whitepaper

Anticipating Scale

Infrastructure, Strategy, and the future of ATMPs in Europe

Cryoport Systems

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The European advanced therapy medicinal product (ATMP) sector is on the edge of scale as it enters a phase of accelerated maturity.

Scientific advances in cell and gene therapies are reshaping clinical possibilities, building momentum behind therapeutic innovation as new approaches to improving human health are entering clinical trials or commercialization seemingly every day. Yet the infrastructure required to support these therapies remains uneven and under strain. The challenge is not simply logistical. It's structural, systemic, and deeply tied to how the industry prepares for scale.

> **The future of ATMPs in Europe will be shaped by the infrastructure decisions made today.**

As therapy volumes increase and clinical programs grow more complex, the need for infrastructure that is both robust and regionally attuned becomes more urgent. Developers are contending with fragmented regulatory environments alongside limited manufacturing capacity at the same time as expectations for precision and speed are rising. These pressures are converging at a time when the industry needs to deliver not just innovation, but access.

In order to address the demands of the moment, it's time to rethink how therapies are supported from development through delivery. The future of ATMPs in Europe will be shaped by the infrastructure decisions made today. Building for the next phase of growth will require a focus on operational readiness and long-term scalability as a strategic imperative.

The State of the ATMP Market in Europe

The European ATMP landscape, at present, reflects a push-pull of both progress and constraint. There are incredible advancements happening, like seeing CRISPR-based therapies advance through clinical milestones and autologous treatments reaching broader patient populations, developments that signal a sector that is moving beyond early adoption. At the same time, the underlying systems that are required to support this growth are still catching up.

Despite increasing approvals, overall patient access remains limited. Many eligible patients are not able to receive advanced therapeutic treatments due to a myriad of roadblocks like logistical bottlenecks, reimbursement delays, and even operational inefficiencies. Developers are being asked to accelerate timelines and reduce costs, even while the overall landscape is still fragmented and resource-constrained.

Europe's ATMP market is rich in scientific capability, but uneven when it comes to delivery. Innovation alone doesn't guarantee impact. Execution determines reach. Bridging this gap will require coordinated investment across the sector, including areas like infrastructure, policy, and operational strategy, with strong partnerships among stakeholders.

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Regulator Fragmentation & Market Access Challenges

Centralized approvals from the European Medicines Agency (EMA) provide a streamlined entry point for advanced therapeutics, but EMA approval in and of itself does not guarantee market access. Each member state within the European Union (EU) maintains its own frameworks for aspects such as pricing and reimbursement structures, customs clearance procedures for materials and therapeutics, and local policy implementation. This creates a patchwork of requirements for therapy developers to know and navigate individually for each member state in which they operate.

The complexity compounds upon itself when you move outside the EU and into other markets, such as the United Kingdom (UK), Switzerland, and the Middle East. Each of these markets presents distinct regulatory conditions, and as a result, therapeutic developers find themselves needing to manage a multitude of reimbursement pathways, documentation standards, and port-specific clearance processes. All of these introduce variations that can lead to delays due to the complicated planning required, as well as increased costs.

> **Regulatory fragmentation is a structural barrier to scale.**

Until harmonization efforts gain traction across the region, success in Europe will depend on the forethought and planning that developers put into anticipating jurisdictional variation. Regulatory fragmentation is a structural barrier to scale. As a result, it is increasingly important to build supply chains that reflect both centralized and local realities.

Operational Complexity Creates Supply Chain Strain

Advanced therapies demand a level of coordination that is more nuanced and complex than that of traditional pharmaceutical models. Autologous treatments, in particular, require precise coordination between the collection of patient material via clinical scheduling, customized to match manufacturing slot availability, and the logistics execution needed to pick up the starting material and deliver it to the designated location, arriving exactly when it's needed, with full temperature control and compliance adherence. With so many nuances in play, any deviation from the plan can have a ripple effect downstream, potentially impacting product integrity or delaying treatment.

Infrastructure limitations add additional layers of complexity. For example, manufacturing slots need to be carefully coordinated and reserved in advance. Raw materials can face supply constraints, and even staffing can become a bottleneck as specialized and skilled personnel are in short supply. As therapy approvals increase, the systems required to deliver them remain underdeveloped. The result? A widening gap between therapeutic potential and patient access.

To close this access gap, it is increasingly important that developers work hand-in-hand with their vendor network. Operational complexity is the defining challenge of ATMP scalability. Overcoming this challenge requires robust supply chains that are not only compliant and efficient but also deeply integrated with clinical workflows and responsive to real-world constraints.

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Proactively Designing for Resilience

Resilience in ATMP logistics is not easy, given the complexity of the highly sensitive materials and the therapeutics that need to go from bench to bedside. This requires a supply chain architecture that is purpose-built to withstand disruption while maintaining continuity of care. As clinical trials expand across borders or as commercialization strategies become global, therapies will need to navigate complex regulatory environments (and do so while maintaining continuity of care). 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, 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.

One of the most effective ways to build this resilience is through a single-vendor model. When developers partner with an end-to-end provider capable of managing the full scope of the supply chain, from cryopreservation and biostorage to logistics and consulting, they gain more than operational efficiency. They gain alignment. They gain risk mitigation. They gain compliance. Cryoport Systems offers this integrated model, enabling therapy developers to consolidate oversight while reducing handoffs, ultimately minimizing risk and streamlining compliance while building for scale.

> **Resilience is not a feature of the supply chain, but the outcome of strategic integration.**

By working with a single partner throughout the therapy lifecycle, developers can collaboratively design supply chains that are robust and intelligent. Cryoport Systems' end-to-end supply chain platform supports proactive risk mitigation and informed regulatory filings, while enabling seamless coordination as programs move between clinical and commercial operations. Resilience is not a feature of the supply chain, but the outcome of strategic integration. This is resilience by design, built specifically to support the development of advanced therapies.

Outsourcing to Minimize Capital Expenditures

In ATMP development, a traditionally resource-constrained environment, outsourcing is a strategic decision that allows developers to conserve capital while maintaining operational capability (and preparing for scale). Rather than heavily investing in internal infrastructure that can quickly outpace current needs, working with specialized partners can provide access to integrated supply chain support that is scalable, compliant, and seamlessly integrated into internal processes from the outset.

Cryoport Systems offers this kind of flexibility. Purpose-built infrastructure and services are specifically designed to support advanced therapy programs, expanding or contracting based on development needs in real time, whether that's supporting a single clinical site or coordinating commercial distribution across the globe. This elasticity enables organizations to focus their capital on innovation while relying on strategic partners to manage the complexity of ATMP logistics and supply chains.

Importantly, this isn't just outsourcing for today's needs. Strategic supply chain partnerships, such as those offered by Cryoport Systems, are designed with future scalability in mind. Services are customized and planned to evolve in tandem with therapeutic development, ensuring that as clinical programs grow and eventually transition into new geographies or commercialization, the supply chain is already structured to support this growth.

Engaging partners early can help developers to fully leverage a comprehensive outsourcing strategy. Outsourcing with foresight minimizes capital strain and builds a foundation for scalable growth. Strategic

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partnerships that prioritize flexibility and long-term alignment allow developers to respond to change without overextending (already limited) resources. This results in a supply chain, proactively designed, that easily evolves in tandem with therapeutic development and responds to changing market dynamics or conditions.

Geopolitical Pressures and the Need for Agility

Alongside the typical growing pains of a developing industry, global instability is reshaping the ATMP industry and logistics. With changing trade policies and unpredictable international relations coming into play alongside legacy hurdles like the impact of Brexit, new layers of complexity are being added to the industry. But while this is a time of uncertainty, it is also a time of opportunity.

Many developers are using this moment to reevaluate their supply chain strategy, exploring alternative approaches and deepening their ties with third-party partners. This shift naturally builds resilience by enabling organizations to absorb disruptions better and maintain continuity across borders.

At the same time, regulatory bodies are reframing their approaches to advanced therapies. These changes may open new pathways for clinical development and market entry, particularly in regions that have been historically difficult to access. Developers who view these shifts not as obstacles but as catalysts for change that create adaptability and agility will be best positioned to adapt and grow, fully meeting the moment.

Supply chains that are truly resilient are designed to pivot, not pause, as geopolitical pressures create change in the greater environment. Agility is the operational currency of global ATMP delivery. By investing in flexible, customized infrastructure that has been built from the earliest stages to support growth, developers can navigate volatility alongside their third-party partners while laying the groundwork for long-term expansion.

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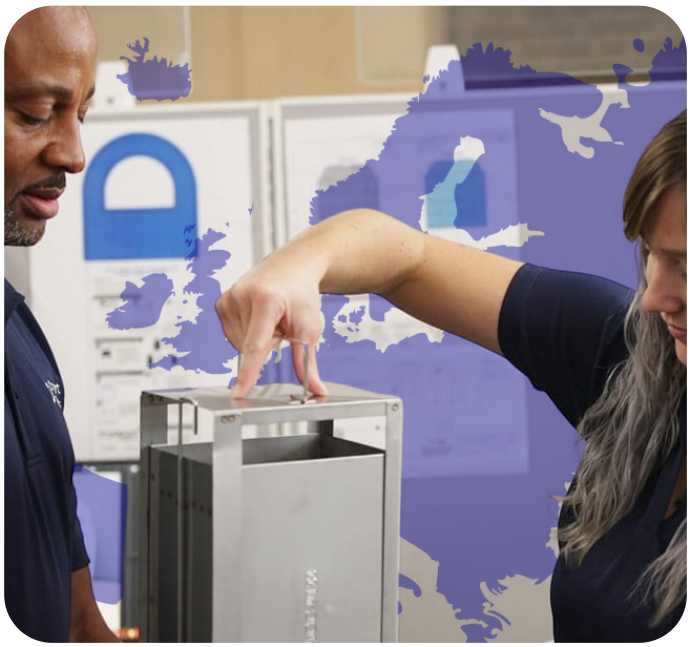
Building Now for What's Next

Infrastructure quickly moves beyond a support function to become a strategic foundation that lays the groundwork for scalability. As the ATMP market evolves, developers need partners who are not only equipped to meet today's demands but are also actively building for the complexity of tomorrow. Cryoport Systems is doing just that.



With a growing global footprint and deep local expertise, Cryoport Systems is investing in infrastructure that anticipates the next wave of ATMP growth. The new Global Supply Chain Center near Paris exemplifies this approach, bringing together logistics excellence and the world's largest wholly owned fleet of custom-engineered shipping systems to enable responsive, fast-turn that allows for dispatch in as little as 24 hours (or less). With the coming addition of GMP biostorage, kit production, secondary packaging, and Qualified Person (QP) release, developers benefit from the efficiencies gained by housing end-to-end supply chain services under one roof. This facility complements a broader network of Global Supply Chain Centers in the United States and a broader network of sites across Asia-Pacific, the UK, the Netherlands, Belgium, and France, creating a connected platform for both clinical and commercial development.

As the ATMP market in Europe continues to mature, the need for strategic supply chain management only becomes more critical. Infrastructure built intentionally and with foresight is laying the groundwork for advanced therapies to reach their full potential. As regulatory frameworks continue to evolve and clinical pipelines expand, Cryoport Systems is creating the scalable, compliant operations that are responsive to real-time

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market dynamics. Rather than just keeping pace with the market, Cryoport Systems continues to lead by developing infrastructure that naturally adapts alongside advanced therapy programs as they mature from early development through global commercialization.

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.

Designing the Future of ATMP Delivery

The future of advanced therapy delivery in Europe depends on more than innovation alone. It requires infrastructure and operational strategies that support it. As clinical pipelines expand and regulatory frameworks evolve, therapy developers will find themselves increasingly navigating a landscape defined by complexity and fragmentation.

Meeting these challenges requires a deliberate rethinking of supply chain architecture. Developers need to assess which capabilities are mission-critical to retain in-house and which are better supported through specialized partners with proven infrastructure and regulatory expertise. Building for the future requires developing a supply chain strategy that is both compliant and scalable, ensuring it operates in full alignment with the operational realities of advanced therapies from day one.

Cryoport Systems is actively investing in infrastructure that anticipates these needs. Our Global Supply Chain Centers, including the new facility near Paris, alongside our expanding global footprint, are engineered to support rapid dispatch, cryopreservation of leukapheresis-derived starting materials, GMP biostorage, clinical sample management, kit production, secondary packaging, and QP release, all under one roof. This integrated model reduces handoffs while minimizing risk and accelerating readiness for both clinical and commercial operations.

By aligning infrastructure with strategic intent, therapy developers can move beyond reactive logistics to proactive supply chain design. Cryoport Systems enables this shift by offering an integrated, end-to-end platform that supports regulatory alignment and operational flexibility that spans the globe. The next phase of ATMP growth will be defined by those who have the foresight to build for complexity while planning for scale. Cryoport Systems is not just supporting this evolution; we're helping lead it.

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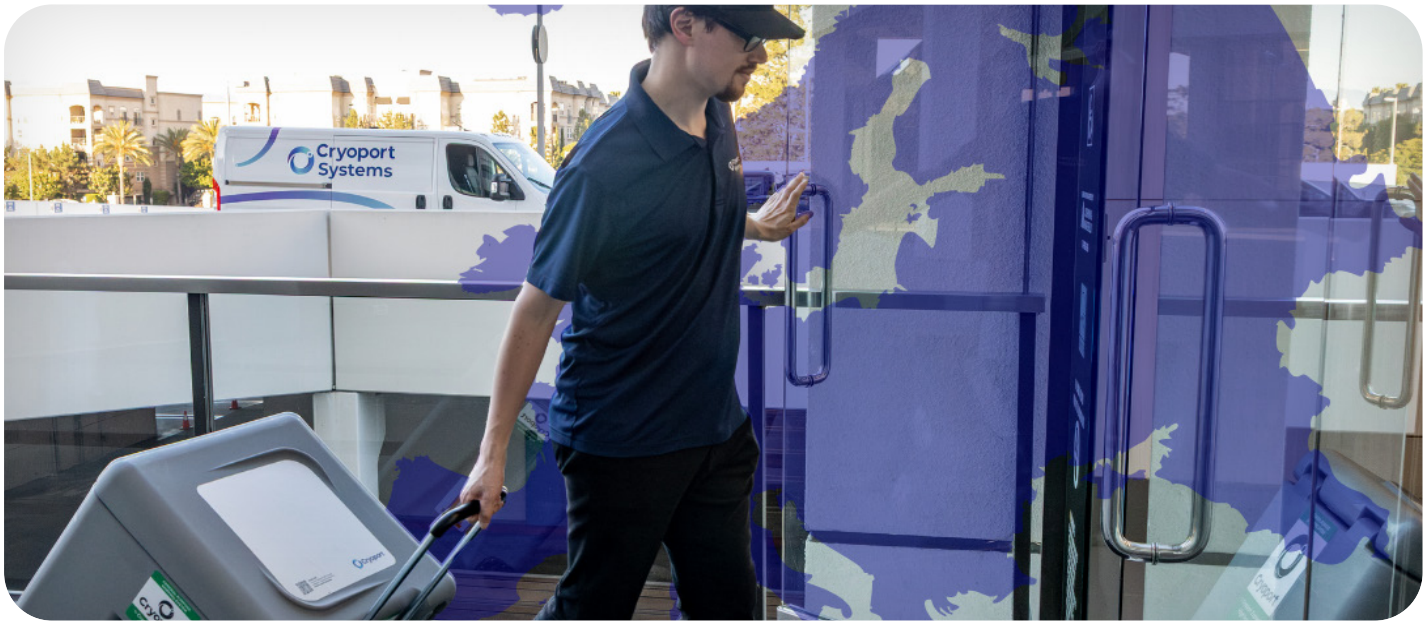

Enabling the OUTCOME™

Trusted expertise guiding you through the temperature-controlled supply chain

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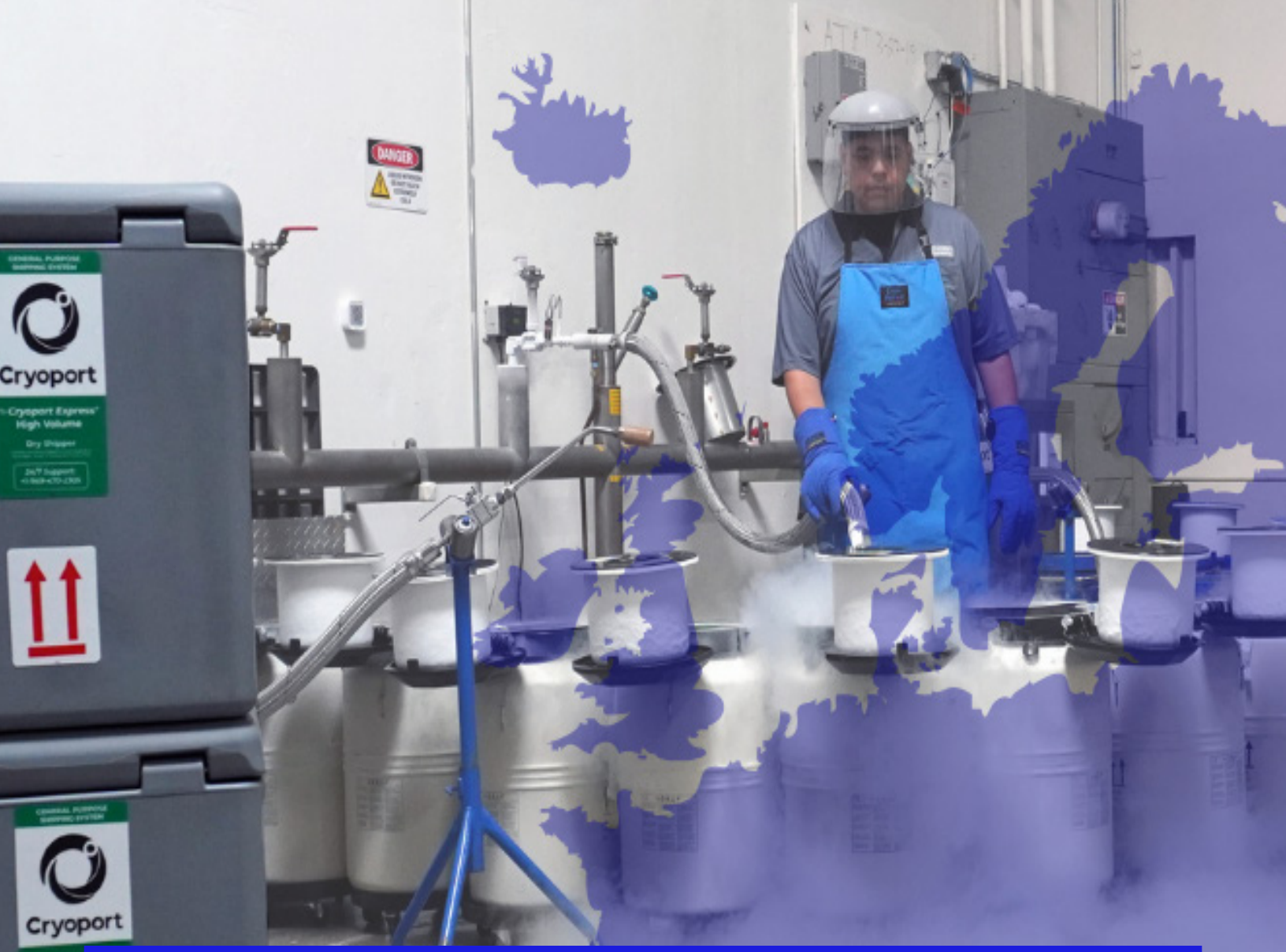

About Us

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 how Cryoport Systems is Enabling the Outcome™ for ATMP developers in Europe, please scan the QR code.

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