

Managing A Cold Supply Chain



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Cold supply chains play a vital role in biomanufacturing, allowing for the safe transportation of temperature sensitive pharmaceutical materials and products.

We sat down with James Klingelhoef to gather his thoughts and opinions on how biomanufacturers can best manage their global cold supply chain.

What are the main challenges in managing a temperature controlled supply chain?

The challenge associated with managing a temperature controlled supply chain is a vast topic. As the pharmaceutical industry has evolved, we've witnessed an ever expanding global supply chain that requires shipping to developing countries that often times lack the infrastructure to maintain the required temperatures of the products. In order to meet the temperature requirements for the aforementioned shipments to difficult locations, it is imperative that the manufacturers work with their logistics partner to effectively plan a temperature control strategy before the shipment is picked up from the shipper's location.

Why do biomanufacturers struggle with with this?

Outside of shipping to new destinations, we've also seen growth in the variance of required temperature control ranges for pharmaceutical product (i.e. CRT, -15c to -25c, cryogenic temperatures, etc).

Therefore, it is important that the supply chain is carefully analyzed before executing the initial shipment. What's more is that the proper packaging to maintain the required temperature range must be thoughtfully considered. Often times, we do find that Biomanufacturers struggle with managing a temperature controlled supply chain. Common obstacles include, but are not limited to: incomplete consideration for regulatory requirements for the product (i.e. import permit/license), insufficient lead time available to source appropriate packaging, thinking that packaging alone is the total solution, insufficient knowledge regarding valuation of the product and resulting VAT implications, and lack of time to help effectively plan their supply chain.

Additionally, the evolution of clinical trial design (e.g. adaptive dose, immunotherapy with a circular supply chain, direct to patient) has impacted the requirements for strict transit times, and failure at any point in the supply chain can result in a domino effect of consequences.

Even companies with a wealth of experience on staff can struggle because of the tight parameters of their supply chain.

How can these challenges be overcome?

All of the above mentioned challenges can be overcome by effective planning, and more importantly, proper execution. If you work with your partners, you can outline expectations to ensure that you are not scrambling at the 11th hour to accomplish your supply chain objectives. Also, it is prudent to work with partners with a proven track record of supporting manufacturers with not only optimal lead times, but also constrained timelines as well (as this is very often the case where pharma sponsors have to react immediately to the demands of the supply chain)

How does a global supply chain affect regulatory compliance? What are some of the factors that biomanufacturers should be aware of?

Regulatory compliance has an absolutely critical impact on the global supply chain. With the EU GDP guidelines, we find that manufacturers are forced to scrutinize their supply chain at a granular level. Based on the EU GDP, we suggest that manufacturers investigate the answers to some of the following questions: who is transporting my product and what are the quality standards of the transport provider? Have I executed a risk assessment of my delivery lanes to confirm if temperature controls are necessary? Do I work with partners who incorporate quality in their Standard Operating Procedures?

What are the most important elements for building a successful temperature controlled supply chain?

Effective planning for the supply chain is necessary. However, it is important to involve all stakeholders early in the planning process so that the landscape is fully understood before implementation.

How does World Courier help biomanufacturers overcome the challenges of managing a temperature controlled supply chain?

Simply stated, World Courier mitigates the risk within a biomanufacturers temperature controlled supply chain. As the industry progresses towards increased regulatory scrutiny (i.e EU GDP), it is important that biomanufacturers seek partners whose foundation rests upon quality. For World Courier, we've always embraced a culture of quality, and this theme is particularly evident in our standard operating procedures that are based on the guidance documents of GMP, GSP, GCP, and GDP.

What advice would you give to an organization looking to build or optimize a global temperature controlled supply chain?

At face value, transporting a product from point A to point B may appear simple. However, supply chain failures occur, and it is important to understand any weak points in your supply chain. Biomanufacturers should ask questions: "Is my transport partner GxP compliant? Will transport of my product be outsourced to a secondary agent who likely does not have the same quality standards as my transport provider of choice?". By identifying weak points in the supply chain, biomanufacturers can make informed decisions regarding their risk mitigation strategy.

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