

Quality

Safety Initiatives

As the duty of a company that is committed to the betterment of life, the Otsuka Group thinks first of the customers and patients who use its products. We pursue business activities that place the highest priority on the quality and safety of our products.

Priority Initiatives

Quality and Safety Control

The Otsuka Group has established rigorous quality control systems suited to the characteristics of each of its businesses, including pharmaceuticals, medical devices, cosmetics, and foods, in pursuit of product quality and safety. The Otsuka Group's quality control systems comply with regulatory requirements, government and industry standards, including Japan's Pharmaceuticals, Medical Devices and Other Therapeutic Products Act as well as Japan's Food Sanitation Act. The Group is also promoting the acquisition of international certifications such as ISO 9001 for quality, ISO 13485 for medical devices, and ISO 22000 for food safety. Furthermore, in order to ensure thorough quality control, it has adopted traceability systems covering all processes, from raw material procurement to production, distribution, and sales. Meanwhile, its operating companies conducting global business have established global quality assurance systems. In fiscal 2014, in order to clarify the roles and responsibilities of affiliated companies outside Japan, it fundamentally reexamined its approaches to global quality assurance systems to unify its concept of quality assurance. In this way, it is constantly striving to improve the product quality and earn the trust of customers worldwide by thinking about quality assurance systems on a global level.

Priority Initiatives

Listening to Customers

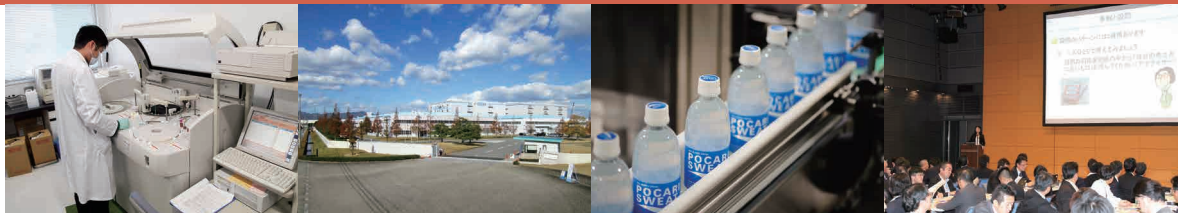
In order to field and respond to customer inquiries appropriately, the Otsuka Group operates departments that are organized along product lines. Otsuka Pharmaceutical has established the Drug Information Center to respond to questions about pharmaceuticals from patients and medical practitioners, and provides information on proper use. The Customer Relations Desk, Planning and Reliability Promotion Office responds to customer inquiries about OTC, quasi drugs, and cosmetics. The Customer Relations Office responds to inquiries about functional foods and beverages. The staff listens carefully to customers' questions and inquires, and tries to provide clear and polite explanations.

The company has also established the Telephone Service Center to respond to all inquiries made after office hours, which often involve a level of urgency. This is part of a system put in place for responding appropriately to customer questions, inquiries, and feedback.

Information regarding the safety and quality of any products is immediately reported to the relevant departments, which monitor risks, take steps to provide the necessary information to ensure proper use, and work to develop and improve products.

Quality Control in the Otsuka Group

Compliance to Regulatory, Government and Industry Standards	Certification	Otsuka Group Policies and Schemes
<p>Pharmaceutical and Medical Device Act Legislation aimed at securing the quality, effectiveness, and safety of pharmaceuticals, quasi drugs, cosmetics, and medical devices</p> <p>GLP Standards for securing the reliability of nonclinical testing for safety</p> <p>GMP National standards for manufacturing control and quality control of pharmaceuticals and quasi drugs</p> <p>QMS National standards for manufacturing control and quality control of medical devices and external-use diagnostic pharmaceutical products</p> <p>GQP National standards for quality control</p> <p>GVP National standards for safety management in the post-marketing</p> <p>Food Sanitation Act Law to ensure safety by establishing principles for standards, labels, and inspections for food, additives, and other substances</p>	<p>ISO 9001 Standard for establishing and achieving continuous improvement of quality control systems for products and services</p> <p>ISO 13485 Standard for quality management systems in the medical industry for continuous manufacturing and supply of the safe and effective medical devices</p> <p>ISO 22000 Standard for food safety management systems (FSMS) to supply food to consumers safely</p> <p>Hazard Analysis Critical Control Point (HACCP) International standards formulated by Codex Alimentarius for methods of managing hygiene and sanitation to ensure food safety</p>	<p>Formulation of quality systems</p> <p>Formulation of codes of conduct</p> <p>Establishment of total quality management systems (TQMS) for pharmaceuticals and medical devices</p> <p>Establishment of traceability systems</p> <p>Employee training</p>



Initiatives on the Production Site

The Otsuka Group strives to improve production site safety and efficiency as well as product quality through the establishment of appropriate systems. The factories in Otsuka Chemical and Zhangjiagang Otsuka Chemical (in China) implement an equipment maintenance system that allows for the sharing of equipment maintenance information and the results of quantitative assessment in maintenance work. As a result, the Otsuka Group has improved operational and production stability by lowering the rate of equipment breakdowns and reducing production shutdowns.

The Otsuka Group strictly manages reagents, some of which are toxic, under a key control system in order to ensure the safe use and storage of these substances. The system prevents unauthorized access and automatically generates access logs to avoid oversights and omissions that can occur with manual access logs. Otsuka Foods was commended as a facility with excellent food hygiene at the Fiscal 2014 Gunma Prefecture Food Hygiene Convention.

agent Pletaal OD tablets. Additionally, it reduced the size of the container for the dry powder inhaler Meptin Swinghaler, in order to improve portability. Meanwhile, Otsuka Pharmaceutical Factory developed an I. V. solution bag that improved safety and convenience. Taiho Pharmaceutical adopted a pictogram for some anticancer agents including TS-1 Combination Granule in an effort to prevent accidental ingestion by children.



Otsuka Chemical: Building a structure for global quality assurance

Sharing Quality Data Internally

The Otsuka Group suitably manages information to improve quality and processes, in order to reduce quality risks and enhance quality. It centrally manages product information as well as inquiries and requests from patients and customers in a database on an internal network. It has accomplished rapid responses by sharing the information with all the parties concerned in a timely manner. In addition, meetings are regularly held among personnel responsible for different departments including sales, production, and quality control, in an effort to improve customer satisfaction.



Otsuka Pharmaceutical: Product name printed on both sides of tablets as a measure to prevent medical malpractice

Priority Initiatives

Example of Product Improvement

Otsuka Pharmaceutical has made a variety of improvements, including to packaging, labeling, and patient medication instructions, in order to facilitate the safe and proper use of its pharmaceuticals by healthcare professionals and patients. It adopted a color universal design in usage instructions for the bronchodilator Meptin (for inhalation). It also adopted Universal Design Font for PTP sheets and individual packing boxes for all productions to improve readability. As a measure to prevent medical malpractice, it prints the product name directly on tablets for its products such as the antiplatelet



Otsuka Pharmaceutical Factory: ELNEOPA Injection No. 2, 1,500 ml quad bag preparation

Soft bags are divided by partitions into several chambers, each filled with a drug solution. Pressing on the soft bag from the outside to open the partitions allows the different drug solutions to be mixed easily and safely.