

Material Issue **12**

# Assurance of Product Reliability and Safety

## Management of Priority Issues

<b>Reason for being a priority issue</b>	Quality assurance and safety management of pharmaceutical products are fundamental to our business. If a problem were to occur in either of these areas, it would be a serious risk that could violate our corporate philosophy, harm the health of patients, and significantly reduce our social value and raison d'être.
<b>Vision over the medium to long term</b>	A global specialty pharmaceutical company with established organizational systems for appropriate quality assurance and safety management.
<b>Indicators</b>	<ul style="list-style-type: none"> <li>• Completion of quality assurance and safety management systems for global business</li> <li>• Zero significant findings from regulatory inspections</li> <li>• Zero recalls of Ono products</li> </ul>
<b>Major initiatives</b>	<ul style="list-style-type: none"> <li>• Create appropriate global systems for product quality and safety management</li> <li>• Establish an operation to study safety signals of investigational products</li> <li>• Establish a system to respond to inspections of products for the U.S. market in preparation for the launch of ONO-4059 in the U.S.</li> </ul>

### Initiatives for Ensuring the Stable Supply of High Quality Pharmaceutical Products

To supply high-quality pharmaceutical products, ONO manufactures all drugs under an appropriate quality assurance system both in our plants and in outsourced plants. At our plants, we established a quality assurance system complying with global regulations, such as GMP (Good Manufacturing Practice; standards for manufacturing and quality control systems) in each country and PIC/S GMP, etc. When outsourcing, we confirm that appropriate manufacturing control and quality control are implemented by conducting periodic quality audits. In quality assurance, we don't just meet the legal requirements as a manufacturer and distributor, we have established a pharmaceutical quality system. Through continuous improvement of this system, we strive to provide high quality pharmaceutical products from the perspective of patients, caregivers, and healthcare professionals.

We strive to provide high-quality products through multiple measures, e.g. training for all employees engaging in production and quality assurance, enhancing the quality system based on the ICH Q10 Pharmaceutical Quality System, and the development of risk management systems at manufacturing sites.

To ensure that these quality assurance and supply activities can be carried out throughout the entire group, including overseas,

we are working to build systems and establish a global structure.

**Web** Quality System and Training System  
[https://www.ono-pharma.com/company/business\\_activities/manufacturing.html](https://www.ono-pharma.com/company/business_activities/manufacturing.html)

### Initiatives to Ensure Safety

In terms of safety management, ONO establishes a risk management plan for each drug, gathers and manages safety (adverse reaction) information. We evaluate the details of gathered information and take safety measures, such as the revision of the "Precautions for Use" text accompanying pharmaceutical products and provide information related to the proper use of drugs, etc. as necessary. After the launch of the anticancer drug OPDIVO, safety information in and outside Japan increased drastically.

We strive to use it properly by evaluating it based on the opinions of an external expert committee on proper use and other medical experts and then disseminate it through various information delivery materials, academic societies, medical journals, etc.

In safety management activities, too, we are working to build a system and develop a global structure so that the entire group, including overseas offices, can conduct these activities.

### Safety Information Gathering and Management System

