

## Global drug development partners and World Courier operational excellence deliver biologic breakthroughs to patients

**For two global drug innovators, commercializing a ground-breaking biologic treatment required shipping active pharmaceutical ingredients (APIs) to a third manufacturing partner.**



### \$2.6 billion

Approximate cost to successfully develop a drug according to Tufts

To optimize production efficiency of this monoclonal antibody (mAb) drug, the manufacturer needed a logistics provider to execute a precise delivery schedule. World Courier's operational excellence and dedicated logistics network were more than ready to tailor a solution this developer could not find with existing logistics partners.

**Scenario: Critical drug manufacturing supply chain made stronger, faster, and more resilient**

Successful drug development is increasingly becoming a multi-partner, multinational affair, with progressively intricate and lengthy supply chains. Research and clinical development are now often accomplished across several countries and manufactured in another. APIs are routinely procured from one or more sources. These are then transported by a contract development and manufacturing organization (CDMO) to a separate facility for use in the manufacturing process of the drug product and to be prepared for physician and patient use. This contemporary drug strategy boasts large benefits, but also adds logistical complexity to each stage of development and manufacturing.

For a broad range of financial and regulatory reasons, developing and marketing a breakthrough first-in-class biologic now usually involves an intricate logistics arrangement among several commercial partners. So was the case with this collaboration of two development partners and a manufacturing partner. A first-in-class designation by regulators means the new drug is the best treatment for the condition and supersedes other treatments. Because of the enormous costs involved – approximately \$2.6 billion to successfully develop a drug, according to Tufts – it makes sense to share risk, as well as reward, among trading partners.

However, completing this manufacturing supply chain's critical last mile proved to be a greater challenge than anticipated. For this liquid injectable drug product, the APIs required tightly scheduled transshipment to a CDMO in another state for filling and finishing into prefilled syringes. Before production could start, a validated shipping container solution needed to be included in the receiving CDMO's chemistry, manufacturing and controls (CMC) filing to regulators. To that end, an industry-standard shipper solution was specified for the task.



**Between  
+2°C and +8°C**

temperature required  
to maintain API and  
product integrity  
during transshipment

In their CMC filing, the drug manufacturer designated a qualified provider that specified the container technology for shipping the mAb-based APIs. The reason for this choice was because the technology was validated to maintain the APIs at 2 – 8°C and product integrity during transshipment between facilities.

The partnership's existing logistics provider was unable to provide guarantees in terms of meeting the strict time slots for both pick-up and delivery. This presented an unacceptable risk of interruption, and disruptions at this stage in the supply chain had the potential for significant financial losses with little room for manoeuvre. Therefore, an alternate logistics provider's solution was necessary: World Courier.

**Solution: Dedicated network, operations know-how, and a container-agnostic closed loop shipping cycle**

Both the APIs' supplier and the CDMO's quality departments placed strict requirements on how these shipments were to be managed. The drug's production schedule required the CDMO to receive a regular supply of APIs to a tight, prescribed schedule. Containers are delivered to the manufacturing site, then plant operators receive the contents. The empty containers leave the CDMO, then are shipped to a central warehouse facility before they are returned to the APIs supplier for refilling.

World Courier were selected not only for their dedicated shipping network, operational excellence, and cold-chain capabilities guaranteeing this customers' production schedule. Their approach to managing logistics-associated risk and container integrity was also another key differentiator.

World Courier's solution called for leasing re-usable temperature-controlled shippers, and then placing them in rotation to and from the commercial partners' locations. World Courier's trucks leave the shipper warehouse with five containers and head to the APIs supplier where four are loaded, with a fifth held in reserve. The shipment is also accompanied by a redundant container to mitigate the effects of malfunction or damage, reducing risk to virtually zero.

All containers are then shipped to the CDMO where the APIs are unloaded and then prepared for processing and finishing into the final drug product. While these containers are held at the CDMO, World Courier repeats the cycle, so that when the next shipment arrives, the driver leaves with the emptied containers from the previous shipment and takes them back to the warehouse. Transit to and from the sites of both inbound and outbound containers are subject inspection and quality control – another key aspect of this solution that helps reduce risk and cost efficiently assures compliance.





**Outcome: A superior treatment for a chronic debilitating condition finally reaches patients in need**

The formulation approved to treat a chronic and debilitating immune disorder of the skin is now being distributed globally to the tremendous relief of many patients. Because World Courier's dedicated network and operations were container agnostic, it was able to deliver the solution the partnership needed. For this customer, and as with every customer, World Courier's flexibility and white-glove service allows strategic commercial partnerships with contemporary drug developers to reach markets and patients as fast as possible.

"With the increasing complexity and value of biotech drugs making their way to market, we recognize the growing need for robust and reliable specialty logistics solutions. This understanding paired with our expertise in minimizing risk in complex supply chains and global reach, were the deciding factors for this biologics manufacturer choosing to work with World Courier."

**Mads Skovvang**  
Sales Manager, World Courier

**Summary**

World Courier is intimately familiar with the logistical complexities associated with drug manufacturing, and especially with today's biologics which require cryogenic cold chains to distribute compliantly and to assure drug product safety and efficacy. For this customer, world-class operational capabilities and a completely dedicated but flexible logistics network were all this partnership needed to choreograph their life-changing drug's dance all the way to the patient.

**We'll provide the flexibility, end-to-end visibility, and dedicated logistics network you need to transport any drug substance or drug product, virtually anywhere on time and at a set temperature. Contact us to find out more about our solutions.**