

# 7. Quality Initiatives for Safe and Reliable Products

Maintaining quality is an important responsibility for companies involved in healthcare and is the foundation of Terumo's corporate value. At Terumo, all associates are committed to improving the quality of our products and services to enable our customers to use our products safely and with peace of mind.

## Quality assurance system that meets international standards

In 1995, we established a quality management system to meet strict international standards in response to European medical device directives. This system blended one that is capable of meeting global requirement with the advanced quality assurance system based on the existing pharmaceutical GMP (Good Manufacturing Practice)<sup>1</sup> standard. In later years, Terumo obtained ISO13485<sup>2</sup> certification. As international standards and the Pharmaceutical Affairs Act continue to be revised and put into effect, we are striving to continually improve our quality management system in anticipation of their requirements.



Strict quality control conducted at the factory

1 Pharmaceutical GMP: Guidelines for the manufacture of pharmaceutical products issued by the regulatory authorities to ensure the safety and quality aspects of the products comply with the specifications throughout all phases, from the receipt of materials to manufacturing and shipment of products.  
2 ISO13485: An ISO standard to assure the quality of medical devices and equipment.

## Quality policy aimed at safety and security

Our top management sets up quality policies to develop and operate our quality management system and maintain its effectiveness. Each division also sets policy targets based on these quality policies. In this way, policies devised by top management are incorporated into individual associates' targets.

### 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.

June 30, 2004  
TERUMO Corporation  
Takashi Wachi  
Representative Director &  
Chairman

Akira Takahashi  
Representative Director &  
President

## Auditing system to maintain high quality

To maintain and improve quality, we implement internal audits that objectively evaluate whether our quality management system is being appropriately complied with and operated. The audits are conducted by trained associates who have met predetermined standards. The results are reported to our top management, who direct improvements which are then incorporated, allowing us to continually upgrade our quality management system. In addition, we undergo several external audits each year to prove that we meet various regulations ranging from the Pharmaceutical Affairs Act to international regulations expanding from Europe to the entire world, as well as individual demands from our corporate customers.

## Strict quality control at overseas facilities

As the role played by our overseas factories increases in importance, we provide overseas associates with the know-how we have cultivated in Japan for improving quality, while we, in turn, learn much from them about system-related aspects, including systematic ways of thinking and standardization. As these exchanges increase, overseas factories have also begun introducing *Shoki Ryudo* (initial quality assessment\*), an evaluation method developed in Japan.

\* Initial quality assessment is a system designed to reaffirm quality and product specifications of new products when shifting to mass production.