Quality Control

Basic Policy

The MEDIPAL Group considers it its social mission to comply with pharmaceutical laws and regulations beginning with the Pharmaceutical and Medical Device Act, and to distribute safe, reliable pharmaceuticals and medical equipment, etc. To accomplish this mission, we strive to implement thorough quality control processes, from pharmaceutical product receipt to delivery to medical institutions.

Maintaining Quality

For quality control in the storage and distribution of pharmaceuticals, medical equipment, and other products, the MEDIPAL Group strives to build and operate appropriate systems by creating manuals on logistics operations, supervising pharmacist operations, etc., based on ordinances issued by the Ministry of Health, Labour and Welfare, and on JGSP[1] and JGSP2008.

The Group also formulates manuals for quality control and standard operating procedures (SOPs) in accordance with the globally harmonized JGSP/GDP,* revised to reflect PIC/S[2] GDP, and with GDP guidelines issued by the Ministry of Health, Labour and Welfare. In addition, the MEDIPAL Group works to enhance management systems, provide opportunities for suggesting improvements at GDP review meetings, and implement educational activities.

Education and Training

The MEDIPAL Group provides systematic and ongoing training to maintain the integrity of pharmaceuticals, etc. The training is based on the annual education and training plan formulated at the beginning of the fiscal year and covers quality control manuals and SOPs for employees and personnel in charge of merchandise management and distribution. The training combines multiple methodologies including online training sessions, classroom study, and on-the-job training (OJT) to meet various roles and levels of mastery.

Introductory Education and Training

Scope	New assignees/personnel
Contents	Learn the basic procedures and acquire knowledge for performing work in each department
Hours	Approx. 5 hours

Regular Education and Training

Scope	Employees and personnel responsible for product management and distribution
Contents	Acquiring knowledge of GDP and knowledge related to quality control matters such as drug regulatory affairs and supply of pharmaceutical products handled by the Company
Hours	10+ hours

Why counterfeit drugs are not a growing concern in Japan

The spread of counterfeit drugs is becoming a severe problem worldwide. However, there is largely no room for counterfeit drugs to enter the Japanese drug market. The main reasons for this are the thorough preparation of and compliance with relevant laws and regulations beginning with the Pharmaceutical and Medical Device Act, and the fact that the distribution system is one in which nearly all prescription pharmaceutical distribution (roughly 96%) is performed by pharmaceutical wholesalers.

The existence of pharmaceutical wholesalers has the following results, which support highly trusted distribution in Japan: (1) distribution routes are simplified; (2) a single company is responsible for everything from procurement to delivery; and (3) structures of close cooperation are established between pharmaceutical manufacturers, medical institutions and dispensing pharmacies.

The existence of high-quality distribution platforms and ongoing investment to support these are essential for preventing the spread of counterfeit pharmaceuticals. In that sense, the Japanese pharmaceutical wholesale industry is also responsible for safety and social costs.

The Group conducts lot traceability management, and has constructed a system that allows it to accurately determine what has been sold, when, to whom, and in what quantities.

For this reason, in the event of a voluntary product recall by a pharmaceutical company, this system allows the Group, at the pharmaceutical company's request, to rapidly provide information to the medical institutions and other customers to whom the products have been sold, and recall those products.

1. The Japanese Good Supplying Practice (JGSP) is an industry-internal practical standard by the Federation of Japan Pharmaceutical Wholesalers Association for quality and safety management in the supply of pharmaceuticals, aimed at preventing loss of quality due to the effects of temperature, humidity and light in each of the stages of storage, shipping and transportation. JGSP applies to prescription pharmaceuticals, while JGSP2008 applies to over-the-counter pharmaceuticals.
2. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) is an international cooperative framework for the quality management of pharmaceuticals

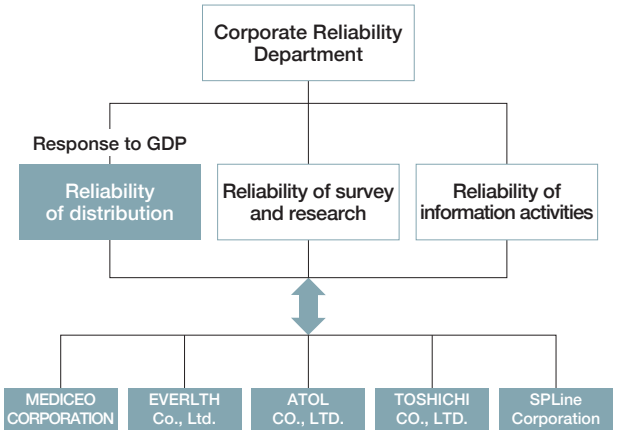
* Please refer to page 75 for explanations of technical terms.

Compliance with the Japanese Version of the GDP* Guidelines

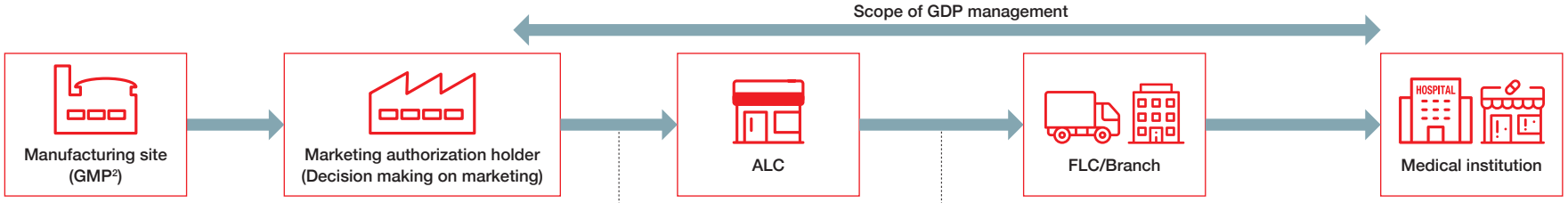
The MEDIPAL Group is now providing training based on quality control manuals and SOPs to the logistics departments of the five prescription pharmaceutical wholesalers[1] as well as to all ALCs.* In addition, we carry out regular quality reviews to promote and enhance the quality of GDP activities. In FY2022, we also expanded our GDP activities, which had previously focused on distribution centers, to FLC* and branches. At EVERLTH Co., Ltd. and ATOL CO., LTD., we confirmed consolidation of such activities in FY2023. We also advanced the development of GDP activities at MEDICEO CORPORATION and TOSHICHI CO., LTD., completing these efforts in FY2025.

Organization and role of the Corporate Reliability Department

The Corporate Reliability Department supervises the status of logistics quality control at the five prescription pharmaceutical wholesalers. At ALC, in particular, which is a logistics site, the Corporate Reliability Department is promoting efforts aimed at consolidating methods based on the GDP guidelines and at improving ongoing logistics quality. Furthermore, the department is also working to outfit FLCs and branches throughout Japan with organizational systems based on the guidelines and the necessary capital investments, while implementing educational activities for employees responsible for product management and distribution. In addition, to increase reliability in logistics quality, the department is further enhancing our pharmaceutical distribution practices by strengthening cooperation not only with relevant internal departments but also with pharmaceutical companies, distributors, and other external partners.



Pharmaceutical Supply Chain



MAH → ALC

Using DP-Cool[3] (Mitsubishi Logistics Corporation + forwarding agencies), etc.

Characteristics of DP-Cool

- Compliant with the PIC/S GDP guidelines
- Cooling temperature control throughout transportation
- Round-the-clock monitoring by the temperature control center
- Terminals with dock shelters directly connected to cold insulating warehouses
- Authorized drivers, etc.

ALC → FLC/Branch

Using mainly refrigerated storage owned by the Company

- ALC shipping berths with dock shelters
- Constant mapping taking into account seasonal variations for temperature-controlled transportation
- Staff trained using "Basic Knowledge about Distribution"
- Regular OJT training by a trainer, etc.

1. MEDICEO CORPORATION, EVERLTH Co., Ltd., ATOL CO., LTD., TOSHICHI CO., LTD., and SPLine Corporation
2. Good Manufacturing Practice
3. Refrigerated transportation service for pharmaceuticals compliant with the PIC/S GDP guidelines

* Please refer to page 75 for explanations of technical terms.