whitepaper

Enabling the Outcome™

Cryoport Systems

The Power of an End-to-End Supply Chain Platform for Advanced Therapies

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Cryoport Systems is transforming the advanced therapies supply chain with integrated services that support every stage of development from early clinical to commercial scale.

As the field of advanced therapies evolves, so too must the supply chains that support them. From personalized cell and gene therapies (CGTs) to high-value biologics, today's treatments require a level of precision, compliance, and customization that far exceeds traditional pharmaceutical logistics and management. And yet, many organizations still rely on fragmented, multi-vendor supply chain models that introduce inefficiencies, elevate risk, and slow progress.

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At Cryoport Systems, we believe the future of advanced supply chains is end-to-end: a fully integrated platform upstream and downstream of manufacturing that connects cryopreservation, biostorage, packaging, consulting, quality, and logistics into a single, seamless ecosystem. This is not a vision for tomorrow, it's the infrastructure we've already built for today's most impactful therapies. And it's already delivering measurable value for both manufacturing and sponsor companies.

Meeting the Moment: A Shifting Therapeutic Landscape

The demand for advanced therapies is accelerating. With more than 3,000 regenerative medicine trials underway globally and over 20 CGTs now commercially approved, developers are racing to scale innovation safely, efficiently, and globally. At the same time, variability in clinical trial design, evolving regulatory frameworks, and increasing scrutiny around product integrity are placing new demands on the supply chain.

No longer is it enough to simply ensure a shipment arrives on time. Today's temperature-controlled supply chain must manage biological variability, ensure chain of custody and chain of condition, and flex to support increasingly global and personalized programs. This requires a platform, not a patchwork.

Built for Complexity, Designed for Continuity

Cryoport Systems has designed the industry's most robust, fully integrated supply chain platform for supporting the complete lifecycle of CGTs, biologics, and other temperature-sensitive therapeutics. This ecosystem includes IntegriCell® cryopreservation services, which delivers standardized, optimized cryopreservation of leukapheresis; BioServices and biostorage, providing cGMP compliant storage, labeling, kitting, secondary packaging, and clinical sample management; consulting and advisory services, offering strategic guidance on packaging validation, shipping lane qualification, regulatory strategy support, and global trade compliance; logistics and Cryoshuttle® services, managing temperature-controlled shipping systems and logistics across air and ground with consistent monitoring, tracking, and risk mitigation; and quality and compliance, maintaining the industry's most stringent standards including proprietary processes like Chain of Compliance® and Veri-Clean® alongside robust requalification of every shipper, every time.

These services are modular but connected, enabling biopharmaceutical developers to get the right level of support to fit the stage and phase of their program and scale support as programs move forward to clinical and commercial distribution.

Standardizing Cryopreservation for Greater Manufacturability

Variability in starting materials has long been a headache for cell therapy programs. With many developers relying on disparate apheresis centers and inconsistent collection and/or freezing protocols, downstream manufacturing can be unpredictable and challenging to scale. This complexity is further compounded by the time constraints inherent in working with fresh leukapheresis products, as these materials are on a short timeline before viability begins to degrade. IntegriCell cryopreservation services aim to address this challenge head-on.

By starting with IntegriCell's automated closed process approach to cryopreservation (or by bringing your own protocol to our expert team via tech transfer), we meet the highest compliance standards and ensure consistency and quality while addressing product stability issues associated with fresh donor-derived cellular material. This optimized approach enhances manufacturing efficiency and streamlines operations, while integrating seamlessly with logistics for immediate transition into biostorage or through to manufacturing.

> IntegriCell meets compliance and quality standards while addressing the stability issues of fresh cellular material.

BioServices to Support Upstream and Downstream Supply Chain Needs

At facilities across the U.S. and Europe, we provide secure, compliant support for the cGMP storage, packaging, and distribution of high-value biological materials. These services include cGMP biostorage across all temperature bands, secondary packaging and labeling, custom kit production that ensures site-to-site consistency, and clinical sample management for processing and data integration.

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These services are essential both upstream of manufacturing (to manage starting materials, clinical samples, and collection, manufacturing, and administration kits) and downstream (to support final product labeling, distribution, or long-term storage). Because Cryoport Systems maintains ownership and control of the infrastructure, quality systems, and personnel at each site, developers benefit from consistent processes and reduced handoff risk by working with a single, integrated provider rather than a patchwork of decentralized vendors.

Building Resilience from the Start

Even the most well-designed therapy can run into roadblocks if it doesn't have a robust supply chain strategy. That's why Cryoport Systems has built a team of experts with decades of experience in consulting and advisory services, helping organizations assess their current models, identify gaps, and implement future-ready solutions.

Wherever you are in your development process, our team delivers expertise in packaging and shipper qualification, shipping lane validation and risk mitigation strategies, and regulatory trade guidance and customs documentation. This advisory function enables support for regulatory filings and smarter decision-making across the program lifecycle, helping organizations avoid unnecessary capital expenditure, reduce launch delays, and meet complex global requirements without building new infrastructure.

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Products Developed for Real-World Demands

Cryoport Systems brings deep engineering and design expertise to our integrated platform of support through custom product development. For some advanced therapy programs, an off-the-shelf solution simply doesn't meet the stringent demands for thermal protection, continuous monitoring, physical durability, or program-specific specifications. That's why we continue to invest in proprietary shipping solutions and packaging innovations that solve real-world problems in high-stakes environments.

Cryoport Elite® Ultra Cold Shipping System for Dry Ice

One such innovation is the Cryoport Elite Ultra Cold dry ice shipping system, purpose-built for gene therapies and sensitive materials requiring -60° to -80°C temperature bands. Scientifically engineered to reduce risk and surpass industry hold time standards, the Cryoport Elite Ultra Cold maintains the integrity of each payload by combining the best features of packaging, informatics, and logistics. Traditionally, therapeutics shipping at the -60° to -80°C temperature band are packaged in polystyrene foam and dry ice, which introduces immense risk into the supply chain as it fails to guarantee stable temperatures or protect the commodity from unpredictable conditions during transport.

The Cryoport Elite Ultra Cold shipping system was custom engineered to bring all the robust features of traditional cryogenic shipping systems for advanced therapies to a dry ice solution, providing developers with a secure packaging system that safeguards material viability. With features like a robust, hard-shell enclosure, patent-pending payload holding system that eliminates direct contact between the commodity and the dry ice, and integrated condition monitoring plus 24/7/365 tracking and support, the Cryoport Elite Ultra Cold shipping system provides maximum protection during transit of irreplaceable therapies and sensitive biomaterials.

Cryoport Express® Cryogenic HV3 Shipping System

As more CGTs are reaching commercialization, shipping lanes are expanding to community-based care centers, delivering these treatments to a wider patient population that is increasingly geographically distributed. To enable patient access at scale, there is a growing need for cryogenic shipping solutions that meet evolving regulatory and airline-specific shipping requirements.

The Cryoport Express Cryogenic HV3 shipping system offers unmatched reliability and full compliance with evolving global shipping regulations. The HV3 Shipping System's innovative, cube-like enclosure with integrated wheels and retractable handle not only enhances ease of use but also integrates state-of-the-art monitoring and risk mitigation features to ensure safe and secure transport for sensitive cryogenic payloads. Its unique, stackable design enables more efficient handling and storage at point-of-care sites, CDMOs, and other storage locations with improved safety features for clinicians and operators.

By eliminating the need for palletization that is typical for traditional barrel-shaped shippers, the HV3 provides the ability to transport critical materials on narrow-bodied aircraft, ensuring compliance with regional carriers and reducing flight rejections and delays. As regulatory enforcement tightens, the HV3 Shipping System positions you ahead of potential disruptions. Fully compliant with the latest airline shipping mandates (which are already in effect but not yet actively enforced), this next-generation shipping system future-proofs your transportation operations and increases the number of available shipping lanes, which will help improve patient access and enable life-saving therapies to reach patients in underserved areas.

Cryoport Safepak® System 1800

At cryogenic temperatures, starting materials like blood bags and leukopaks are fragile and prone to breakage, necessitating a secondary packaging solution that adequately protects these sensitive and often irreplaceable materials. The Safepak System 1800 is a secure secondary packaging solution that offers increased protection, ease-of-use, and industry-first level of compliance for product safety. Leveraging soft, low-thermal materials to protect fragile materials like blood bags, the Safepak System 1800 prevents the metal-to-metal and payload-to-payload contact that is common in solutions like metal racks to create a secure environment that safeguards the integrity of the materials. This reduces the risk of material breakages mid-transport while its design shields from the effects of vibration and shock events during transit.

These purpose-built solutions are developed in-house, working hand-in-hand with our clients and clinical teams, specialty pharmacies, and sponsors to ensure that the shipping solutions we are innovating address real-world challenges. Our aim is to design solutions not only for product integrity but also to support the realities of clinical or manufacturing sites and end users.

Custom-Built Logistics and Worldwide Transportation

With a decades-long track record of success, Cryoport Systems' logistics services are the engine behind the end-to-end platform. With the industry's largest fleet of wholly owned shipping systems that have been purpose-built for advanced therapies and sensitive materials, Cryoshuttle pickup and delivery services for first- and last-mile support, and global logistics support through our Cryoportal® logistics management system, we deliver unmatched visibility and reliability.

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We provide lane-specific logistics planning using data developed from our more than 900,000 successful shipments supporting more than 700 clinical trials and 19 commercialized cell and gene therapies to select the optimal carrier and routing. Our around-the-clock condition monitoring and tracking, Chain of Compliance® process, and specialized support for clinical and commercial therapies fully integrates with cryopreservation services, biostorage, secondary packaging options, and regulatory support that ensures a seamless flow of materials from donor to patient, and all the stages in between.

Quality and Regulatory Support for Global Compliance with Local Expertise

An end-to-end platform is only as strong as its quality framework. Cryoport Systems has set the standard for excellence, ensuring the highest quality standards and reliability across the entire supply chain.

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As pioneers in creating and adhering to ISO 21973, the standard for the transportation of cells for therapeutic use, we have played a crucial role in shaping the global standards for the safe and effective transport of temperature-sensitive materials. With our proprietary Veri-CleanÒ process, all shipping systems are decontaminated to the industry's highest standards at every use.

Additionally, we are the only provider to fully requalify every shipping system, every time. Our proprietary Chain of Compliance® is a comprehensive system that addresses key compliance aspects, including equipment performance history, commodity history, requalification history, calibration data, and the correlation of in-field events to equipment performance.

In Europe, we offer Qualified Person (QP) services to support the import, release, and

distribution of advanced therapies in compliance with European Union (EU) regulations. Our regional teams also assist with regulatory document preparation, trade compliance and import/export facilitation, and audit readiness.

This quality infrastructure ensures that clients meet the most stringent regulatory expectations while reducing the burden of internal audits, vendor qualification, and compliance tracking.

End-to-End in Action

What sets the Cryoport Systems platform apart is its ability to support activities both upstream and downstream of manufacturing. For example, upstream, a sponsor can use custom kits to collect patient samples at global clinical sites, cryopreserve and store leukapheresis starting material, and leverage logistics to move raw materials to manufacturing. Downstream, once a therapy is manufactured, we provide secondary packaging, labeling, custom administration kits, regulatory clearance, and last-mile delivery to clinical sites or hospitals with Cryoshuttle.

All of these services occur within a unified network, reducing handoffs, enhancing traceability, and maintaining compliance. It's not just supply chain support, it's infrastructure as a service.

A Platform for Today, a Foundation for Tomorrow

Cryoport Systems was built to anticipate the evolving needs of the life sciences industry. With over a milliong successful shipments, 700+ clinical trials supported, and 19 commercially approved therapies under our care, we have grown alongside the industry. Our investment in a connected platform reflects a deep understanding of what it takes to bring a therapy from early development to commercial scale.

As new modalities and applications emerge, geographic needs evolve, and patient populations expand, the value of integration will only grow. Sponsors and CDMOs that align with a partner like Cryoport Systems are not simply outsourcing tasks, they're investing in continuity, scalability, and success.

In a world of increasing complexity, Cryoport Systems offers a rare combination: comprehensive services, global scale, and deep expertise, all delivered through a single, integrated platform of supply chain management and support. By connecting upstream and downstream needs across cryopreservation, BioServices and biostorage, consulting and advisory support, transportation, logistics, and quality, we help our partners reduce risk, accelerate timelines, and deliver therapies that change lives. Because for us, it's never about moving a product. It's about Enabling the Outcome™.

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About Us

Cryoport Systems is a comprehensive supply chain partner for the life sciences industry focused on meeting the challenges of the global cell and gene therapy market. We excel in the specialized management of the biopharma supply chain through our comprehensive offerings in logistics, BioServices and biostorage, cryopreservation, and consulting. With our expansive platform and decades of temperature-controlled supply chain expertise, Cryoport Systems helps Enable the Outcome™ for advanced therapies programs, safely and securely guiding critical therapies to patients in need.

For more information about how Cryoport Systems is Enabling the Outcome™, please scan the QR code.

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