



Defragmenting the CGT Supply Chain

*Building Scalable, Integrated
Infrastructure for Advanced Therapies*





Cell and gene therapies (CGTs) are redefining what's possible in real time as new therapeutic approaches are reaching clinical and commercial milestones every day.

Recognizing the promise of these therapies, however, is often undermined by the reality of legacy supply chain approaches, which tend to be fragmented and designed for traditional pharmaceuticals rather than custom-designed for the realities of advanced therapies. From initial collection to final patient infusion (bench to bedside), the end-to-end supply chain is fraught with weak links along the way, including common pain points like disconnected systems, manual handoffs, inconsistent standards, and a fragmented vendor network of providers operating within their own quality frameworks. The inefficiencies of this journey actively threaten therapeutic success. When the supply chain hits a weak link, patient access becomes even more challenging for a population seeking curative interventions with few or no alternatives.

Supply chain fragmentation is a systemic vulnerability that's compounding as the industry matures and the complexity of logistics grows exponentially. The consequences of disjointed infrastructure are becoming increasingly pronounced, and sponsors, regulators, and providers alike must confront the reality that without integration and defragmentation, the promise of advanced therapies will remain out of reach. The stakes are high, and the margin for error is narrow. Advanced therapies must navigate the bench-to-bedside path without deviation from validated conditions (and do so while maintaining continuity of care), with an audit-ready trail to prove their efficacy. A resilient supply chain needs to be anticipatory and proactive, rather than simply reactive, if things go wrong.

For all the challenges of the current advanced therapy infrastructure, this is also a

time of incredible opportunity. Therapeutic developers can capitalize on this by prioritizing supply chain design from the earliest stages of development, planning in advance for future clinical and commercial needs. Fragmentation kills momentum. Integration saves lives. By investing in cohesive, integrated infrastructure, the industry can begin to shift from reactive problem-solving to proactive delivery, ensuring innovation reaches patients (and does so consistently and at scale).



Fragmentation kills momentum. Integration saves lives.

Where Fragmentation Begins

The advanced therapy supply chain consists of a complex web of stakeholders. Clinical sites, couriers, cryopreservation facilities, CDMOs, regulators, care teams... each node is critical, yet all too often they operate in isolation. Sponsors are stuck navigating a landscape where data systems don't talk to each other, chain of custody runs into vulnerabilities at every handoff, and end-to-end visibility is limited. This creates a fragile ecosystem where even minor disruptions can quickly cascade into major consequences.

This fragmentation occurs when therapeutic developers attempt to integrate legacy systems and siloed operations that were never designed to support the demands of personalized medicine.

The lack of interoperability between vendors and sites inevitably creates blind spots that can compromise quality and increase risk, while simultaneously increasing inefficiency and creating roadblocks to scalability.

To build a resilient supply chain ecosystem, developers need to rethink how each component of the supply chain interacts. Every handoff is a risk, but every connection is a safeguard. Supply chain success will come from integration that is designed into the system from the start, allowing for shared standards and unified data platforms spanning the entire vein-to-vein journey.



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The Hidden Cost of Siloed Systems

Fragmentation introduces risk at every stage of the development lifecycle. Manual processes increase risk and reduce reliability, for example, while incompatible data platforms hinder coordination and traceability. Chain of custody and identity gaps threaten product integrity and regulatory compliance, and variations in regional requirements complicate global scalability. This is the daily reality facing therapy developers.

The most obvious costs of fragmentation aren't subtle. They're felt in the form of delays. Lost product. Compromised clinical trials. But they also manifest in less visible ways, like increased overhead or regulatory scrutiny, even diminished investor confidence. As more therapies progress through clinical trials and into commercialization, the costs that were once simple inefficiencies at early clinical stages become strategic liabilities when it comes time to commercialize them globally.



Disjointed systems bleed value, whereas **unified infrastructure** delivers certainty. Starting with the end in mind allows for every step within the supply chain infrastructure to be interconnected and traceable.

Designing for Integration

A truly integrated supply chain management strategy lays a strong foundation for operational excellence. Sponsors are increasingly looking to build (or leverage) infrastructure that connects the dots across the therapy lifecycle, linking together interoperable digital platforms, standardizing procedures across distributed sites, and working with strategic partners who can consolidate services across the vein-to-vein continuum. Continuous monitoring and integrated services reduce risk and accelerate timelines, ultimately enabling scale.

An integrated supply chain takes into account the full scope of therapeutic development and the movement of materials from bench to bedside. How are starting materials handled, and are leukapheresis-derived starting materials being processed while fresh, or being cryopreserved to extend manufacturability? How are starting materials being moved to manufacturing, and is there any biostorage required in the meantime? How is the finished drug product reaching the patient? What does the secondary

Overcoming these challenges requires taking a systems-level view of supply chain design from the earliest stages of development, aligned from the start. Disjointed systems bleed value, whereas unified infrastructure delivers certainty. Starting with the end in mind allows for every step within the supply chain infrastructure to be interconnected and traceable. Planning for (and investing in) infrastructure that is flexible and purpose-built supports interoperability and maximizes opportunities for automation and efficiency.



packaging look like, and do the shipping systems adequately protect the product at every stage? Have shipping lanes been thoroughly validated? Have all risks been evaluated with contingency planning in place for every possible "worst case" that could come up? Is every step of transportation validated to conform to applicable compliance standards like ISO 21973:2020.



Ultimately, **integration** is the engine that drives scale.

As much as integration is about technology, it is also tied to strategic alignment. Ultimately, integration is the engine that drives scale. When therapy developers are building their supply chain strategy, it's critical that they select partners who understand the nuances of advanced therapies and can offer infrastructure that adapts to clinical and commercial needs as the program progresses. This includes harmonized processes and centralized data

systems as well as shared accountability across the supply chain. By designing for integration from day one, sponsors not only avoid costly retrofits and bottlenecks; they develop a forward-compatible supply chain that supports innovation while meeting regulatory expectations, allowing them to deliver therapies with confidence.

The Value of End-to-End Integration

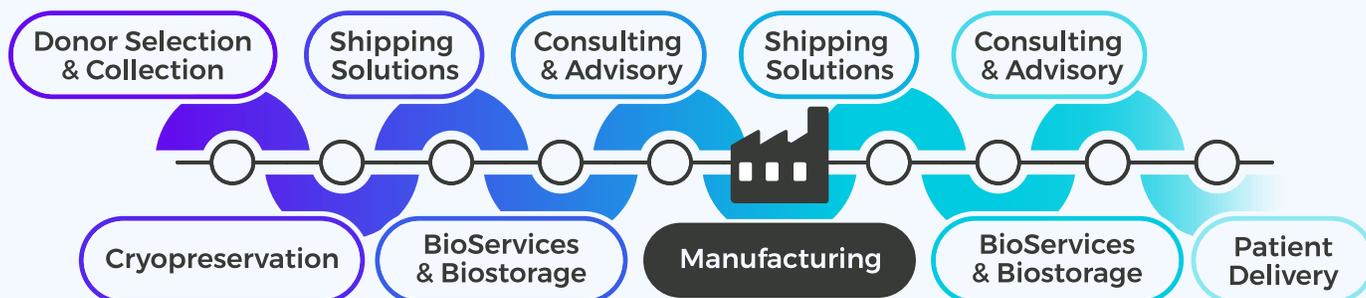
As programs move from clinical trials into commercialization, the complexity multiplies. Sponsors need partners who can scale with them, not just in volume but also in capability. Cryoport Systems offers an integrated supply chain platform that spans the full vein-to-vein workflow, enabling efficiency at scale that reduces handoffs, improves compliance, and enables sponsors to focus on innovation while Cryoport Systems manages end-to-end supply chain management both upstream and downstream of manufacturing.

Upstream of manufacturing, Cryoport Systems delivers the standardization and control advanced therapy programs need to manage starting materials. From custom,

standardized apheresis collection kits to pre-conditioned shipping systems delivered directly to collection sites, sponsors are ensured consistency and compliance from the point of collection. IntegriCell® cryopreservation, using an automated closed process, preserves cellular viability while reducing variability, and secure biostorage plus just-in-time delivery to manufacturing, alongside early-phase consulting and advisory services for risk assessments, shipping lane qualifications, and shipper and packaging performance qualifications, de-risks critical upstream workflows and eliminates fragmentation before manufacturing even begins.

Downstream of manufacturing, validated shipping systems safeguard sensitive final products as they are transported to clinical sites and patients, while advanced BioServices streamline operations with pick, pack, label, and distribution services tailored to therapy-specific requirements.

As programs scale, consulting and advisory services support geographic expansion by qualifying new shipping lanes, while regulatory services facilitate qualified person (QP) release across the European Union. With Cryoport Systems as a single vendor partner, therapy developers avoid delays and reduce risk.



Cryopreservation as the First Point of Control

Cryopreservation of leukapheresis-derived starting materials is often the first (and most frequently overlooked) opportunity to reduce variability. Fresh leukapheresis-derived cells have a limited window for processing, and variability across collection sites and handling processes can compromise cell viability, in turn delaying clinical progress.

Over the course of a program, early decisions around fresh versus frozen and cryopreservation protocols have a lasting impact. Leveraging a standardized cryopreservation protocol, especially one that follows an automated closed process, maintains cell viability and functionality across patient samples, reducing both variability and risk while enhancing manufacturability.

Cryoport Systems' IntegriCell cryopreservation services represent a shift from fragmented, site-specific practices to a validated and consistent global solution using an automated, closed process.

Cryopreservation sets the tone for precision by reducing variability and enhancing reliability. By embedding quality and consistency at the source, Cryoport Systems helps sponsors build resilient supply chains that are compliant and ready for scale from the first collection.



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Regulatory Evolution and the Push for Standardization

Standardization doesn't just eliminate risk from a manufacturability standpoint. Regulators, for example, are increasingly expecting harmonized standards as well as new levels of comprehensive documentation and digital traceability that is audit-ready at a moment's notice.

Sponsors need to proactively prepare to meet these expectations by investing in infrastructure that supports compliance from day one. By aligning processes across geographies and partners, sponsors can reduce variability while improving audit readiness and accelerating market access as programs move from early clinical stages to global commercialization.

Integration, however, is not a one-size-fits-all approach. Emerging companies just entering pre-clinical development and later-stage biopharmas planning for commercialization, for example, face different challenges and will have different integration strategies.

Early-stage developers require flexibility alongside compliance to support first-in-human trials and early regulatory filings, whereas commercial organizations seek scalable, cost-efficient systems that facilitate global distribution.

The end-to-end supply chain must be designed to meet the maturity, scale, and strategic objectives of the sponsor at every stage. Smart infrastructure adapts. Strategic infrastructure leads. Cryoport Systems delivers that flexibility, working collaboratively to design infrastructure that meets immediate needs while setting the foundation for future growth.



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Advanced therapies demand advanced supply chains. Cryoport Systems delivers both.

Future-Proofing the Supply Chain by Shifting from Fragmentation to Integration

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Future-proofing is about preparation more than prediction. By designing supply chain strategies that are modular and responsive, sponsors can navigate complexity without compromising quality as therapies move from bench to bedside.

The cell and gene therapy is approaching an inflection point where fragmented vendor networks are no longer sustainable. Integration of end-to-end supply chain management under a single-vendor partnership is the path forward. Advanced therapies demand advanced supply chains. Cryoport Systems delivers both.

By aligning infrastructure with strategic intent, sponsors can move beyond reactive logistics and toward proactive, strategic supply chain design.

The therapies of tomorrow deserve supply chains that are built to deliver. Cryoport Systems is building that future, today.



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 Cryoport Systems can support your cell therapy supply chain needs, please scan the QR code.



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