

Quality Control

Basic Policy

The MEDIPAL Group considers it its social mission to comply with pharmaceutical laws and regulations such as the Pharmaceutical and Medical Device Act, and to distribute safe, reliable prescription 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, etc., to maintain the integrity of delivered products.

Maintaining Quality

For quality control in the storage and distribution of pharmaceuticals, medical equipment, and other products, the MEDIPAL Group ensures the operation of 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 JGSP¹ 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/S² GDP, and with GDP guidelines³ 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.

1. JGSP (Japanese Good Supplying Practice: Practices regarding quality control and safety management in the supply of pharmaceuticals): Industry practices defined by The Federation of Japan Pharmaceutical Wholesalers Association in order to protect the safety of products and prevent their degradation due to temperature, humidity, sunlight, etc., during storage, shipping, and transport. JGSP applies to prescription pharmaceuticals, while JGSP2008 applies to over-the-counter pharmaceuticals.
2. PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme)
3. GDP (Good Distribution Practice) guidelines set out appropriate procedures for ensuring the proper management of distribution (purchase, storage, and supply), maintaining the integrity of pharmaceuticals, and preventing the entry of counterfeit drugs into regular distribution channels.

Education System

The MEDIPAL Group offers ongoing training for employees engaged in product management and distribution using quality manuals and SOPs to maintain the integrity of pharmaceuticals and other products.

Why counterfeit drugs are not a growing concern in Japan

The spread of counterfeit drugs is becoming a severe problem worldwide. However, there is no room for counterfeit drugs to enter the Japanese drug market. The main reasons for this are the development of laws (the Pharmaceutical and Medical Device Act, etc.) and compliance with these laws, as well as the fact that nearly all prescription pharmaceutical distribution (roughly 96%) is performed by pharmaceutical wholesalers.

The existence of wholesalers (1) simplifies distribution channels, (2) makes it possible to handle everything from purchase to delivery in-house, and (3) creates close relationships with all clients: pharmaceutical companies, medical institutions, and dispensing pharmacies. High-quality distribution is the key factor in preventing the spread of counterfeit drugs, and investment in such distribution is essential. In that sense, the Japanese pharmaceutical wholesale industry is also responsible for safety and social costs.

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

Compliance with the Japanese Version of the GDP Guidelines

The Group is now providing training on quality control manuals and SOPs to the logistics departments of the four prescription pharmaceutical wholesalers¹ as well as to ALCs, Tokyo Chuo FLC and the Nishi-Nihon Distribution Center.

In addition, we carry out regular quality reviews to promote and enhance the quality of GDP activities. In 2022, we began offering our GDP programs at FLCs/branches as well as at ALCs and other centers, progressively rolling out the programs to Group wholesalers, starting with EVERLTH Co., Ltd.

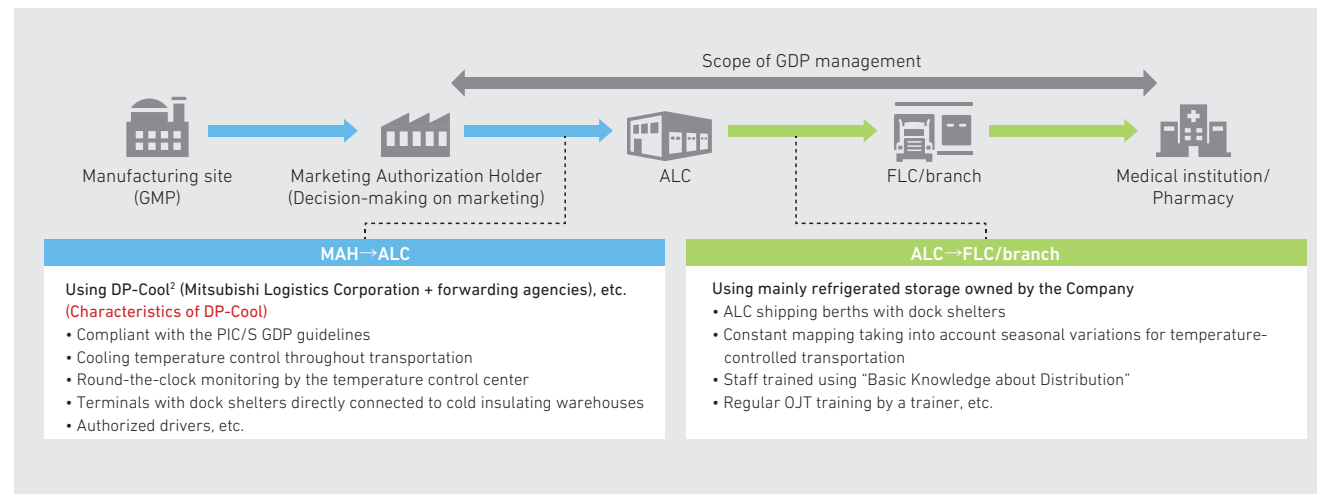
In response to the spread of COVID-19, in 2021 we took responsibility for handling the distribution of Moderna Japan's vaccine Spikevax intramuscular injection, which requires

temperature-controlled storage at -25°C to -15°C , and in 2022 we took responsibility for the distribution of Takeda Pharmaceutical's Nuvaxovid intramuscular injection, which requires temperature-controlled storage at $2-8^{\circ}\text{C}$. We ensure high-quality logistics through temperature mapping, which measures temperature distribution in cold storage warehouses and shipping containers.

With these measures in place, we have worked with government bodies and local wholesalers to distribute supplies to large-scale vaccination sites operated by national and local governments and to workplace vaccination sites.

1. MEDICEO CORPORATION, EVERLTH Co., Ltd., ATOL CO., LTD., SPLine Corporation

Pharmaceutical Supply Chain



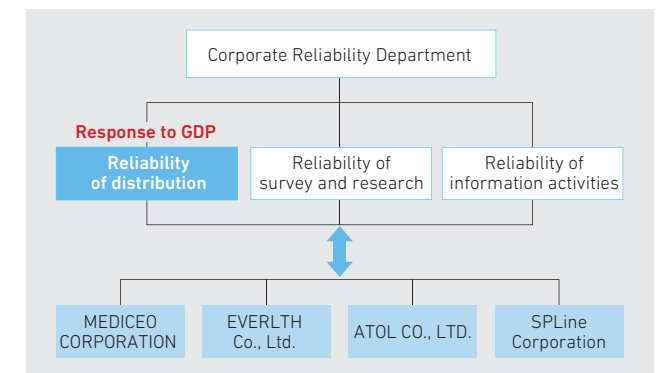
2. DP-Cool: Refrigerated transportation service for pharmaceuticals compliant with the PIC/S GDP guidelines.

Organization and Role of the Corporate Reliability Department

Many of the specialty pharmaceuticals and regenerative medical products that have been developed in recent years have strict requirements for temperature control during storage and transportation. As a result, pharmaceutical company audits require that distributors meet not only GDP guidelines but also the stricter global standards of the respective company.

The Corporate Reliability Department supervises the status of logistics quality control at four prescription pharmaceutical wholesalers and is working to promote methodologies based on GDP guidelines at ALCs and to continuously improve the quality of logistics. 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, we are 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.

Organization and Role of the Corporate Reliability Department



Note: As of March 31, 2023

* Please refer to [☐](#) page 72 for explanations of technical terms.