



info brief



## The Power of an Integrated Cell & Gene Therapy Supply Chain

*Cryoport Systems provides an end-to-end, next-gen approach to managing the complexities of the advanced therapy supply chain.*





## *Insights with Matthew Frazzetta, Vice President, Global Accounts, BioServices*

Cryoport Systems provides one of the most globally comprehensive end-to-end solutions for managing, storing, packaging, labeling, kitting and transporting cell and gene therapies and biologics. From standardized cryopreservation, extensive BioServices solutions and agile logistics to specialized consulting services, its expansive offerings are fully integrated to create a comprehensive platform.

With expertise in the specialized requirements of biotherapies, Cryoport Systems bridges the gap between CDMOs and sponsors, handling all

“A seamless, accountable, and expert-driven experience, leveraging our specialized knowledge in global cell and gene therapy applications.”

logistics from patient sample collection to final product delivery. Its contingency plans and 24/7/365 continuous monitoring mitigate risks in the supply chain, while the company’s flexible, tailored BioServices support each therapy’s unique needs.

With an integrated platform of scalable, risk-mitigating solutions, innovative technologies, and a dedicated team of experts, Cryoport Systems supports the evolving life sciences industry. As the cell and gene therapy field expands beyond oncology into new applications, Cryoport Systems’ global footprint is positioned to scale alongside the increasing demand for these transformative therapies.

In this Q&A, Matthew Frazzetta, Vice President, Global Accounts, BioServices at Cryoport Systems, and an accomplished Biopharma supply chain executive, discusses the company’s integrated end-to-end solution, risk mitigation, contingency planning, and its role in supporting CDMOs and partner organizations.

***How does “enabling the outcome” with Cryoport Systems’ solutions differ from the end-to-end offerings seen elsewhere in the market?***

**Matthew Frazzetta:** Cryoport Systems provides a truly integrated, end-to-end solution, encompassing all necessary services within our global network. This means we manage the entire process, from starting materials to finished product, including biostorage, packaging, labeling, regulatory services, and distribution, under a single infrastructure and quality platform that is consistent across all our sites worldwide.

We own and control the industry’s largest fleet of shipping systems and employ specialized personnel who are trained to handle these sensitive materials at every step. This integrated approach allows us to manage materials from receiving and storage under cGMP conditions, through batch processing, and finally, to delivery for patient administration. Unlike the fragmented market where multiple providers handle different parts of the process, we ensure all services occur under a single vendor model with consistent quality standards, significantly increasing efficiency and reducing risks compared to traditional models.

### ***So, it's a seamless experience?***

**Frazzetta:** Exactly. A seamless, accountable, and expert-driven experience, leveraging our specialized knowledge in global cell and gene therapy applications.

### ***Specifically, what are the critical BioServices and logistics involved in managing, storing, and transporting these cell and gene therapies and high-value biologics?***

**Frazzetta:** We offer a unique, comprehensive service, managing the movement of materials into our facilities using our fleet of specialized shipping systems as well as to manufacturing or clinical sites directly. We employ a courier-neutral approach to logistics partners, selecting the most appropriate resources for each shipping lane. Our BioServices are tailored to the unique needs of cell and gene therapies, offering flexible solutions for biostorage, packaging, labeling, and regulatory requirements. We understand that these therapies require specialized handling, and we adapt our services to meet the specific needs of each product.

### ***How does Cryoport Systems support both CDMOs and sponsor therapeutics partners?***

**Frazzetta:** We bridge the gap between manufacturers and sponsors, managing the critical logistics of cell and gene therapies. We handle the logistics from starting material to manufacturing, through to patient delivery. This can include everything from biostorage, labeling, and secondary packaging, to clinical and commercial distribution, ensuring the therapeutic is safely transported at every stage. We also offer Clinical Sample Management Services (CSM) to support processing, storage and data management. To provide a uniform approach across clinical sites, we can provide custom kits for collection and administration to support site-to-site consistency. This is especially

important when scaling clinical trials across geographic borders.

We work closely with both manufacturers and sponsors to define clear responsibilities and implement appropriate logistics models. We focus on risk mitigation, implementing contingency plans to address potential disruptions and using decades of data to validate the approach across our global network. Our Chain of Compliance® addresses key compliance aspects, including equipment performance history, commodity history, requalification history, calibration data, and the correlation of in-field events to equipment performance.

Specifically, when it comes to CDMOs, we act as a fully integrated partner, extending their cGMP standards throughout the development process. In addition to our BioServices offerings, we offer regulatory support, direct distribution, and Qualified Person (QP) services for materials moving into, through and out of the European Union, tailoring our services to meet the specific needs of each program. Our integrated supply chain platform addresses pre-production, production, and post-production needs to ensure a seamless handoff from the manufacturer.

### ***What contingency plans does Cryoport Systems have in place for potential disruptions in the end-to-end supply chain?***

**Frazzetta:** We prioritize proactive planning, ensuring a thorough understanding of each site's capabilities and the specific requirements of the program. We work closely with sponsors and manufacturing sites to map out the entire process, identify potential risks, and develop contingency plans. Our 24/7/365 customer service team monitors shipments, addressing any issues in real time. Our systems track location, temperature, and other critical parameters, allowing us to assess and mitigate risks as they occur. With our Cryoport® logistics

management system, clients also have the ability to track location and condition. We ensure clear communication and alignment between all parties to handle any deviations from the planned process effectively, should they occur.

### ***Is there anything else you'd like to share?***

**Frazzetta:** The cell and gene therapy field is at a pivotal point, with expanding applications beyond oncology into immunology and other exciting new frontiers. This expansion will challenge logistics due to larger patient populations and variability between clinical sites. We're focused on scaling our services to meet this growth, ensuring seamless delivery of these life-saving therapies. The industry faces challenges with scalability, and we're continually focused on building now to prepare for where the industry is heading.

It's critical to understand the entire engagement, employ the right tools, and mitigate all risks. Planning our end-to-end supply chain partnership from an early development stage allows for custom solutions optimized for a given program, ensuring a smooth transition from clinical to commercial distribution.

With over one million successful shipments supporting over 700 clinical trials and 19 commercially approved therapies, we've evolved alongside the industry over the last 20 years. Working closely with manufacturers and sponsor companies as a true end-to-end supply chain partner, we are building today to anticipate tomorrow's challenges. I couldn't be more excited about the future of personalized medicine and look forward to playing a part in delivering next-generation therapies to the patients who depend on these advancements.

**Learn more at**  
**[www.cryoport.com](http://www.cryoport.com)**



## 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 BioServices and how it can support your advanced therapy supply chain needs, please scan the QR code.



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