cryoport
SCIENCE. LOGISTICS. CERTAINTY.

CRYOPORT'S INTEGRATED PACKAGING, MONITORING AND SOFTWARE TECHNOLOGIES CREATE A VIABLE SUPPLY CHAIN FOR A TOP 10 GLOBAL PHARMA IMMUNOTHERAPY

When Cryoport's client experienced a problem with shippers tilting during transit, compromising the effectiveness of the liquid nitrogen coolant and jeopardizing a CAR T-cell immunotherapy clinical program, Cryoport solved it with a comprehensive solution.

Background

A clinical trial for an innovative immunotherapy required reliable and complete logistics to transport apheresis material drawn from the patient from point-of-care to the manufacturer and then back to the point-of-care for administration to the patient. It was essential the materials be maintained under cryogenic conditions during each leg of the supply chain and the chain of condition and chain of custody be tracked throughout transport.

Advanced liquid nitrogen (LN_2) dry vapor shipping containers called dewars were used to transport the apheresis material and manufactured therapy during transit. These shippers are capable of maintaining temperatures of -196°C for up to 10 days. However, they only work as intended if they are kept in a vertical position. Even when labeled appropriately, the shippers can shift and tilt or be incorrectly positioned during transit, potentially putting the products at risk.

SmartPak II™ Monitors

- Location
- Temperature
- Pressure
- Light
- Orientation
- Humidity
- Shock

Problem

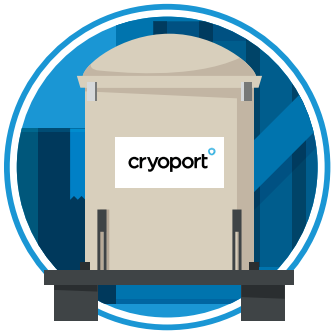
During the conduct of the study, the client experienced shipping problems that continued to occur regardless of the carrier or airline. The shipper would be tipped during transit, causing its LN_2 vapor to sink to the lower side of the dewar, interrupting data collection and reducing dewar hold time. If the shipper's orientation wasn't rectified, the product quality, the clinical study data and potentially the efficacy of the patient treatment would continually be endangered.

The problem was further compounded by the value of the shipments. The study concerned an autologous therapy for a chronic disease, and patients were often too weak to undergo another apheresis procedure or withstand a delay in treatment in the event of a shipment failure. A solution needed to be implemented quickly.

Solution

The client enlisted Cryoport's expertise to identify a solution. Cryoport provided an integrated solution that eliminated the package orientation problem while addressing the specific needs of the different stakeholders in the supply chain: the client, the clinical trial investigator, the point-of-care personnel, the manufacturer and the material handlers. Cryoport's advanced solution includes:

- **The SmartPak II™ Condition Monitoring System**: Tracks and records package orientation, location (GPS, cellular and Wi-Fi triangulation), temperature (internal and external), barometric pressure, exposure to light, humidity and shock events to ensure the quality of the product.



- **The SlideRite™ Pallet**: Locks the shipping container in place to eliminate tipping and enforces the correct orientation at all times with quick-release rubber latches to make retrieval easy. The SlideRite™ pallet can still be used with or without standard material handling equipment, such as a pallet jack or forklift, creating a more ergonomic approach to material handling at the point-of-care.
- **The Cryoport Express® Large Capacity Shipper (dewar)**: Maintains materials under cryogenic conditions of -196°C for up to 10 days in a scientifically engineered, reusable shipping container that can be shipped and stored safely.

- **The Cryoportal™**: Provides cloud-based transparency to the entire cold chain process with a single integrated data stream that consolidates all logistics, condition monitoring and equipment qualification data for every shipment.

Outcome

Cryoport's integrated solution reduced the incidence of carrier mishandling events from 32 to zero. This is especially important with this patient-critical supply chain where the patient's own cells may be the key to the cure. The client's clinical trials are continuing without shipper orientation issues.

The solution can accommodate any material handling scenario. No special material handling equipment was required for the SlideRite™ pallet; standard equipment can be used if available.

The end-to-end condition monitoring enabled by the SmartPak II™ system provided the client with real-time visibility through the Cryoportal™, assuring the client that the condition of the materials was maintained during transit.

Conclusion

Cryoport's integrated cold chain logistics solution not only solved the client's problem encountered during clinical development, Cryoport created a viable logistics framework as the client begins to plan for commercialization.

Cryoport's expertise is dedicated to temperature-controlled logistics, offering solutions that combine science, technology, specialized packaging and storage, shipping and fulfillment services. When there is no room for error, **Trust Cryoport**.