



Minimizing Capital Expenditures through Supply Chain Integration

An integrated supply chain partner can reduce risk, enable scalability, and preserve capital in today's volatile market.



The Advanced Therapies Sector is No Stranger to Complexity.

But in today's environment, marked by global economic uncertainty, shifting regulatory dynamics, and continued pressure on both public and private funding streams, the stakes have never been higher. For manufacturing organizations and sponsor companies alike, the traditional build-to-own model of developing supply chain infrastructure can be an unsustainable burden on balance sheets. With changing international trade policies, redefined FDA priorities, and new scrutiny around federal grant programs, the pressure is mounting to do more with less.

In this climate, strategic outsourcing to a true end-to-end supply chain partner is not just a cost-saving tactic, it's a forward-looking approach to preserving flexibility, increasing efficiency, and ensuring operational continuity. At Cryoport Systems, we see this shift firsthand. Companies across the development lifecycle are looking to minimize capital expenditures while gaining access to the infrastructure, expertise, and operational excellence needed to bring advanced therapies to market.

Navigating Today's Economic Pressures

The cost of developing and commercializing cell and gene therapies (CGTs) is already substantial, and current market conditions are compounding financial risk. The capital required to build, qualify, and maintain cGMP-compliant storage facilities, packaging suites, specialized equipment, and logistics infrastructure is significant. In an era where funding rounds are tightening and timelines are shifting, these upfront investments may delay development or further strain already-lean balance sheets.

Moreover, the uncertainty around international trade compliance, evolving European Union (EU) import/export rules, and geopolitical tensions are introducing new risks for globally distributed supply chains. Regulatory unpredictability (including shifts in the FDA's approach to accelerated approvals and cell-based therapies) has only added to the pressure.

In this environment, building your own infrastructure can create more questions than answers: What if trial enrollment slows? What if the regulatory pathway changes? What if a new geographic region opens or closes? Each of these questions introduces risk that is amplified by capital that is already sunk.



The Case for Outsourcing to an Integrated Partner

Cryoport Systems offers a globally integrated supply chain platform designed to eliminate the need for costly capital outlays. From biostorage and kit production to temperature-controlled packaging, labeling, Qualified Person (QP) release, and specialized logistics, we offer a single-source model that scales as your program evolves without requiring you to build it yourself.

We operate a network of strategically located facilities in the U.S., Europe, and Asia-Pacific including standardized cryopreservation services, cGMP-compliant biostorage sites, Cryoshuttle® pickup and delivery services for specialized first- and last-mile support, and custom supply chain services that flex with program needs. Whether you're a CDMO looking to extend your services without overextending your footprint or a sponsor looking to avoid building an internal logistics team, our infrastructure is designed to adapt without delay.

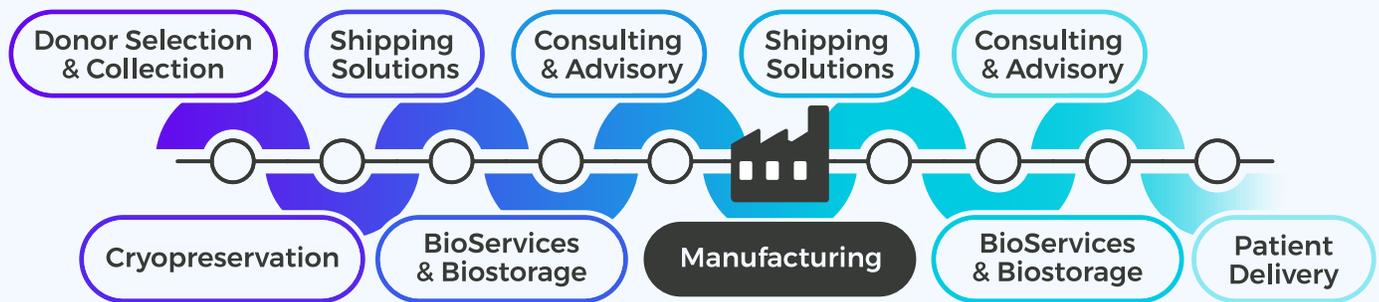
By partnering with a true end-to-end supply chain management platform like the one built by Cryoport Systems, you avoid upfront costs for infrastructure that may only suit your needs for a limited time or volume. You gain scalability to meet growing demand or consolidate as programs wind down, and reduce risk by leveraging proven systems, processes, and people. Most importantly, you stay focused on science and development, not facility management.

A Better Approach to Flexibility and Scale

An integrated supply chain management model is purpose-built to scale up or down in real time. As programs move from pre-clinical to Phase I, or from Phase III to commercial, for example, the demands on the supply chain change in real time. Shipping volumes increase. Regulatory documentation becomes more complex. Instead of hiring staff, acquiring space, or retrofitting processes, companies working with Cryoport Systems can scale capacity, capabilities, and compliance to meet their evolving needs.

And when conditions shift, whether due to regulatory delay, enrollment challenges, or a pivot in the clinical plan, our infrastructure doesn't become a stranded asset. We absorb these fluctuations, your capital doesn't.

Our platform is built to support cryopreservation of starting materials, short- and long-term biostorage needs, clinical sample management, secondary packaging and labeling, custom kitting for site-to-site consistency, regulatory and trade compliance, and temperature-controlled shipping and logistics with full regulatory compliance. Each of our services is modular but interconnected through a single quality and data framework, enabling a seamless transition between stages of development under a streamlined single vendor management model.



Why Integration Matters More Than Ever

“Fragmented outsourcing models where logistics, biostorage, packaging, and regulatory support are spread across multiple vendors, **create risk at every handoff** by introducing room for error, inconsistencies, delay, and cost overages.”

Integration isn't just about convenience, it's about continuity. Fragmented outsourcing models where logistics, biostorage, packaging, and regulatory support are spread across multiple vendors, create risk at every handoff by introducing room for error, inconsistencies, delay, and cost overages.

Cryoport Systems eliminates those handoffs by providing a fully integrated ecosystem. Our global facilities operate under a unified quality system, our people are trained to the same standards, and our digital platform provides continuous monitoring and control. Whether materials

are moving between manufacturing sites or to clinical endpoints, we offer end-to-end traceability, compliance, and support.

This approach is especially critical in a global context. With an expanding global network of facilities, we enable global trial execution and commercial distribution while addressing local regulatory compliance through in-region QP services, customs documentation, and country-specific logistics strategies.

Not Just a Provider, A Strategic Partner

At Cryoport Systems, we believe that your supply chain partner should be just that, a partner. Not a transactional vendor, but an extension of your team. We engage early, often as early as pre-clinical planning, to build a roadmap for supply chain integration that meets your needs now and in the future.

Our consulting and advisory services help organizations assess their current infrastructure, identify opportunities to outsource, and implement right-sized strategies that reduce fixed costs. We support everything from shipping lane optimization and packaging qualifications to regulatory submissions and contingency planning. In doing so, we don't just provide services, we help build resilient supply chains that are prepared for uncertainty and ready for growth.

Preserving Capital. Preserving Progress.

When capital is tied up in infrastructure, it's unavailable for science. Every dollar not spent building and maintaining storage or logistics networks in-house is an asset that can go toward developing a therapy, expanding a trial, or accelerating a regulatory filing.

Cryoport Systems enables preservation of capital and enablement of scalable progress by delivering the infrastructure you need, only when you need it. As programs scale, services scale with them. As conditions change, we adapt. It's a model built not just for today's market, but for tomorrow's therapies.

At a time when uncertainty is the only constant, an integrated supply chain partner isn't a luxury. It's a strategic imperative.

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Enabling the

OUTCOME™

*Trusted expertise guiding you through
the temperature-controlled supply chain*

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



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