Info Brief:

Comprehensive Risk Mitigation for Viral Vector Logistics

Cryoport Systems

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Comprehensive Solutions for the Safe & Compliant Shipping of Viral Vectors in Gene Therapy

Gene therapy, a rapidly advancing field within the life sciences, relies heavily on the safe and compliant transport of viral vectors. These vectors, crucial for delivering genetic material into cells, require specialized handling and transportation conditions to maintain their integrity and efficacy. Cryoport Systems is the industry leader in developing and providing comprehensive, end-to-end supply chain management solutions tailored to the unique challenges advanced therapy developers encounter. By understanding and addressing common roadblocks and pain points in the temperature-controlled supply chain for advanced therapies, we can more effectively support our clients in delivering life-saving therapies to patients worldwide.

Customized Shipping System Manufacturing and Selection

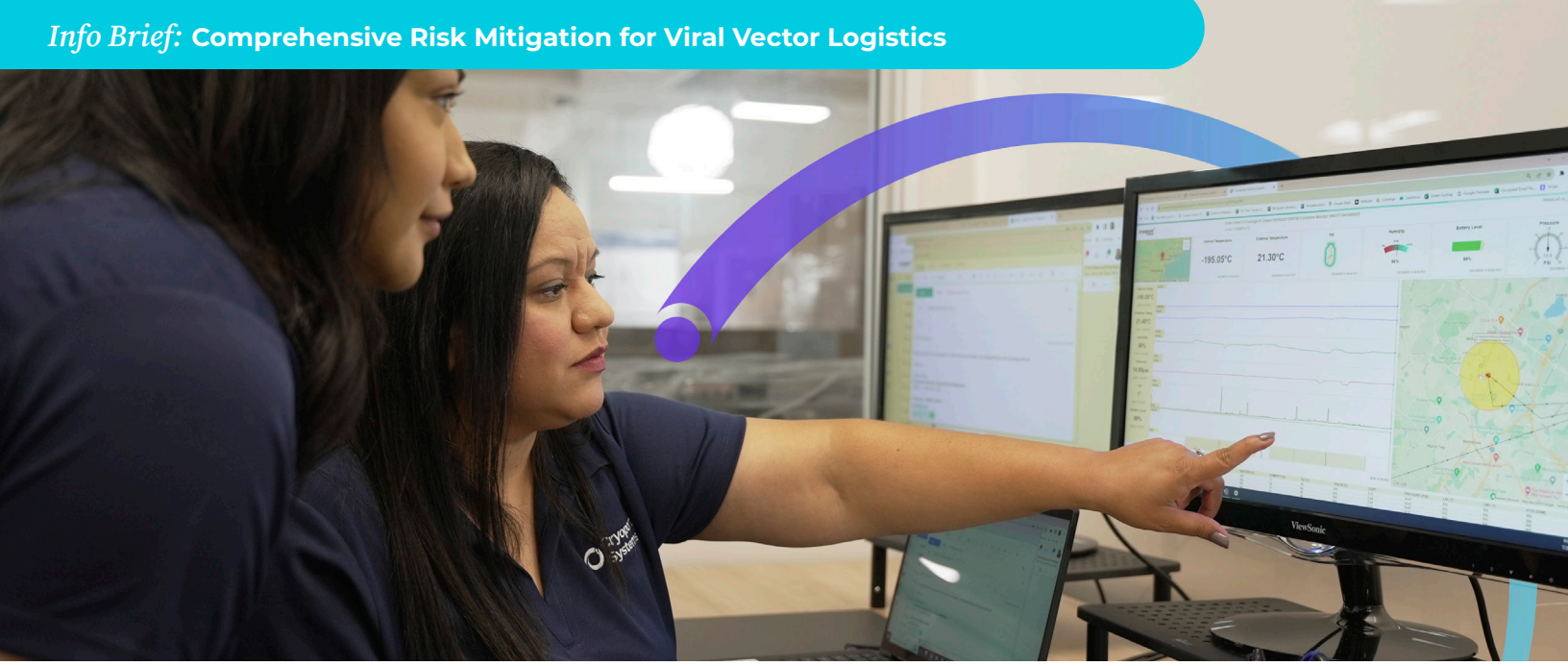
One of the primary concerns in shipping viral vectors is the assurance that these critical materials remain stable and viable throughout the transportation process. Recognizing the temperature-controlled supply chain challenges faced by companies developing advanced therapies, Cryoport Systems has focused on developing purpose-built, customized shipping solutions created to meet the unique needs of the life sciences.

Our Advanced Therapy Shipper™ (ATS) fleet is specifically designed for the unique requirements of cell and gene therapy supply chains, supporting both clinical and commercial applications. Engineered to address common challenges such as temperature fluctuations and physical shocks, these shipping systems ensure the specific conditions needed for viral vectors and advanced therapies are maintained throughout transit. The ATS fleet includes various temperature band solutions, notably the Cryoport Elite™ Ultra Cold dry ice shipping system that offers industry-leading hold times of 140+ hours.

The Cryoport Elite™ Ultra Cold dry ice shipping system fills a crucial need in the industry by providing total protection and comprehensive shipment monitoring for extremely sensitive materials. Designed to meet stringent compliance standards and featuring a robust, hard-shell, and reusable design, this system is custom engineered to meet the specialized needs of gene therapy and viral vector transport. Unlike traditional dry ice shipping solutions intended for single use, the Cryoport Elite™ Ultra Cold system is built for proactive risk mitigation, effectively managing variability throughout the transportation journey.

These purpose-built solutions ensure that each shipment can meet the unique demands of transporting viral vectors and gene therapies, with proactive risk mitigation integrated into every stage.

> “Standard off-the-shelf shipping solutions often fall short of meeting the specific needs of gene therapies and viral vectors, leading to potential risks in product integrity.”



Comprehensive Shipment Monitoring

Maintaining the integrity of viral vector and advanced therapeutic shipments requires more than simply tracking their location; it demands comprehensive monitoring of internal and external environmental conditions throughout transit. Cryoport Systems understands the critical necessity of advanced monitoring and has developed the industry's most comprehensive monitoring technology and processes for critical shipments of valuable commodities.

Our intelligent logistics solutions provide full visibility into each shipment, going beyond basic location tracking to monitor critical parameters like temperature, pressure, light exposure, orientation, humidity, and shock. This is achieved by integrating our Smartpak II® condition monitoring system with our Cryoportal® 2 logistics management platform and Live View™ display.

For clients, this ensures near real-time access to detailed data about the conditions their viral vectors or therapies are exposed to during transport. Any deviation from the optimal conditions can be immediately identified and addressed – for example, if a temperature excursion occurs, our system alerts our expert team, who can then take prompt corrective actions to prevent any potential damage to the shipment.

This level of monitoring is essential for ensuring the viability of viral vectors and advanced therapies throughout the entire temperature-controlled supply chain. With comprehensive insights into the transportation process and 24/7/365 support, our team can proactively manage any risks that a shipment may encounter during transit, ensuring critical materials are effectively monitored, managed, and protected throughout the entire journey.

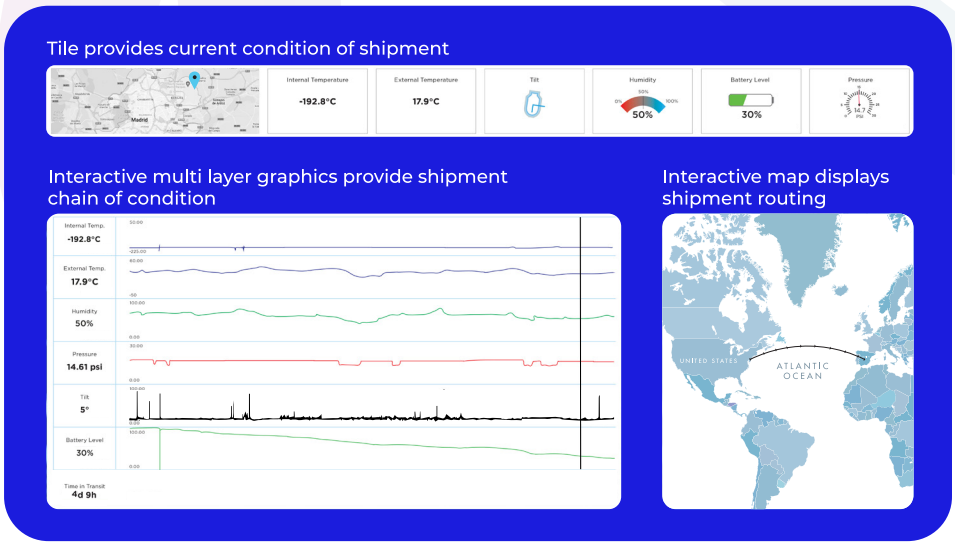


Figure 1: Cryoportal® 2 provides near real-time data about a shipment's internal temperature, external temperature, orientation/tilt, location, and other metrics.

This proprietary and enhanced logistics management system is validated to demonstrate compliance with 21 CFR Part 11 (Code of Federal Regulations) and ISPE GAMP (International Society for Pharmaceutical Engineering, Good Automated Manufacturing Practices).

Advanced Consulting Solutions that Mitigate Risk

Transporting viral vectors and advanced therapies requires navigating a complex web of potential risks, from environmental challenges to logistics hurdles. To proactively address potential roadblocks, Cryoport Systems offers a suite of advanced risk mitigation solutions.

An example of a key consulting service is shipping risk assessment. By analyzing cross-carrier data across various temperature bands, shipping system types, and global shipping lanes, we can identify and quantify potential risks specific to each client's transportation needs. This detailed analysis allows us to recommend the most effective risk mitigation strategies, ensuring that advanced therapy shipments are protected from common pitfalls.

Another example of a risk-mitigating service is shipping lane validation. This involves conducting practice runs of planned routes to proactively identify and address threats that could negatively impact the integrity of biological products during transportation. Through validating shipping lanes, we can provide clients with quality technical reports detailing potential risks and the measures that can be taken to mitigate them, ensuring a smoother and safer temperature-controlled transportation process.

Our consulting team works closely with clients on packaging and accessory design to develop custom packaging solutions that provide optimal protection. From concept development and product design to implementation, our team ensures that each packaging solution is tailored to meet the specific needs of the client's materials. This bespoke approach significantly reduces the risk of damage during transit, safeguarding the integrity of the viral vectors and advanced therapies within the shipping system.

Additionally, our shipper/package qualification service offers customized qualification processes for validating client packaging and shipping systems. This can include physical, thermal, and custom qualifications to quantify and manage common risks associated with packaging, logistics, and shipping systems. By ensuring that each shipping solution is rigorously tested and validated, clients have the assurance that their viral vectors and gene therapies will be transported safely and compliantly.

> Our Consulting Services team leverages extensive industry experience and data from over 800,000 shipments to provide clients with customized, tailored strategies for safeguarding their critical materials.

Rigorous Requalification Processes

The integrity of viral vectors and gene therapies depends not only on the initial quality of the shipping solution but also on the continued reliability of the equipment used. To this end, Cryoport Systems has implemented rigorous requalification processes for our reusable shipping systems, making us the only provider to requalify every shipping system after every transport.

Our requalification process ensures that each shipping system maintains the highest standards of quality and performance throughout its lifespan and adheres to ISO 21973 standards. Our proprietary Veri-Clean® process is the industry's first validated cleaning and disinfection protocol, ensuring that every shipping system is free from contaminants before reuse. Physical suitability tests include thorough visual inspections of both internal and external conditions, ensuring that the equipment is in optimal condition for continued use.

For our cryogenic shipping systems, LN2 capacity checks are conducted to verify that the shipping system can maintain the necessary liquid nitrogen levels throughout the transit. For our Cryoport Elite™ Ultra Cold shipping systems, capacity checks are conducted to ensure the shipping system can maintain the necessary hold time throughout transit. These capacity checks are crucial for ensuring that the shipping system can reliably provide the required cooling capacity to preserve the integrity of viral vectors. We also enforce a minimum hold time threshold, ensuring that our shipping systems maintain the required, industry-leading hold times to provide ample safety margins for transit delays or unforeseen circumstances.

If any equipment fails to meet our stringent requalification criteria, it is promptly removed from our fleet after a final quality assurance evaluation. This rigorous approach ensures that clients can trust the integrity of their viral vector or gene therapy shipments, knowing that every shipping system has been thoroughly vetted and certified for safe use – every shipping system, every time.

Enabling the OUTCOME™

Cryoport Systems is your strategic partner for comprehensive solutions that protect high-value gene therapies throughout the supply chain.

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About Us

Cryoport Systems offers a comprehensive, end-to-end platform of temperature-controlled supply chain solutions that are specifically designed to address the unique challenges faced by companies needing to transport viral vectors for gene therapy. By focusing on customized shipping system manufacturing and selection, comprehensive monitoring of shipments, advanced risk mitigation solutions, and rigorous requalification processes, we provide clients with the confidence that their valuable materials are in safe hands.

Our commitment to quality, precision, and client satisfaction ensures that we meet or exceed the standards required for the safe and compliant transport of viral vectors and advanced therapies. With Cryoport Systems as a trusted partner, clients can focus on their core mission of developing and delivering life-saving therapies, secure in the knowledge that their critical materials shipments are protected every step of the way.

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