

Transparent cold chain clinical supply strategy delivers better patient access model for a global drug developer

For most pharmaceutical companies conducting clinical trials on their journey to market approval has only become more challenging. It has also become more resource-intensive.

To cope, much of the pharma industry turns to third party service providers to handle the complexity of delivering drugs in clinical trials to patients. For one innovator with a promising candidate, World Courier's clinical trial supply (CTS) solution was perfectly positioned to be the first to deliver its breakthrough biologic to participants, then ensuring commercial supply to patients post-approval.

Clinical trial designs are more complex than ever and made even more so by the cold chain logistics associated with delivering advanced biopharmaceuticals to research sites and trial participants. To deliver trial medications safely to patients successfully biopharmaceutical developers continue to rely on World Courier's CTS offering to provide a comprehensive, effective solution that keeps drug products in control, protected and, safe during all phases of handling and transport.





Scenario: Long relationships and insights identifies a strategic solution

For one long-term customer with a major R&D site in Germany, World Courier's comprehensive CTS offering has been at the center of this biologics developer's clinical trial supply strategy for more than 15 years. Focused on investigational new drugs (INDs) to fight cancer, this pharmaceutical innovator has been at the forefront of developing highly effective biologic drugs to fight disease.

Already established to manage the cold chain custody and product integrity of the company's past clinical trial efforts, World Courier had a successful history of controlling its product's temperature in a range between +15°C and +25°C for this client. Given the nature of the business and the close relationship formed over time, it was only a matter of time before a new opportunity to deliver a cold chain solution was proposed to World Courier's business lead.

Although for most biologics delivery timing and temperature control are rigidly sacrosanct, the new CTS opportunity presented new technical and operational challenges including a lower, tighter product temperature range between +2°C to +8°C. Another new requirement included transit and handling over longer distances, all while providing strict regulatory oversight.



Between +15°C and +25°C

The temperatures at which World Courier has a successful history of controlling for this client.

Solution: Visibility and compliant control over time and distance

In this case World Courier's CTS offering, the solution was already in place already proving effective at compliantly delivering this client's clinical supplies to sites in Germany and Europe. Leveraging an already established supply chain, operation managers simply added the client's new temperature requirement to its supply chain setup and then confirmed World Courier's pioneering Cocoon shipping and temperature container was validated for use.

World Courier's expertise in time and temperature-sensitive transport has always been at the center of the successful relationship with this client. In addition to maintaining optimum temperature control across the clinical supply chain, the end-to-end transparency of World Courier's data systems and network communication provide the real-time transparency the company relies on to supply clinical sites. Essential to deliver patients access to medications in trial, the cold-chain clinical supply logistics of temperature-sensitive biologics will very much mirror what will be required to assure commercial supplies as well. For most biologics in development market approval depends on a validated cold-chain strategy – all the way from the lab, the factory, clinic, and patient.



Outcome: Delivering mission-critical, and strategic commercial support

As with any client, especially those World Courier has had a successful long-term relationship with, experience brings insights that supports the development of an even stronger alliance – one that often delivers better business results. Understanding the implications and the likelihood their promising candidate would win approval, World Courier's business lead was interested in how the company's commercial team was progressing their plans to distribute the sensitive drug product post approval.

Queries from the clinical side of the business revealed the commercial side was only at the very earliest stages developing the product's commercial distribution and cold-chain strategy. Partners had not been considered and the commercial team's business developers were only just beginning to frame its go-to-market planning. The timing was perfect because even though in essence the commercial group did not have an operational partner to manage cold-chain logistics, its clinical group did, much of the program already fully integrated into the organization's core operational and procurement systems. With logistics outcomes (and investment) demonstrated so clearly over time, selecting World Courier as its commercial third party provider would be a winning strategy and the best way to distribute their breakthroughs safely and securely.

Summary

World Courier is intimately familiar with the cold-chain integrity today's advanced biologics require to reach patients. Because most commercial biologic drugs are sterile liquid injectables they will always require strict temperature controls – from manufacture to patients. A clear cold chain custody will always be necessary to assure drug product safety and efficacy. For this customer, a close working relationship based on a solid CTS offering provided valuable strategic planning insight that ultimately sets the stage for the successful commercial launch of their life-saving drug product.

We'll provide the end-to-end visibility and security you need to transport your safety samples, on time and within temperature. Contact us to find out more about our solutions.