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World Courier

Deep frozen supply chain essential for the safe delivery of essential ingredients for a life-saving breast cancer treatment

A secure supply chain allowing the delivery of essential active pharmaceutical ingredients (APIs) — under the required temperature controls to ensure optimum quality — is important throughout the drug development process. But, at the commercialization stage, it becomes mission-critical to the successful launch of a drug product and to ensure patients can begin to benefit from all those years of research.

For one leading ingredient manufacturer, World Courier's involvement was essential to ensure the timely deep frozen delivery of an innovative API destined to become a life-saving new treatment for breast cancer.

The commercialization stage is a complicated time in any drug development project. Small-batch manufacturing processes for APIs and other ingredients have to be rapidly scaled up for commercial manufacture without sacrificing quality and efficiency. At the same time, supply chains have to be rethought to ensure that large quantities of ingredients can be transported quickly and safely, under the right environmental conditions to maintain their integrity. When the API in question requires strict sub-zero temperature controls during transit, this process becomes a lot more complex.

It is no surprise, then, that so many drug developers and their ingredient suppliers rely on World Courier's Commercial Supply Chain (CSC) solution. By providing a comprehensive cold chain supply service capable of securing the manufacturing supply chain, it can enable pharma companies and their providers to navigate commercialization complexity.

Scenario: Addressing deep frozen manufacturing supply issues

A leading Japanese API manufacturer had recently received regulatory approval for a new API destined for use in an innovative treatment for breast cancer developed by a Japanese pharmaceutical company. Both companies were ready to begin scaling up to commercial production, keen to launch the potentially life-saving product on the market so that patients could benefit.

However, the API in question had strict logistical requirements that needed to be addressed before they could successfully transport it in commercial-scale quantities from where it was manufactured to the drug product facility where it was needed.

The API had to be shipped in powdered form, in large drums, from the originating site in India, to the destination site in Japan, within one week of an order being placed. Complicating matters, these drums needed to be transported in temperatures consistently between -80°C and -60°C — any excursion from these parameters while en route could lead to the molecule degrading, with consequences for the performance and safety of the finished drug product.

The API manufacturer turned to logistics provider World Courier, for support. The manufacturer had already been working with the logistics specialist for many years, benefiting from their expertise to ship investigational new drugs (IND) to customers. World Courier also supported the manufacturer in shipping this API in the clinical trial stages. It was confident that World Courier had the capability and knowledge to provide a solution to this deep frozen conundrum.

Solution: Temperature-controlled containers and real-time monitoring

To support the API manufacturer, World Courier harnessed the well-established infrastructure of its CSC solution to ensure a reliable and compliant supply network capable of shipping the API from site to site with minimal delay.

Between -80°C and -60°C

temperature required to transport API drums

In order to address the deep frozen requirements of the API, World Courier proposed transporting the drums — up to six per shipment — within global dry ice (GDI) 80 thermal boxes. These would maintain internal temperatures of between -80° and -60°C, assuring the quality of the API within. Moreover, they were already validated for use by the client, helping to streamline the integration of the new supply chain solution into the manufacturer's processes.

GPS temperature loggers were attached to the GDI boxes to provide real-time monitoring of the conditions inside at every stage of the shipment's journey from India to Japan to ensure consistent environmental control throughout.

In addition to providing a time and temperature-sensitive logistics solution to the API manufacturer, World Courier supported in managing the regulatory and customs compliance required to ship the product successfully across international borders with minimal delay.

Outcome: A key link in the commercial manufacturing chain

Central to World Courier's success in this project was its ability to integrate insights from its previous relationship with this API manufacturing client, and from other customers into its recommended solution. Lessons learned from previous projects have helped it design ever more effective cold chain supply networks and identify potential bottlenecks before they occur, minimizing the risk of unnecessary delays or temperature excursions.

As a result, the solution World Courier designed for this supplier has been highly effective at delivering commercial-scale quantities of temperature-sensitive API in accordance with the strict timeline for commercialization of the final drug product. Talks are now underway to extend the terms of the initial 12-month contract and to expand the quantities being shipped, enabling the API manufacturer and its customer to continue to benefit from World Courier's expertise, quality, and reliability.

Summary

World Courier has an in-depth understanding of the complexities facing ingredient suppliers and their pharmaceutical company customers in maintaining cold chain integrity throughout an ingredient's journey from site to site.

No two APIs are alike — they all have their own unique transit requirements that need to be taken into account to ensure that they arrive at their final destination in the same condition they left the production line and their originating facility.

For this particular API, an effective, high-performance deep frozen supply chain was essential to meeting this goal. By working closely with World Courier, this customer was able to provide this logistical solution for its product, setting the stage for the effective commercialization of a breast cancer drug with the potential to deliver better health outcomes for thousands of patients.

We'll offer the comprehensive cold chain transport you need to secure your commercial manufacturing supply chain. Contact us to find out more about our solutions.