Ensuring the Safety and Quality of Products and Services

Basic Approach

At the Terumo Group, we strive to enhance product quality and achieve continuous improvement in quality systems and processes to promise safety and reliability to medical settings. High product quality is one of the hallmarks of the Terumo Group, and we work to improve quality in every process from product design to manufacturing. We do this by identifying and acting on even the smallest matters that could improve safety and reliability, by concentrating on improving the quality and speed of individual processes, and by pursuing the 3Gs principle that places great importance on *Gemba* (field/floor), *Genbutsu* (actual product), and *Genjitsu* (reality). In addition, we seek to ensure that our products are used in a safe and appropriate manner by providing training opportunities for medical professionals, practicing proper information disclosure, and actively communicating with customers.

Contained in the Mid- to Long-term Growth Strategy, which covers the five-year period from fiscal 2017 to fiscal 2021, is the Mid- to Long-term Vision, which calls on us to earn the trust of medical settings globally as a top brand and to ensure world-class trust with Total Quality comprising reliable products, supply, and services.

Quality Management Structure

The Terumo Group has developed a quality management structure headed by its Chief Quality Officer (CQO). As the head of Groupwide quality divisions, the CQO is responsible for overseeing efforts to promote stringent Group quality governance and improve the quality of products.

With this structure in place, the Terumo Group has established a quality assurance system, promotes compliance with domestic and overseas regulations, and provides product quality improvement guidance to production sites. Furthermore, global meetings are held regularly, and these meetings are attended by the CQO as well as by associates responsible for quality at individual production sites. These meetings provide opportunities to share and disseminate Group policies, build consensus with regard to issues, formulate improvement measures, and exchange information on trends in the regulations and standards of various countries. We also strive to prevent quality issues by implementing a PDCA (plan-do-check-act) cycle that entails gathering quality-related information from across the Group, analyzing quality risk, conducting assessments, pursuing improvements, and sharing quality information.

In 2018, the Terumo Group developed its Global Quality Policy, which details the practices we expect associates to adhere to across the Group. Guided by this policy, we are working to achieve higher levels of quality management on a Groupwide basis.

Quality Management System

Quality Management System Compliant with International Regulations and Standards

Since establishing a quality management system in response to European Medical Device Directives in 1995, we have been striving to blend our international-standard system into an existing quality assurance system based on the pharmaceutical Good Manufacturing Practice (GMP) standard. Following the acquisition of manufacturing and sales approval for regenerative medicine products in Japan, we put in place the related quality assurance systems in fiscal 2016. Today, we continue efforts to ensure that our quality management system is compliant with global requirements. As part of these efforts, all medical device production sites have acquired certification under ISO 13485, the international quality standard for medical devices.

We also keep up to date with and respond swiftly to developments regarding Japan's PMD Act (the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics) and regulatory trends and requirements for medical devices and pharmaceutical products outside of Japan, including U.S. Food and Drug Administration (FDA) regulations, which have been strengthened in recent years; the Medical Device Single Audit Program,* which has been enacted in response to global harmonization trends; and emerging country regulations, which are rapidly being tightened. Furthermore, in response to the May 2017 launch of the European Medical Device Regulation (MDR), which is to be enacted in May 2020, we are advancing compliance preparations at relevant divisions and otherwise enhancing our quality management system.

For the purpose of pursuing ongoing improvements to our quality management system, we disseminate information on new standards and regulations among associates in divisions to which this system applies and also conduct education and training every year to elevate the quality awareness of such associates.

* The Medical Device Single Audit Program is a program through which audits are conducted all at once (collectively) based on common standards pertaining to the relevant medical device regulations in each country. Participating countries include the United States, Canada, Brazil, Australia, and Japan.

Ensuring the Safety and Quality of Products and Services

Quality Policy

Group company managers have established the Quality Policy, from which we develop, operate, and effectively maintain our quality management system. Each division also sets quality objectives based on the Quality Policy. The policies devised by top management are incorporated into the objectives of individual divisions and associates.

The customer perspective, which appears at the top of Terumo's Quality Policy, forms the basis of the Group's quality assurance.

Quality Policy

In order to deliver safety and reliability to healthcare fields, we shall

- pursue products valuable for our customers;
- understand our own roles in the quality system and practice them; and
- always review and improve our ways of doing business.

Internal and External Audits to Improve Effectiveness of Quality Management System

Terumo conducts internal audits to objectively evaluate whether its quality management system is being appropriately implemented and followed. The audits are conducted by associates who have been trained and received internal certification authorizing them to perform internal audits.

In addition, we undergo several external audits conducted by government authorities, certification bodies, and other organizations each year to verify our compliance with Japan's PMD Act; regulations in the U.S., Europe, and other countries; and the requirements of corporate customers.

We continuously improve our quality management system based on the results of these internal and external audits.

Collection and Disclosure of Safety and Quality Information

Terumo has established frameworks for collecting safety and quality information from customers and disclosing this information based on the laws and regulations of countries of operation. We also analyze information from customers and share the findings with relevant divisions for use in improving quality and in developing new products.

Medical representatives (MRs), who are responsible for providing information to medical institutions, encourage customers to properly use medical devices and pharmaceuticals. MRs also collect accurate information from medical institutions and swiftly provide information to institutions to ensure the effectiveness and safety of our products.

The Terumo Call Center in Japan receives about 210,000 telephone and email inquiries per year from general consumers, medical institutions, and distributors. We respond to emergency calls, such as those pertaining to peritoneal dialysis or diabetes-related products, 24 hours a day, 365 days a year. As Terumo handles a wide range of products—from those designed for medical institutions to those for home medical care—the call center staff includes experts in every required field to ensure that all inquiries are addressed promptly and appropriately. To improve the quality of service at our call center, its staff are trained regularly on product knowledge and communication skills and are tested twice a year to ensure that they are properly equipped to respond to inquiries and provide customers with satisfactory results.

The Post-Market Surveillance and Vigilance Department collects and evaluates information on safety, quality, and proper use of post-market products and issues reports on these matters to government authorities. The collected information is utilized in prompt and detailed communication by delivering this information in various ways, including incorporating important information in package inserts, transmitting information through our website or via industry organizations, and sending MRs to medical institutions to provide explanations face-to-face. Furthermore, we use the accumulated information to develop, refine, and improve products and support medical safety training at medical institutions (T-PAS*). Terumo is also moving forward with the development of safety information management systems and the reinforcement of monitoring of information collection activities overseas.

* For information on T-PAS, please refer to page 20.

Ensuring the Safety and Quality of Products and Services

Training of Medical Professionals

Basic Approach

Terumo believes that medical devices can be effective only if they are used correctly. Accordingly, we have long endeavored to enhance the quality and safety of medical care by actively creating training opportunities for medical professionals to learn how to use medical devices properly and how to apply treatment procedures. The information collected from the medical field through these activities is utilized in the development of new products and in the refinement and improvement of existing products.

Terumo Medical Pranex™ Comprehensive Medical Training Facility

Terumo Medical Pranex was established to develop and spread the use of medical technologies. Using spaces that realistically simulate hospital facilities and private homes, Terumo Medical Pranex provides practical training for medical professionals and serves as a venue for collaborative product development. Visitors to the facility include medical professionals from Japan and overseas as well as foreign officials. Terumo Medical Pranex has hosted over 140,000 visitors since its opening in 2002. The facility is equipped with catheterization laboratories, where trainees can use blood vessel models that faithfully recreate the flow of blood through the brain and heart along with Terumo's original training tools to learn how to perform advanced interventional therapies. There are also operating rooms where medical professionals can receive training in cardiovascular surgery using an extracorporeal life support system as well as on how to operate heart-lung machines, which are critical to cardiac surgery, among various other types of training. With a simulated hospital environment including operating rooms, an intensive care unit (ICU), medical ward, and staff station, Terumo Medical Pranex offers a realistic environment for conducting a broad array of trainings for physicians, nurses, pharmacists, clinical engineers, and others. It has also developed unique training programs on the basics of proper and safe use of medical devices and for expert trainers who can train new medical professionals.

Training being performed at Terumo Medical Pranex

Support for Training at Medical Institutions to Improve Medical Safety

To prevent accidents during the use of syringes, IV solution sets, and other medical devices, Terumo conducts training sessions known as T-PAS*1 at medical institutions.*2 T-PAS emphasizes critical points in the use of individual devices among those described in package inserts and enables medical professionals to learn through hands-on training scenarios. The value of this program is illustrated by the feedback of medical professionals that have participated, which indicates that T-PAS training provides a tangible sense of the situations that can lead to accidents and demonstrates why the understanding of device use must be based on more than just assumptions or casual advice from others. The benefits of T-PAS training are often reported on by hospitals throughout Japan at the Annual Congress of Japanese Society for Quality and Safety in Healthcare.

T-PAS training session

*1 T-PAS stands for Terumo Proactive Action for Safety. T-PAS training is based on Terumo's own assessments of accident prevention needs.

*2 From fiscal 2009 through fiscal 2017, T-PAS training was conducted in approximately 1,500 venues, including regional training sessions, sales agent locations, and 1,250 medical institutions.

Managing Supply Chains That Support Stable Supply

Basic Approach

Based on the Code of Conduct for the Terumo Group (SAKURA Rules), Terumo promotes fair, impartial, and highly transparent procurement activities and compliance with the laws of all relevant countries. Moreover, we have established business continuity plans (BCPs) regarding material procurement to help us develop sustainable value chains to ensure the stable supply of high-quality products for medical settings. We also ask suppliers for their understanding and cooperation with regard to quality, compliance, and environmental, health, and safety (EHS) initiatives and coordinate with these partners in these areas.

Promotion System

The Procurement Department of Terumo Corporation plays a central role in establishing and implementing procurement rules, developing BCPs regarding procurement, and promoting thorough compliance with Japan's Act against Delay in Payment of Subcontract Proceeds, Etc. to Subcontractors (Subcontract Act) and other purchasing-related laws. This department also coordinates with relevant divisions when selecting new raw materials and components to be procured and conducts inspections on these articles from the perspectives of supply reliability, safety, and environmental impact.

In actual purchasing activities, domestic and overseas factory purchasing teams manage suppliers based on the Group's Quality Management System. The Procurement Department coordinates with these teams to facilitate purchasing activities that are optimal from a Companywide perspective with consideration to quality, prices, and supply reliability. In recent years, we have been pushing forward with the globalization of our procurement functions in response to the global expansion of our sales and production activities accompanying overseas acquisitions. For example, the Procurement Department held the Global Procurement Management Meeting in fiscal 2017, which was attended by representatives from domestic and overseas factory purchasing teams. Future initiatives aimed at the global optimization of our procurement functions will include sharing information and examining the possibility of establishing Groupwide procurement policies.

Furthermore, the Environmental Management Department coordinates with the Procurement Department in EHS initiatives implemented across the supply chain, which are advanced while gaining the understanding and cooperation of suppliers.

Reinforcement of Quality Management

In order to further improve product quality, Terumo proactively seeks to strengthen quality management—not only of raw materials, but also of production equipment, mold design, and outsourced processes. In recent years, supplier control has become increasingly important due to tighter regulations pertaining to global quality management systems. We therefore work to gain suppliers' understanding with regard to how the raw materials and services they provide affect the quality of finished products. Suppliers cooperate by continuously improving their quality and allowing us to perform regular audits of their quality management systems.

Procurement-Related BCPs

With quality and supply reliability as its top priority, Terumo strives to procure articles from the most ideal location. In accordance with the basic policy of BCPs—that healthcare must not be stopped—we have formulated a medical supply BCP that incorporates our experience with the Great East Japan Earthquake, the Kumamoto Earthquake, and other disasters. Implemented with the understanding and cooperation of suppliers, this plan is part of our efforts to establish systems that ensure we are able to reliably procure the necessary raw materials.

Managing Supply Chains That Support Stable Supply

Briefings for Suppliers

Terumo holds briefings for major suppliers once a year. These briefings are used as opportunities to explain conditions pertaining to Terumo's management, production, and procurement as well as the Company's production and procurement policies. We also discuss the current state of the healthcare industry and our outlook for the future and work to gain the understanding and cooperation of suppliers with regard to the actions necessary to realize the quality and supply reliability required for medical settings.

EHS Initiatives Related to Procurement

Terumo's business activities hinge on the support of various suppliers. Accordingly, Terumo strives to ensure a stable supply of products by implementing EHS initiatives across the value chain and endeavoring to reduce EHS risks throughout the supply chain. Initiatives in fiscal 2017 included informing suppliers of the raw materials, components, and other articles used in our products of the important matters pertaining to EHS and asking for their cooperation with regard to these items. We also administered surveys to better understand the status of EHS-related initiatives of suppliers.

Important Matters Pertaining to EHS Communicated to Suppliers

- Terumo Global EHS Policy
- Request for respect for EHS laws and regulations and social norms
- Request for management of and cooperation with surveys on information on the chemical substances contained in products
- Request for risk assessments and appropriate management of chemical substances
- Request for energy and resource conservation and other environmental preservation activities
- Request for initiatives to prevent occupational accidents

Compliance Education Regarding Purchasing

Terumo has introduced a purchasing system that features enhanced functions for conducting checks on compliance with the Subcontract Act. By conducting order placement and payment procedures through this system, we aim to ensure compliance with the Subcontract Act. Moreover, an e-learning program on the Subcontract Act was instituted in fiscal 2017 targeting all associates at Terumo Corporation and domestic Group companies.