Info Brief:

Navigating Your Path to Globalization: Untangling the Regulatory Maze of the ATMP Supply Chain

Cryoport Systems

Americas • EMEA • APAC
info@cryoport.com | +1 949.232.1900
cryoport.com

MKT-30032 v1.0

Introduction

In the highly modulated world of advanced therapy medicinal products (ATMPs), conducting clinical trials across the EMEA (Europe, the Middle East, and Africa) region requires a deep understanding of global trade and supply chain regulatory requirements. As operations scale to achieve commercialization, the required knowledge base to sustain an international temperature-controlled supply chain becomes more complex. For many advanced therapy developers, this rapid escalation feels as if the road to success has evolved into a maze of regulatory challenges too complicated and time-consuming to navigate on one's own.

Whether you're planning a global clinical trial or scaling operations for commercialization, Cryoport Systems understands the critical importance of adhering to regulatory requirements for the success of your operation. With Cryoport Systems as your chosen provider, our team of industry experts will act as an extension of your team and utilize our platform of supply chain solutions to guide you through the complexities of the regulatory landscape for a sustained ATMP supply chain across the EMEA region.

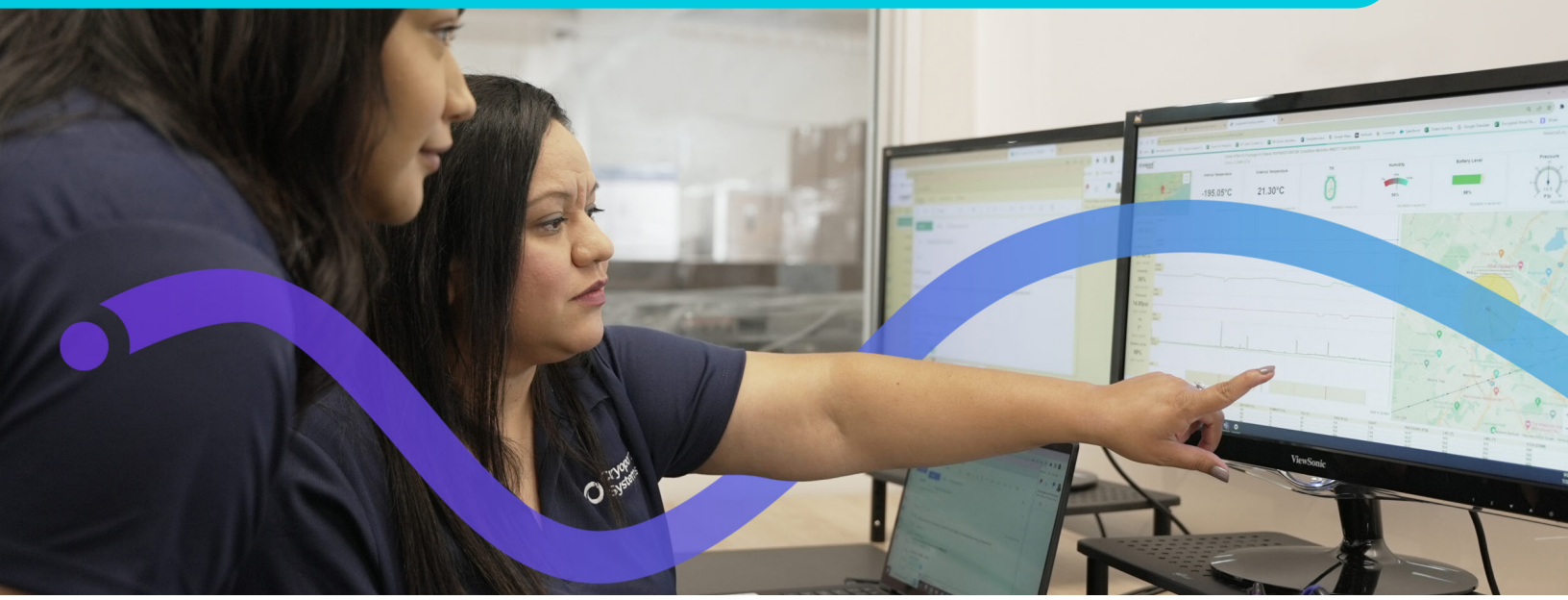
Expert Assistance for Your Team with QP Services

The EU Clinical Trials Directive 2001/20/EC7 requires all drugs manufactured within the European Union to be certified by a Qualified Person (QP). A QP is a designated professional responsible for ensuring that each individual drug batch has "been manufactured and checked in compliance with the laws in force in the member state where certification takes place and in accordance with the requirements of the marketing authorization (MA) with good manufacturing practice (GMP)."[1] While required for every manufacturer, not every organization has an established QP on their team who can navigate the standards and ensure compliance.

Cryoport Systems' EU locations provide a Qualified Person (QP) to facilitate the oversight of import and release for clients to streamline this step in the regulatory process. These Cryoport Systems' employees are academically qualified in pharmacy, chemistry, or biology and work onsite within our facilities. Our QPs are equipped to handle the necessary duties and uphold compliance standards, including:

- Pass-through depot for urgent shipment requests
- Consulting services concerning regulatory requirements
- EU QP audits of manufacturing and testing facilities
- Issuance of QP Declaration
- Certification of drug products
- Importation of pharmaceutical products

Our QP services support the beginning steps of transporting your irreplicable clinical and commercial samples across borders, offering expert guidance and peace of mind that your materials are always handled compliantly throughout their journey.



Navigating International Transport with Customs Clearance and Trade

Alongside expert QP services, our supply chain management capabilities extend to customized solutions for navigating the complexities of international logistics. Cryoport Systems' Consulting Services team comprises subject matter experts (SMEs) who stay up to date on the latest international regulatory requirements. This allows our team to compliantly manage customs clearance of your drug products throughout the EMEA region, which includes the preparation and submission of required documentation, coordination with customs authorities, and management of any issues that may arise during the clearance process. Our proactive approach ensures that your shipments clear customs quickly and efficiently, minimizing delays and reducing the risk of product loss or damage.

In addition to customs clearance, our trade advisory services can help guide decisions on best practices when it comes to international trade. Our team can assist in developing and implementing effective trade strategies that optimize your supply chain operations across the EMEA region.

Personalized Assessments Supporting Risk Mitigation

The ability to actively mitigate risk is paramount to the ATMP supply chain, and our risk mitigation processes start even before your product is packaged for transport. Cryoport System's Consulting Services offer guidance through shipping risk assessments and shipping lane qualifications/validations. Our shipping risk assessments include a detailed analysis of cross-carrier data on 800,000+ tracked shipments across various temperature bands, shipper types, and global lanes. This service is driven by our quality processes that have assisted client regulatory submissions across all stages of clinical and commercial development.

Once evaluated, our team uses the shipping risk assessment to create personalized shipping lane qualifications/validations. First, our team identifies the best available carrier lanes for a specific shipment from the assessments. From there, our team builds a tailored risk mitigation plan for each of the selected lanes. This detailed evaluation guides decisions on lane selections and provides insight into the real-world viability of critical shipping lane assumptions and product-related critical dependencies. Our protocol-driven lane qualifications/validations inform decisions regarding shipment lane/courier selection, handling, and package integrity while also qualifying shippers and payload systems. These risk assessments and shipping lane qualifications/validations are a risk-mitigating combination to provide added certainty around the safe transport of materials across selected routes.

> Shipping risk assessments and lane qualifications/ validations are a risk-mitigating combination that helps to Enable the Outcome™ for clients.

Scalable Technology Unmatched in the Industry

Furthermore, Cryoport Systems' established technology allows you to scale our support of your supply chain from our online system when you need it. Cryoportal® is our industry-leading logistics management system that gives you a comprehensive look inside your materials' shipment process. In conjunction with our Smartpak® condition monitoring system, Cryoportal® provides near real-time data about a shipment's internal temperature, external temperature, orientation/tilt, location, and other metrics while maintaining compliance with 21 CFR Part 11 (Code of Federal Regulations) and ISPE GAMP (International Society for Pharmaceutical Engineering, Good Automated Manufacturing Practices).

Tracking the specifics of your shipments is one of many beneficial features of our logistics management system. Cryoportal® condenses a shipment's inventory, ordering, tracking, documents, and reporting into a single interface. With the Cryoportal®, you can:

- Oversee all order information such as user roles, profiles, contracts, commodities shipped, and more
- Leverage comprehensive data reports based on order history through the Customer Dashboard
- Create new orders from existing templates or from scratch
- Receive customized alerts, exception notices, and automated email notifications on your shipments to your account's contact list

Establishing a streamlined ATMP supply chain hinges on the proficiencies of a superior supply chain provider. Cryoport Systems' knowledgeable team and platform of solutions Enable the Outcome™ for ATMP manufacturers so you can focus on your life-saving work while we handle the intricacies of a risk-free international supply chain across the EMEA region.

References

1. Clinical trials - Directive 2001/20/EC. (n.d.). Health. ec.europa.eu. https://health.ec.europa.eu/medicinalproducts/clinical-trials/clinical-trials-directive-200120ec_en

Enabling the

OUTCOME™

Cryoport Systems is the strategic partner of choice for temperature-controlled global supply chain management of critical materials.

SCAN TO LEARN MORE

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.

Cryoport Systems

Americas • EMEA • APAC
info@cryoport.com | +1 949.232.1900
cryoport.com