Case Study: Global Ultra-Cold Clinical Trial Logistics

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Introduction

According to Pharmaceutical Research and Manufacturers of America (PhRMA), biopharmaceutical researchers predict a 69% increase in the number of personalized medicines in development over the next five years. Increasingly these advanced, customized therapies demand a cold supply chain. The globalization of clinical trials, the prevailing infrastructure and regulatory environment can significantly impact the design of that supply chain. Even the largest pharmaceutical manufacturers can find the required logistics support to be a maze of confusing and at times, daunting options.

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The Challenge

A new United States-based biopharma working on its first cell therapy-based treatment had expanded the scope of their trial and extended its patient pool to include a patient in Beijing, China. Although sophisticated and advanced in their research capabilities, the organization had limited resources and logistics expertise on how to transport its IMP to China. This presented a number of challenges:

- **Identify and secure a shipper solution to maintain a cryopreserved sample**
- **Understand and obtain specialized permits required in emerging market**
- **Minimize risk of import clearance delays**
- **Provide final mile white glove delivery**

The biopharma company turned to their current transportation supplier for guidance, but the complexity of the process proved too challenging and they were unresponsive.

The Solution

The biopharma reached out to Thermo Fisher Scientific. When the Thermo Fisher Corporate Account Manager learned of the impending need for logistics support, they engaged the services of their specialty logistics colleagues.

The Patheon specialty logistics service offering includes customized logistics solutions for the life sciences industry. With specific expertise in specialized transportation solutions, the global logistics specialists had the required experience and resources to accept the challenge.

Working closely with the biopharma's clinical trial project management team, the specialty logistics team designed an end-to-end solution that would meet their needs.

In order to ensure stability of the cell therapy liquid nitrogen (LN2) dewar was required as it would have sufficient hold time to maintain the sample through final delivery to the investigator site. Because the purchase of a dewar for a single shipment was costly, they engaged their Fisher Clinical Services colleagues to provide a reusable ultracold shipper, enabling a cost-effective one-time 'rental' of a preconditioned dewar.

While arrangements for the pre-conditioned dewar were being made, the specialty logistics team served as a consultant to the biopharma, providing additional support, including:

- **Identification / creation of Harmonized Tariff Schedule (HTS) codes for each cell line shipping to China**
- **Assistance in obtaining required export and import permit applications**
- **Arrangement of transportation for each leg of the shipment, including white glove final delivery**

Once the required permits were in place, the team remained on alert pending notice from the biopharma company that the sample was available and the patient was ready. When the shipment was activated, they provided detailed oversight and reporting for each leg of the journey, including the reverse logistics of the dewar return to Fisher Clinical Services.

Conclusion

With a shared vision and purpose, i.e. to help customers to accelerate innovation and enhance productivity, the Thermo Fisher Scientific team quickly collaborated to provide a solution that specifically met the unique needs of this biopharma. Depth of experience, specialized expertise and personalized consultative support were essential to ensure success.

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