

Materiality

Providing Responsible Products, Services, and Solutions

Background

With the growing occurrence of quality issues and problems that undermine product reliability, societal expectations for the quality and safety of products and services are increasing. At the same time, the scope of corporate responsibility is expanding to the entire value chain, including business partners and customers. In addition, the Sustainable Development Goals (SDGs) call for sustainable production practices and improved labor environments. As a company operating in the healthcare industry, where human life and health are directly at stake, Sysmex places particular importance on enhancing the quality and safety of its products and services. Furthermore, proper management of the supply chain is an essential activity that not only contributes to improving the quality of healthcare but also strengthens customer satisfaction and reinforces the brand.

Policies

Sysmex offers safe products and services of high quality in accordance with the Quality Policy of helping to create a fulfilling and healthy society through global business activities in the healthcare domain. Furthermore, in accordance with our Procurement Policy, we promote responsible procurement practices that take into account the environment, human rights, and labor practices, aiming to achieve sustainable growth together with our business partners.

► Policy on Providing Responsible Products and Services

Structure

Under the supervision and management of the President, the Quality Assurance Division leads our quality management efforts. In addition, supply chain management is promoted by the Production and SCM Department, which is overseen by the Senior Executive Officer.

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 83 companies in the Sysmex Group, 35 have been ISO 9001 certified and 21 have been ISO 13485 certified. In fiscal 2024, three cases of nonconformity were identified in an internal quality audit and two 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 standards.)

► <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.

To ensure quality and traceability, we use RFID², GPS and temperature data loggers³ when transporting certain reagents in testing, enabling high-level quality assurance for products that require stringent temperature control.

*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 system that uses radio waves to read and write data on RF tags without physical contact. The RFID tags used are passive type, which do not emit radio waves themselves but receive signals from an RFID reader to allow non-contact and batch reading of information.

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

► Product Quality and Vigilance Control System

► Evolving Customer Care Activities through the Use of Advanced Digital Technologies and Information Assets

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

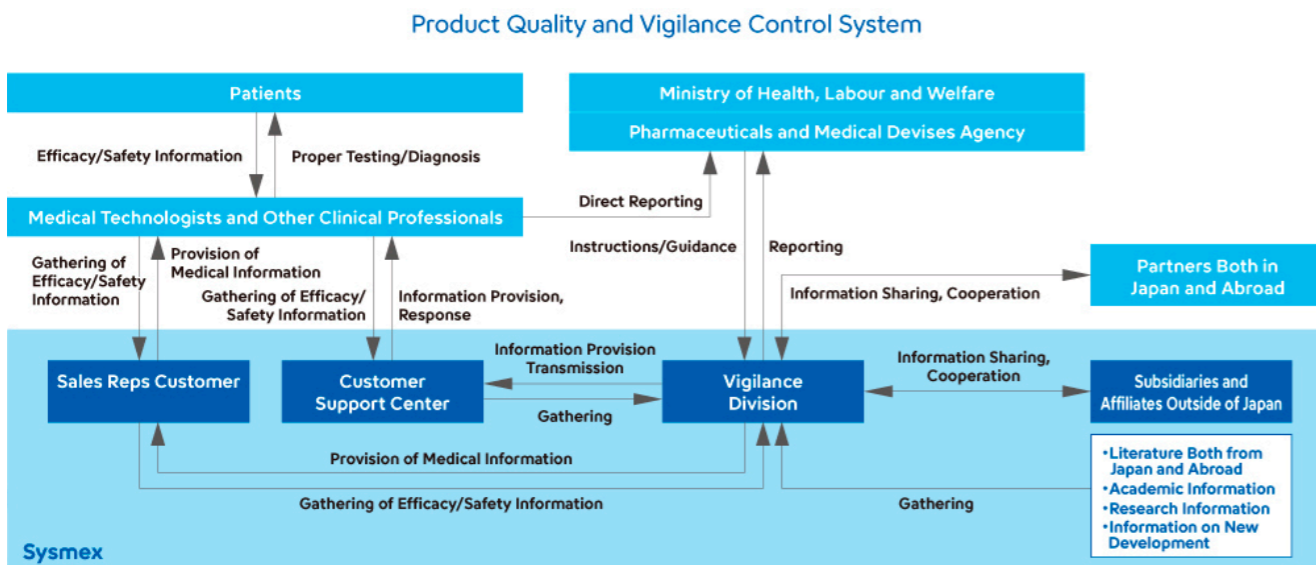
Focusing on Specialized Quality and Safety Training

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 2024, 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

High Marks in Customer Satisfaction Surveys

Sysmex conducts customer satisfaction surveys in various countries and regions. Each country or region uses its own metrics based on the products and services offered in order to provide enhanced service and support. In Japan, we conduct periodic customer satisfaction surveys and disclose the results. Sysmex America has earned the No. 1 ranking for 18 consecutive years in the hematology analyzer manufacturer category of the IMV ServiceTrak™ organized by IMV, a specialist provider of market research to the medical imaging and the clinical diagnostic instruments fields. The company also earned top ratings in 91% of the service-related categories and has received all three IMV awards—Customer Satisfaction, Service, and System Performance—for seven consecutive years.

We’re using our own surveys and third-party evaluations to regularly monitor whether we are providing high-quality products and services that satisfy our customers.

► Results of Customer Satisfaction Survey in Japan (FY2024) *Japanese

► Results of Customer Satisfaction Survey in Japan (FY2023) *Japanese

Customer satisfaction rating in the United States

(On a scale of 1 to 10)

Fiscal 2022	Fiscal 2023	Fiscal 2024
9.4	9.42	9.36

* Research by IMV ServiceTrak



Stakeholder’s Voice

On the Front Lines of U.S. Clinical Laboratories: Solving Issues Through Service and Support

I always tell the Customer Care team, “Every sample is not only a test; it’s a patient. Imagine that your loved one is at the other end of the service you provide and always do your best to solve our customers’ challenges.” I am convinced that Sysmex has been able to build an unwavering service and support brand because our strong sense of purpose—to contribute to patient health—has deeply embedded itself in our corporate culture, especially among the clinical laboratories that are our customers.



Judy Bosko
Senior Executive Officer, Customer Care / Sysmex America, Inc.

Click here for details:

► [On the Front Lines of U.S. Clinical Laboratories: Solving Issues Through Service and Support](#)

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 2024, we gathered approximately 15,000 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.

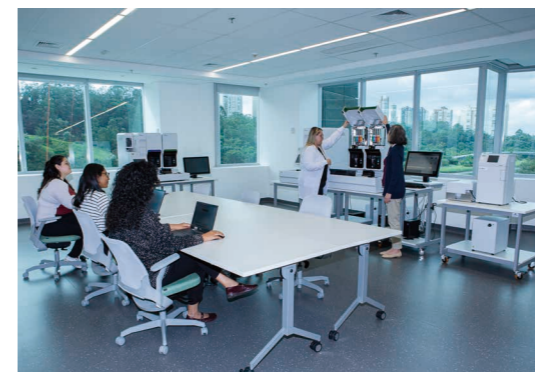
Voice of Customer
VOC
お客様の声が
活かれています

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 a variety of training programs as part of our customer support, including instrument operation, maintenance, and application support, using a globally consistent digital platform called Caresphere™ Academy. In recent years, we have established new training centers in Brazil and Turkey, with the aim of strengthening and enhancing customer care by offering high-quality face-to-face training tailored to local needs.

We are also developing and expanding access to online training environments in regions around the world. In addition to e-learning, which enables customers to develop skills anytime and anywhere, we also offer highly immersive virtual training through full-scale online studios. This enables customers in remote areas to receive standardized, high-quality product training, even if they are far from a training center.



Training Center in Brazil



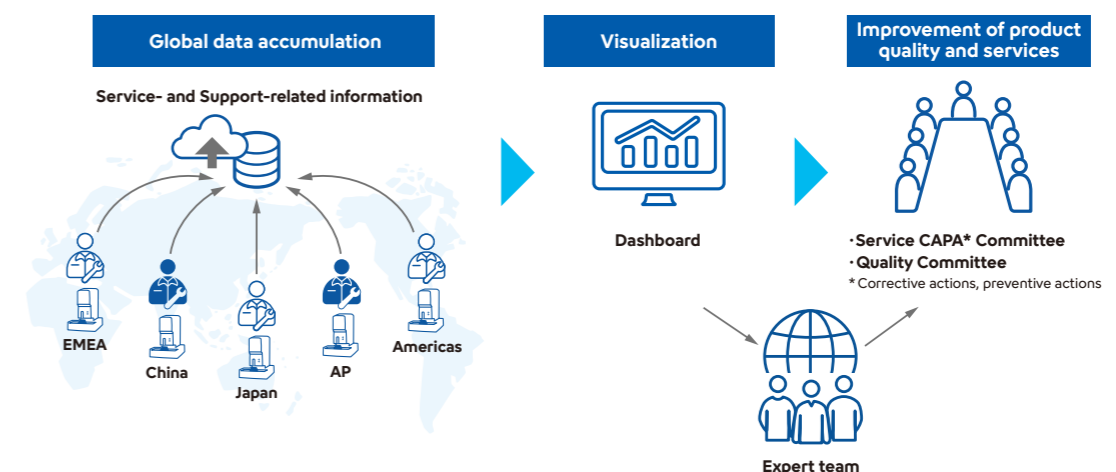
Training Center in Turkey

Evolving Customer Care Activities through the Use of Advanced Digital Technologies and Information Assets

Sysmex pioneered the introduction of network solutions in the industry introduce network solutions that connect testing instruments to a network and remotely monitor their operating status for predictive maintenance purposes. Today, a global team of experts regularly monitors data collected from products provided in more than 190 countries and regions worldwide, including instrument failure status and service conditions, to help improve quality, speed up service improvement processes, and reduce instrument failure rate.

To maintain quality and speed in services, we have revamped our market support escalation system. This new system allows customer issues and inquiries from any region of the world to be escalated to our headquarters along with detailed information, facilitating faster problem resolution. We are also developing an online application to support all service activities by visualizing instrument log data and assessing instrument status using AI models.

By combining accumulated digital information assets with advanced technologies such as AI, we are evolving toward a more proactive service model.



Strengthening Customer Care Functions Through Global Knowledge Integration and Sharing

In 2024, Sysmex launched a system to integrate and share knowledge—expertise, experience, skills, and know-how—acquired through service and support activities across the Sysmex Group worldwide. Knowledge gained through frontline customer care activities is applied to provide high-quality and efficient customer support that does not rely on individual personnel, regions, or levels of experience. Furthermore, by centrally aggregating various resources—such as product information, case studies of inquiries, and academic literature—we are enhancing the academic knowledge of application support staff and improving the efficiency of customer support delivery.

Stakeholder’s Voice

The Backbone of Our Global Leadership: How Sysmex Brings Value to Medical Institutions with Service and Support

Hematology, in which we hold the world’s top market share, plays a fundamental role in disease screening. Despite daily quality assessment, unexpected test results may arise due to patient-specific factors. In such cases, we ensure the reliability of test results by providing prompt support and working closely with the customer to identify the cause and interpret the data.

Click here for details:

▶ [The Backbone of Our Global Leadership: How Sysmex Brings Value to Medical Institutions with Service and Support](#)



Tomoo Yamada, Vice President of Technical Service, Global Management Division
Michiko Yoshimoto, Vice President of Application Support, Global Management Division

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.

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.

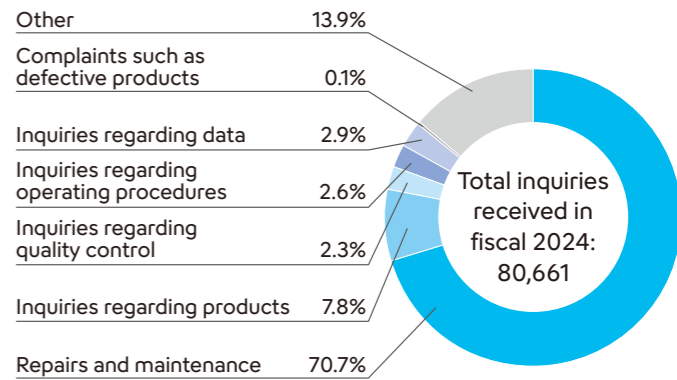
Holding Scientific Seminars for Medical Professionals

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 2024 was “Future Perspectives in Cardiovascular Disease Research,” and the seminar was held onsite and online in a 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.

▶ [Supporting Quality Control and Standardization of Clinical Testing in Asian Countries](#)

Responding to Inquiries at the Customer Support Center



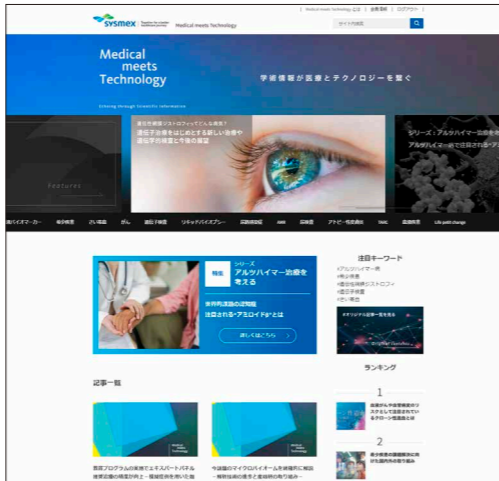
Sysmex Scientific Seminar 2024

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](#)

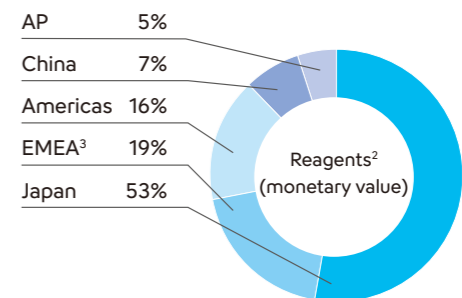
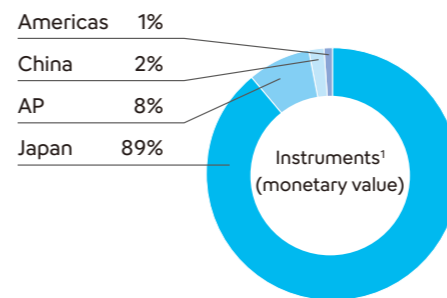
Supply Chain Management

Sustainable Procurement Structure

Sysmex 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 the Senior Executive Officer Mitsuhsa 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 2024)



- 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 Sysmex, 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, competing risks* in securing raw materials for the production of medical products, as well as other ESG risks (i.e., human rights and labor practices, management of chemical substances in products, GHG emission responses, and corruption such as bribery). When selecting new business partners, we verify risks using a CSR survey that includes ESG criteria. 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. Sysmex Europe and Sysmex America conduct sustainability surveys of all new business partners covering areas such as human rights and green procurement. Jinan Sysmex Medical Electronics holds quarterly meetings with its business partners to assess risks, in addition to environmental and occupational health and safety surveys. Sysmex 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.
Sector-specific risks (competing risks in securing raw materials): 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 CSR survey conducted in fiscal 2024 for primary raw material suppliers maintained a high response rate of 94%, consistent with the previous fiscal year. We also analyze the results of the CSR surveys from the previous fiscal year and provide feedback to the business partners surveyed. By disclosing the average scores of companies in the same raw materials category, we help them identify their strengths and weaknesses. For items with existing risks, we encourage corrective actions and work together to advance improvement activities.

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

Sysmex conducted on-site assessments of eleven primary suppliers between fiscal 2022 and fiscal 2024 to further strengthen supplier risk management. When risks are identified, we request improvements and ask suppliers to submit improvement plans. In addition, with cooperation from Tier 1 suppliers, we expanded our CSR surveys of Tier 2 suppliers. During the three years since fiscal 2022, we have conducted CSR surveys of 195 Tier 2 suppliers.

In conducting these surveys, we provide survey formats and aggregation services to Tier 1 suppliers, thereby enabling them to conduct CSR surveys while reducing their burden.

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

Improving the Quality of Supplied Parts and Raw Materials

Sysmex 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

Sysmex 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 fiscal 2022 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 fiscal 2023, 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. In fiscal 2024, we held an SBT briefing session and a study session on the importance and practice of calculating greenhouse gas emissions. We are actively working to reduce CO₂ emissions across the entire supply chain.

We also hold regular meetings with overseas business partners to strengthen collaboration. Sysmex Europe periodically holds meetings with all of its business partners to check their compliance with Sysmex’s environmental and social responsibilities, as well as details of business activities. Sysmex 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

Sysmex 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, since fiscal 2023, we have been providing training on the revised standards of the Subcontract Act promotion standards, as well as on passing on costs such as raw material and labor expenses. In addition, 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 are eliminating cargo waiting times that lead to overwork by truck drivers. We are also mechanizing the handling of heavy loads to improve the working environment for warehouse workers and conducting surveys on respect for human rights, thereby proactively addressing the so-called “2024 problem” in logistics.

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