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.

Quality Management Governance Structure

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

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

In fiscal 2018, the Terumo Group developed its Global Quality Policy, which details the seven practices pertaining to the quality management system that every associate across the Group is expected to adhere to. This policy was further expanded to include provisions on device maintenance and sterilization processes to prevent the recurrence of issues similar to those that had taken place in the past. Guided by this policy, we are continuing to implement measures aimed at achieving even higher levels of production and quality management on a Groupwide basis. We have also established manufacturing control procedures for each manufacturing process in accordance with the specific risks associated with each product. Based on these control procedures, we conduct strict control of manufacturing parameters as well as tests and inspections. By doing so, we have achieved a high level of manufacturing and quality control. Furthermore, we are continuously working to maintain or even enhance the level of manufacturing and quality control.

Meanwhile, global regulatory requirements are becoming more stringent in the pharmaceutical industry with regard to data integrity (DI) in relation to evidence of the quality, safety, and efficacy of pharmaceuticals. The Terumo Group has therefore implemented measures to ensure data integrity in the manufacturing of pharmaceuticals. We also aspire to realize levels of data integrity in the production of medical devices similar to those required for pharmaceuticals.

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 and ensure conformity with 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. In Europe, on May 25, 2017, the institution of the Medical Device Regulation (MDR) made regulatory requirements in this region much stricter. In response to this change, a Company-wide project team was formed in fiscal 2018 to coordinate efforts to achieve compliance in relevant divisions. Terumo was thereby able to receive third-party certification indicating its compliance with the MDR in May 2020.

In Japan, Terumo Group is working to ensure compliance with the revised version of Japan's PMD Act, which came into effect on August 1, 2021, and with the Japanese Guideline for Good Distribution Practice (GDP) for Medicinal Products that is scheduled to come into effect in the near future.

Furthermore, continuous training on our quality management system has been instituted at all Company divisions to share information on the regulations and standards of countries where Terumo operates and to improve quality awareness.

* 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.

Quality Policy

The Terumo Group company managers have established the Quality Policy in accordance with their individual levels of responsibility. This policy guides efforts to develop, operate, and maintain the effectiveness of quality management systems. Each division also sets quality objectives based on the Quality Policy. The policies devised by senior 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 will
- 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.

Improving Effectiveness of Quality Management System through Internal and External Audits

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 have received internal certification authorizing them to perform internal audits. In addition, we undergo several external audits conducted by government authorities, notified bodies, and other organizations each year to verify our compliance with Japan's PMD Act, regulations of countries where we sell our products, and the requirements of corporate customers. We continuously improve our quality management system based on the results of these internal and external audits.

Appropriate Collection and Disclosure of Information on Safety, Quality and Efficacy

Terumo has established frameworks for collecting information on safety, quality, and efficacy from customers and reporting this information to the relevant government authorities based on the laws and regulations of each country where we operate. 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)

- 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 safety, quality and efficacy of our products.

Terumo Call Center

- As Terumo handles a wide range of products—from those designed for medical institutions to those for home medical care—, the Terumo Call Center consists of experts in every required field to ensure that all inquiries are addressed promptly and appropriately. The Terumo Call Center in Japan receives around 200,000 telephone and email inquiries per year from ordinary 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.
- 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 satisfaction to customers. In fiscal 2019, to improve response quality and shorten the amount of time required for responses and record keeping, we redesigned call record systems and introduced artificial intelligence-powered voice recognition and document summarization systems.

Post-Market Surveillance and Vigilance Department

- The Post-Market Surveillance and Vigilance Department collects and evaluates information on the safety, quality, efficacy, and proper use of post-market products, and issues reports on these matters to government authorities in accordance with relevant laws and regulations.
- We are committed to prompt and detailed communication to ensure the proper use of our products, including the provision of necessary information through Information on Precautions, etc., our corporate website, and participation in industry organizations. Also, MRs visit medical institutions to collect and provide information. Furthermore, we use the accumulated information to develop, refine, and improve products and support medical safety training at medical institutions (T-PAS*).
- We conduct vigilance training via e-learning for all associates in Japan to give them a more in-depth understanding of Good Vigilance Practice (GVP).
- 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 10.

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

Terumo Medical Pranex was established in Shonan Center, Terumo's R&D base in Kanagawa Prefecture, as a facility dedicated to developing and disseminating healthcare technologies. It is a vast facility with a total area of 14,000m^2, consisting of Pranex West, which opened in 2002, and Pranex East, which was added in 2007. Terumo Medical Pranex faithfully reproduces a hospital environment such as medical wards, operating rooms, and catheterization laboratories, and also has an exhibition room that introduces the history and technology of Terumo. In this way, this facility allows visitors to better understand the Company from various points of view.

Initially launched as a training center to help healthcare professionals learn how to use Terumo products properly, Terumo

Medical Pranex has continuously expanded its facilities and equipment to make it more beneficial to everyone involved in healthcare. We offer a wide variety of programs, from training in treatment techniques for physicians to multidisciplinary simulation trainings. We also focus on the development of original simulation models and programs for training leaders in the medical field, and we provide them to overseas associations. Sincerely addressing the needs of the medical field, Terumo Medical Pranex has hosted over 160,000 visitors since its opening in 2002.

Through these activities, Terumo aims to offer new solutions that can address issues relating to medical safety and efficiency, and support improvements in healthcare quality so that patients receive better treatment, while also aiming to develop next-generation medical devices.

Training being performed at Terumo Medical Pranex

Terumo Medical Pranex (Japanese only)
https://www.terumo.co.jp/about/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 safety training based on requests by medical institutions. These training sessions, known as T-PAS,* emphasize critical points in the use of individual devices among those described in Information on Precautions, etc., and enable 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. In addition, Terumo has designed and offers a practical training program boasting high levels of learning retention in order to promote proper product use. This program includes DVDs documenting medical accidents as well as hands-on activities recreating device failures.

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