Pharmaceutical Affairs Management

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. In order to accomplish this mission, we strive to implement thorough pharmaceutical affairs management, from product receipt to delivery to medical institutions, etc., to secure the efficacy, safety, and quality of delivered products.

Maintaining Quality

For quality management in the storage and distribution of pharmaceuticals, medical equipment, and other products, the 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 JGSP[1] and JGSP2008. The Group also formulates manuals for quality management and SOP (standard operating procedures) in accordance with the globally harmonized JGSP GDP, revised to reflect PIC/S[2] GDP, and with GDP guidelines[3] issued by the Ministry of Health, Labour and Welfare. The Group also 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 management 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 Group offers ongoing training to cultivate the knowledge and qualifications necessary to appropriately gather and supply information regarding pharmaceuticals and medical equipment (for marketing specialists and pharmacists) and provides manuals and information on SOP to ensure reliable quality (for employees engaged in product management and distribution).

For details regarding education of marketing specialists/pharmacists, please see “Respect for Human Rights” on page 65.

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

MEDIPAL Group Initiatives

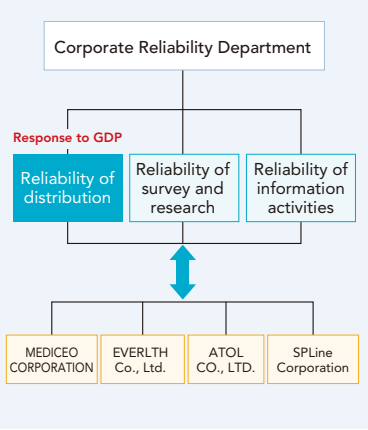
With the addition of SPLine Corporation to the scope of GDP activities in 2021, the Group is now providing training based on the revised quality manuals and SOPs to the logistics departments of the four prescription pharmaceutical wholesalers* as well as to ALCs and Tokyo Chuo FLC and Nishi-Nihon Distribution Center. In addition, we carry out regular quality reviews to promote and enhance the quality of GDP activities.

In response to the spread of COVID-19, we have taken responsibility for handling the distribution of Moderna's COVID-19 (intramuscular injection) vaccine, a preparation that is licensed for manufacture and sale in Japan by Takeda Pharmaceutical Company Limited. The vaccine has strict temperature storage requirements of -25°C to -15°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.

The Corporate Reliability Department, which was established within the Administration Division in 2019, has supported these activities in a number of ways.

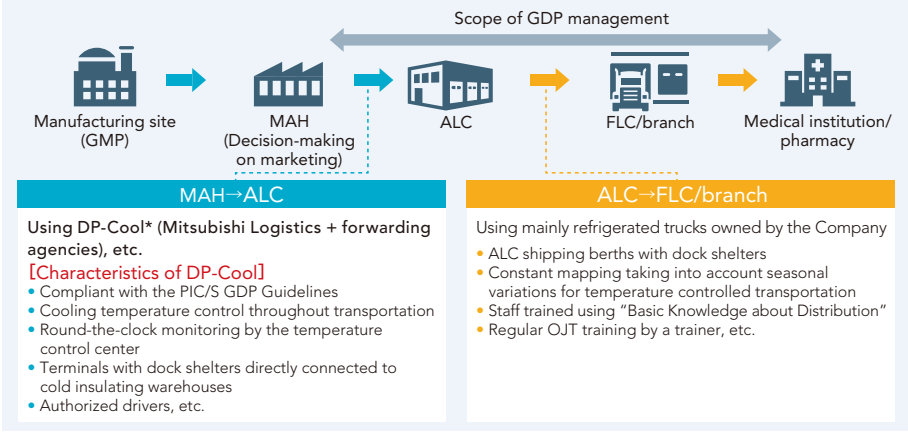
* MEDICEO CORPORATION, EVERLTH Co., Ltd., ATOL CO., LTD., SPLine Corporation

Organization and Role of the Corporate Reliability Department



Note: As of April 1, 2021

Pharmaceutical Supply Chain



* DP-Cool is a new cold insulation transportation service for medical products compliant with the PIC/S GDP Guidelines

Message from the Manager of the Corporate Reliability Department

Akihiro Aoyagi
Manager of Corporate Reliability Department
MEDIPAL HOLDINGS CORPORATION

The Group's GDP activities cover the four prescription pharmaceutical wholesalers MEDICEO CORPORATION, EVERLTH Co., Ltd., ATOL CO., LTD., and SPLine Corporation. Our ALCs, FLCs, and prescription pharmaceutical storage facilities differ in terms of size and the number of products handled. Those responsible for GDP activities include the heads of the logistics and pharmaceutical affairs departments, warehouse staff, MSs, DSs (delivery specialists), and others. GDP activities to date began with ALCs, which are the largest in terms of scale, and have mainly been led by employees from the Head Office, ALC executives, and those responsible for pharmaceutical affairs. However, 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 more strict global standards of the respective company.

In line with growing awareness of GDP and related initiatives, the Corporate Reliability Department is working to promote GDP and continuously improve the quality of logistics, as well as outfit FLCs throughout Japan and the 192 prescription pharmaceutical storage facilities with organizational systems capable of responding to the guidelines and to provide them with the necessary capital investment. At the same time, the department is implementing educational activities for employees, including MSs and DSs. In addition, to increase reliability in logistic and 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.