

The Bushu Pharma Gateway to Asia Solution

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The Bushu Pharma Gateway to Asia Solution

Bushu Pharma’s “Gateway to Asia” service: use of hub and spoke approach for production and delivery of product can greatly benefit global pharmaceutical manufacturers.

Overview

Largely made possible through advancements in medical research and development, the number of new drugs introduced, approved, and distributed as part of the global healthcare system – especially biologic products – has been trending upwards over past ten years. The increase in drugs also correlates with the rise in chronic and other diseases that stem from the longer longevity seen across world populations.

With the FDA approving the second highest number of drugs in the past 20 years (53 drugs in 2020 whereas 59 drugs were introduced in 2018), there is high demand for manufacturing and supply chain support in order to allow these new drugs to reach markets around the world. In response to these requirements and drawing on the company’s GMP expertise developed over the past 20+ years, Bushu Pharma’s “Gateway to Asia” (GTA) service lets international pharmaceutical companies import bulk products into Japan for quality inspection, labeling, packaging and distribution throughout Japan and to other Asian countries. The service is geared towards both manufacturers and distributors – allowing companies to focus on core business activities rather than spending much time and effort on the difficult process of managing lead-time, temperature control, security, inventory, packaging, and urgent order handling across multiple markets. Given the world-renowned quality level of Japanese manufacturing and the country’s expertise in domestic and regional distribution that was developed in line with the country’s focus on just-in-time supply chain management, the GTA service is geared to help respond to the ever-increasing number of new drugs being developed around the world that are targeting Japan and other Asian markets for new launches in 2021 and beyond.

Background

Japan follows the US and China – ranking 3rd globally in terms of consumption of pharmaceuticals according to IQVIA’s 2019 Report and 2023 Outlook. While consumption in South Korea, Taiwan, Singapore, and other Southeast Asian countries is also continuing to rise, there is very little chance that any of those countries can surpass China or Japan. Japan is and will continue to be one of the world’s most important markets in terms of pharmaceutical manufacturing and delivery.

While the notable quality requirements of the Japanese market – especially in terms of visual inspection – create a significant hurdle when overseas companies are considering introducing products to the Japanese market, given the size of the local Japan market, as well as the broader market across Asia, there is however much upside to addressing these challenges and successfully introducing new products

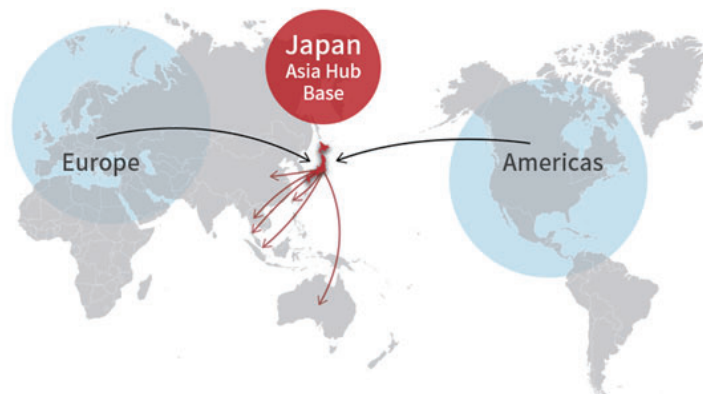
to the market. Indeed, assuming pharmaceuticals meet local Japanese standards, distributors across Asia regularly express that they have a high level of confidence in pharmaceuticals produced in Japan to meet even the most stringent of quality requirements in their respective markets.

In line with the globalization of the pharmaceutical supply chain, the Japanese Pharmacopoeia (JP) is working to promote internationalization. For example, the Pharmacopoeial Discussion Group (PDG), which consists of the JP, USP (U.S. Pharmacopoeia), and EP (European Pharmacopoeia), is focused on harmonizing test methods and elemental impurity test methods. In addition, the Ministry of Health, Labor and Welfare of Japan and the Pharmaceuticals and Medical Devices Agency are aiming to utilize it as a standard pharmacopoeia across the Asian region.

Pharmaceutical Company Global Expansion Strategy

Almost all of the world’s largest pharmaceutical manufacturers have established large scale manufacturing, R&D and sales operations in the world’s largest pharmaceutical markets, such as China and India. These companies also regularly target the ASEAN region, which is dense with emerging markets, for expansion – primarily using Singapore as their regional headquarters.

With regard to the Japanese market, these drug manufacturers often do not have on-the-ground assets, such as manufacturing plants, distribution centers, and distribution networks, and instead aim to enter the Japanese market with minimal resources. With this in mind, they therefore select outsourcing partners for manufacturing, manufacturer logistics, and drug wholesaling in a short period of time after comparing which partners offer the best combination of price, expertise, capacity, and experience. .



Method to Create Efficiency and Cost-Savings

Providing contract manufacturing services from Japan, Bushu Pharma is able to help pharmaceutical manufacturers reach the markets in East Asia (Japan, South Korea, Taiwan, and China) and across the wider ASEAN region – which is densely populated with emerging markets – in an efficient and on-time

manner. Bushu Pharma's competitive advantage in this space stems from the wealth of experience it has developed manufacturing products for export to overseas markets over the past 20+ years, as well as its understanding of the quite strict language and quality requirements of the Japan pharmaceutical market – the world's 3rd largest in terms of annual consumption.

The Bushu Pharma GTA solution furthermore draws upon its broad range of GMP certifications, its overseas inspection experience that started with the FDA, and its manufacturing, packaging, quality testing, and handling capabilities for biopharmaceuticals, regenerative medicine products, and vaccines, including import/export and storage of products.

The service is able to offer global manufacturers the chance to enter markets in Asia without the risk and costs that they would otherwise face by trying to use their own facilities or by seeking out manufacturing and logistics service providers separately on their own.

Some of the key reasons global manufacturers call upon Bushu Pharma to be their partner include:

Shortening lead-time from PO to delivery

When it comes to establishing timely and cost-effective access to markets in Asia, global pharmaceutical companies that rely upon CDMOs and CMOs in Europe or the US will typically find that those options take a much longer time from Purchase Order to delivery to the markets in Asia. For example, it will oftentimes take more than 90 days to complete a delivery from Europe or the United States to a country in Asia. The result of this is that it becomes difficult to optimize general inventory and logistics, and when it comes to packaging sites, there is a possibility that inventory will be held for more than 3 months at US and European sites and more than 3 months at the local warehouses in the Asian countries.

Companies that instead utilize Bushu Pharma as their hub will find that it is instead possible to shorten the lead-time from PO to delivery to their target markets in Asia. The lead time required for routine orders can be reduced to 60 days, while urgent orders can be handled within 30 days. By shortening the lead time, it is also possible to reduce the inventory in the local warehouses in the target markets in Asia.

Requiring reduced warehouse space and optimizing security, packaging and temperature control operations

In addition to being able to shorten the lead time from purchase order to delivery to the target market, warehouse space can be reduced through thorough review of 36-month forecasts, advanced planning for required warehouse space, and consultation for optimal operation for procurement of packaging

materials, securing of packaging slots, and then the packaging itself.

For security control, Bushu Pharma and its partners provide logistics support for bulk import into Japan and then distribution through Japan and export to other Asian countries.

When it comes to packaging, Bushu Pharma can provide advice and cooperation on product and package specifications tailored to each target market, including GS1 serialization and aggregation systems. We are also able to while leverage our experience in print serialization for counterfeit medicine.

For temperature control, which is essential for biopharmaceuticals, regenerative medicines, and vaccines, Bushu Pharma provides services for the pharmaceutical transportation chain, meeting GDP (Good Distribution Practices) requirements. These services cover receipt, storage, inspection, and packaging of the pharmaceuticals at our recently expanded temperature-controlled packaging center in Saitama, Japan. To continuously meet GDP requirements for receipt, storage, inspection and packaging, we will continuously invest in these types of facilities to meet the growing demand for this type of service.

Unmatched quality

To meet the unique and stringent quality specifications that are demanded by the Japan market, Bushu Pharma has leading resources for:

- visual inspection – which is performed and maintained by skilled inspector staff who have passed regular qualification tests; ,
- cold chain warehousing – which provides refrigeration control during the packaging of biopharmaceuticals, regenerative medicine products, vaccines, and other temperature sensitive products; and
- packaging – in which we use packaging lines that include inspection and packaging automation featuring multiple visual inspection cameras and packaging exposure time control.

The Cold Chain Warehouse and the Packaging Line are responsible for the automation of inspection and packaging using visual cameras within the line, and packaging exposure time management.

Expanding Resources

Bushu Pharma is dedicated to being the best partner for global pharmaceutical and medical device manufacturers, constantly reviewing and refining internal quality control and safety protocols. Furthermore, the company strives to ensure it can offer the latest and most relevant facilities to its customers. To that end, Bushu Pharma signed a business alliance agreement on April 19th 2021 with

Suzuken Group, a core player in the pharmaceutical distribution industry that owns a distribution network in Japan enabling the international transport of specialty pharmaceuticals. The agreement was made with the aim of creating a platform to provide one-stop comprehensive support for the launch of products by global specialty pharmaceutical manufacturers that are aiming to newly enter the Japanese market. The three major effects of the agreement are:

(1) Establishment of a one-stop logistics center in Soka City, Saitama Prefecture, for manufacturing operations and general logistics.

By securing an area within the Suzuken's planned Metropolitan Area Distribution Center (Soka City, Saitama Prefecture), Bushu Pharma will be able to conduct contract manufacturing operations, and the two companies will work together to offer one-stop services for specialty pharmaceuticals. Services will include MAH (marketing authorization holder/drug approval holder) consulting, import, inspection, manufacturing, storage (manufacturer logistics), wholesale distribution, PMS (post-marketing survey), and patient support.

In addition, through use of a specialty drug traceability system developed by Suzuken, Bushu Pharma will be able to provide increasingly efficient and high-quality delivery of products all the way to patients. The Cubixx specialty drug traceability system can address the need to strictly monitor and control temperature for specialty drugs. Based on the use of this system, Bushu Pharma will be able to provide an environment in which medical professionals can offer medicines safely and securely without risk for patients.

(2) Establishment of the Bushu Pharma Kazo Packaging Center within Suzuken subsidiary Chuo Unyu's Kazo Pharmaceutical Joint Logistics Center and start of contract manufacturing operations.

Bushu Pharma will utilize the spacious cold storage area -- spanning 1,465 sqm -- newly established within the Kazo Pharmaceutical Joint Distribution Center of Chuo Unyu Co., Ltd. (hereinafter "Chuo Unyu"), which is a consolidated subsidiary of Suzuken. The area will make it possible for Bushu Pharma to carry out contract manufacturing centered on secondary packaging such as inspection, labeling, and packaging.

(3) Initiation of joint proposal business in the United States for pharmaceutical manufacturers aiming to enter the Japanese market.

In addition to sharing staff between businesses, Bushu Pharma, will join together with Suzuken companies, including its consolidated subsidiary S.D. Collaboration Co., Ltd., for joint proposal sales to specialty pharmaceutical manufacturers who are planning to enter the Japanese market.

Making access to Asia a reality

Many large global pharmaceutical companies have several key manufacturing bases in India, China, and Singapore to expand their business in Asia, while in Japan, one of the top three pharmaceutical markets in the world, they have avoided using their own factories as much as possible due to the unique and strict quality requirements, the Japanese language, and the labor cost, which was once considered to be extremely high in Asia.

Nowadays, many pharmaceutical manufacturers do not have assets such as manufacturing plants, distribution centers, and distribution networks, and are aiming to enter the Japanese market with minimal resources. Many pharmaceutical manufacturers are selecting outsourcing partners for manufacturing, manufacturer logistics, and pharmaceutical wholesaling in a short period of time.

However, Bushu Pharma, which has been in the contract manufacturing business for more than 20 years and has passed GMP certifications in more than 43 countries around the world, is a global market-oriented company specializing in contract manufacturing that meets Japan's strict quality requirements for inspection, packaging, storage, and transportation. Bushu Pharma can reduce and optimize the inventory of bulks, packaging materials and finished products by shortening the lead time from purchase order to delivery to Asian markets and flexibly responding to urgent orders. It will also reduce and optimize inventory, and reduce logistic fees from the US and Europe to the Asian markets.

The innovative solution of using Bushu Pharma as an Asian hub, "Gateway to Asia", will help European, American and other global pharmaceutical manufacturers to efficiently launch and supply their products in Japan and throughout Asia with the highest quality.

About Bushu Pharmaceuticals Ltd.

Drawing on its experience and knowledge as a contract development and manufacturing organization (CDMO) it has cultivated over 20 years, Bushu Pharma manufactures solid preparations, solid preparation primary packaging, injection manufacturing, and injection packaging not only for domestic pharmaceuticals but also for global pharmaceutical manufacturers. Bushu Pharma is capable of providing a wide range of products and services -- from clinical trial supplies to commercial product development support to commercialization -- and has numerous manufacturing facilities and technologies.

From project start to approval, Bushu Pharma is a leading domestic contract manufacturing company that can provide optimal solutions such as technology transfer, production, packaging, and logistics in Japan.