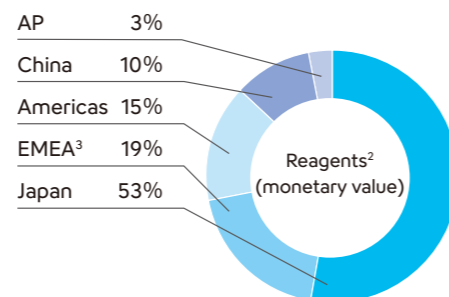
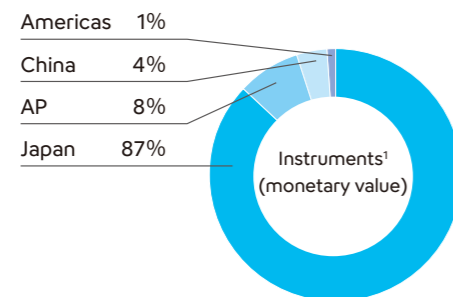
Supply Chain Management

Sustainable Procurement Structure

Systemex provides accurate test results and sound security by delivering high-quality products to the world. We ensure a stable supply of products and services based on our social mission to support healthcare. Strengthening supply chain management has been identified as a materiality, and Senior Executive Officer Mitsuhsisa Kanagawa has been placed in charge of overseeing risk management for the entire supply chain. He has been promoting sustainable procurement, beginning with supplier evaluations and the drafting of remedial plans. Furthermore, CSR survey response rates, the number of training sessions for suppliers, and other factors were set as sustainability targets, and the status of their related initiatives is reported to the Managing Board semiannually.

▶ [Establishment of a Business Continuity Plan \(BCP\)](#)

Procurement Region Analysis (Fiscal 2023)



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

Supplier Screening and CSR Surveys

At Systemex, taking into account the importance of sustainable procurement, we identify significant suppliers through desk assessments on supplier risk. For significant suppliers that have been identified, we conduct a CSR survey annually and monitor their status of sustainability-related initiatives.

In addition to procurement costs and difficulties in substitution with alternatives, desk assessments also take into account geopolitical risks, manufacturing country risks, and competing risks in securing raw materials for the production of healthcare products* as well as CSR and environmental risks (i.e., human rights, labor practices, management of chemical substances in products, and GHG emission responses). In particular, by rapidly identifying high-risk materials, we avoided major supply issues amidst the COVID-19 pandemic from 2020 to 2023 and the dispute in Ukraine, providing a stable supply of diagnostic reagents to our customers.

For CSR surveys, we use the CSR/Sustainable Procurement Self-Assessment Tool Set developed by Global Compact Network Japan. This covers a wide range of issues such as human rights, labor practices (including the health and safety of employees), corruption, and

the environment. We do not conduct business with new partners having inadequate CSR initiatives. In addition to CSR surveys, we hold management interviews with new business partners, and 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. Furthermore, we review CSR survey results with buyers during the annual evaluation of business partners and ensure that supplied parts come from business partners with low-risk levels in the CSR surveys. We have been implementing CSR surveys of business partners since 2013 and of secondary business partners since 2021 with the support of our primary business partners.

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

* Responses for Each Type of Risk:

Geopolitical risks: Surveys were conducted for products manufactured in Europe at the onset of the dispute in Ukraine and for products manufactured in South Korea and northern China when North Korean risk was rising.

Manufacturing country risk: Surveys were conducted for diagnostic agent containers and disposables, leading to procurement from various countries.

Competing risks in securing raw materials for producing healthcare products: Surveys were conducted for glass bottles, rubber stoppers, biochemical buffering agents, raw materials for PCR, and raw materials for cultivation.

▶ [Undertaking the Never-Ending Mission of “Creating a Stable Supply of Reagents”](#)

▶ [Flowchart of New Supplier Assessment](#)

▶ [KPIs for Supplier Screening](#)

Results of CSR Surveys

The response rate for surveys of primary raw material suppliers conducted in FY2023 was 95%, meaning that the previous fiscal year's high response was maintained. We also analyze the results of the CSR surveys from the previous fiscal year and provide feedback to our business partners included in the surveys. We disclose the average scores of the companies in the same raw materials category to our business partners to identify their strengths and weaknesses. For items with existing risks, we encourage corrective actions and carry forward improvement activities together.

CSR On-Site assessment and Cooperation for Supplier's CSR Initiatives

Systemex conducted on-site assessments of four primary suppliers in FY2023 to further strengthen suppliers' risk management. In addition, with cooperation from Tier 1 suppliers, we expanded our CSR surveys of Tier 2 suppliers. During the four years since FY2020, we have conducted CSR surveys of 96 Tier 2 suppliers.

In conducting these surveys, we shared our knowledge regarding our survey format and aggregation tools with Tier 1 suppliers. Using the same format, we seek to reduce the burden on the Tier 1 suppliers through our CSR surveys.

▶ [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.

Conducting Briefing Sessions and Meetings for Suppliers

Systemex strives to strengthen its relationships with trading partners by holding annual briefing sessions for our suppliers to ensure their understanding of our business and procurement policies. At the FY2022 CSR briefing session, we introduced examples of CSR initiatives of other companies to encourage initiatives that are in line with a single company's size. In FY2023, we hosted a briefing session for suppliers to explain our newly formulated long-term corporate vision, supply chain policies, and eco-social strategies. The session was well attended, with approximately 250 companies and 500 people.

We also hold regular meetings with overseas business partners to strengthen collaboration. Systemex Europe periodically holds meetings with all of its business partners to check 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.

Compliance with Procurement-Related Legislation and Training for Persons in Charge of Procurement

Systemex uses an electronic procurement system to prevent undue price reductions and product returns. In October 2020, we announced a declaration of partnership building and have been working to increase added value across the entire supply chain. Additionally, in observance of desirable transaction practices between large procuring enterprises and subcontractors (promotion standards based on the Act on the Promotion of Subcontracting Small and Medium-sized Enterprises), we are proactively taking initiatives to correct transaction and business practices that hinder the building of partnerships with business partners.

To enable this, the procurement departments at our domestic Group companies receive training related to the declaration of partnership building, the Subcontract Act, and the roles of companies placing orders in CSR activities. For new employees in the department, we conduct training on procurement policies, CSR procurement, and procurement risk.

Initiatives for the Optimization of Working Hours for Transportation and Logistics Work

In response to the Work Style Reform Law for transportation and logistics work, which comes into effect on April 1, 2024, we have stopped same-day shipping of normal temperature reagents and consumable goods and have changed to shipping the day after the order is received.* Through these efforts, we proactively address the so-called "2024 problem in logistics," such as eliminating the cargo waiting time that leads to overwork by truck drivers.

* We have been offering same-day order placement and next-day shipping for refrigerated reagents, equipment, and other products as before.