Production and Quality Control

Product supply to support global expansion

At Sumitomo Dainippon Pharma, our greatest mission as a pharmaceutical company is to provide a stable supply of high-quality pharmaceuticals based on fundamentally secured safe operation.

For our production sites in Japan, we have closed the Ibaraki Plant and the Ehime Plant, making a transition to be a two-plant operation: Suzuka and Oita. We have developed a global supply chain which is based on manufacturing at these two plants and includes contract manufacturers in Japan and other countries and overseas procurement of raw materials and pharmaceutical intermediates. By doing this, we have achieved a structure for the stable supply of products.

In terms of logistics sites, we also relocated the aging distribution center in Kazo (Saitama Prefecture) to Saitama (Saitama Prefecture) in fiscal 2018, realizing a structure that can deliver products promptly to our pharmaceutical wholesalers all over Japan from our two sites in Saitama and Kobe (Hyogo Prefecture).

Quality assurance system that supports safe and reassuring products

The production of pharmaceuticals requires a high level of quality assurance. Consequently, rigorous GMPs (Good Manufacturing Practices) have been established in each country. The manufacturing, shipping, and global distribution of Sumitomo Dainippon Pharma’s products have been rigorously reviewed and obtained the approval of overseas health authorities, including the FDA, the EMA (the European Medicines Agency) and the TGA (Australia’s Therapeutic Goods Administration), in addition to Japan’s Ministry of Health, Labour and Welfare. Furthermore, we have established a high level of facility design and quality assurance systems that pass audits by overseas partner companies and meet strict quality standards at the global level such as guidelines from the ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), which deliberates on the harmonization of EU, U.S. and Japanese pharmaceutical regulations.

CSR procurement

We consistently conduct “transactions that are balanced, fair and transparent” based on Sumitomo Dainippon Pharma’s Ethics in Procurement. We evaluate and select business partners according to the standards outlined in our Criteria for Selecting New Business Partners. These criteria provide the standard for selecting new business partners on the basis of their CSR activities in the areas of compliance, trustworthy business activities, social contribution, information management, respect for human rights, and environment protection and consideration. We also encourage our business partners to cooperate with us in promoting their CSR procurement.

Prevention of medical malpractice

Since packaging and label designs for pharmaceuticals are highly regulated, including the provision of information, which is stipulated by law, the appearance of the packaging and labels for each company’s products are becoming quite similar, and this has become a cause of drug mix-ups.

Therefore, Sumitomo Dainippon Pharma is promoting initiatives to prevent mix-ups of drugs by medical institutions and patients, such as printing the product name onto tablets and the lids (top side) of bottles and changing to highly distinctive packaging and label designs.

Initiatives for environment conservation and occupational safety and health

Our plants in Japan have obtained ISO 14001 certification, the international standard for environmental management systems. We continue to conduct ecofriendly production activities through the automation of facilities and other laborsaving measures, appropriate inventory control and the introduction of co-generation systems in addition to the development of green products, the design of green facilities, and the operation of green logistics guidelines.

We also operate an occupational safety and health management system in order to operate without accidents and disasters based on the thorough observation of compliance.

* Good Manufacturing Practice: A standard for managing the manufacturing and quality of pharmaceuticals and quasi-pharmaceuticals.