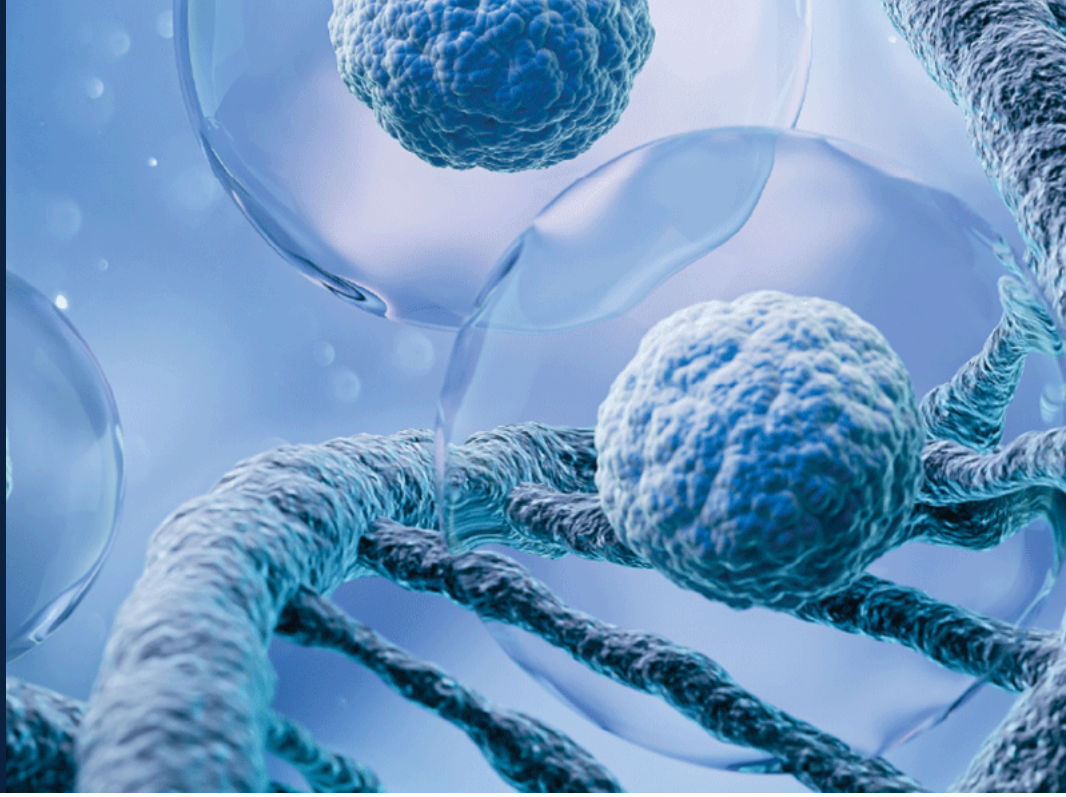

Rethinking logistics, the key barrier to scaling cell and gene therapies

For cell and gene therapies to scale, they need simple, flexible supply chains.

Personalized cell and gene therapies offer a beacon of hope to patients in need and vast financial prospects for emerging companies in the pharmaceutical industry. Because of their high cost of development, batch size of one, and complex shipping requirements, most remain boutique treatments, prized – and costly – options of last resort. It's why companies stretch every dollar to push their therapeutics through clinical trials, going as far as to charter planes to deliver each dose of bespoke therapeutic to its patient.

But the hard truth is that, as life-changing as these treatments may be, to scale to thousands of patients and survive on the market, they'll need to break out of the boutique. This will require rethinking their supply chain and logistics.

It's hardly surprising that cell and gene developers often consider logistics as an afterthought. With therapeutic viability uncertain until the last minute, the intricacies of shipping and distribution tend to take a backseat to all the effort involved in moving a breakthrough discovery to clinical trials and towards commercialization.

By the time treatments show signs of promise in humans, logistics operations need to be swiftly adapted to meet regulatory requirements and the needs of patients, drug developers, and investors. This urgency often leads to reliance on pre-existing, standardized logistics solutions, which can come with significant costs and may limit market penetration and accessibility.

"As an organization, we have a long history of helping companies solve deep logistical challenges, such as the rapid scale up of COVID-19 vaccine distribution. At CSafe, our commitment as a technology agnostic partner allows us to apply the best approach and to scale position as a supplier-neutral logistics partner allows us to quickly and effectively build and deploy optimal distribution solutions tailored to each project."

Emilio Frattaruolo, Vice President, Cell & Gene Therapies

A race against the clock with zero margin for error

The success of cell and gene therapies hinges on mitigating risks on their journey between the clinic and the lab. Whether they are autologous – derived from the patient's own biological material – or allogenic – sourced from a donor – they typically need to ship at cryogenic temperatures in a race against the clock fraught with zero margin for error.

The easiest way to mitigate these risks is to reduce transportation. That's why many therapies today are only available in university hospitals and centers of excellence, where biological material can be sourced, processed, and administered on-site. It's been a huge success for the beneficiaries, but hardly a recipe enabling the therapies to scale.

Back to the basics

As in every example of cold chain logistics, the success of cell and gene therapy logistics hinges on the ability to preserve goods at cold temperatures while moving them around. Only in this case, the goods in question are hypercritical, irreplaceable, and life-saving therapeutics. If the therapies are to live up to their promise, succeed on the market, and reach those in need, the businesses behind them need to be economically viable. With distribution and logistics forming the main financial bottleneck in the commercialization of cell and gene therapies, the path forward will require moving from a complex, costly, and highly customized white glove distribution service to nothing short of standard shipping.

Mitigating risks on the journey from the lab to the clinic

Packaging is instrumental in cutting the cost and complexity of cell and gene therapy logistics. Our latest generation of dewars supports cryogenic cooling at below -150 degrees Celsius for more than ten days, ensuring proper preservation in the event of delays. Integrated tracking technology provides real time location data at every step from the clinic to the lab and back, supporting a continuous chain of custody and identity. Qualified to industry standards, they ensure high quality and hassle-free handling.

In principle, solutions like these should let cell and gene therapy manufacturers take advantage of existing logistics infrastructure. But getting clearance to do so requires navigating a bureaucratic minefield, demonstrating regulatory compliance, meticulous traceability, risk management, and contingency planning. On the practical side, it involves defining tailored transport routes with sufficient security, trained handlers, and dedicated storage facilities to eliminate the risks of cold chain interruptions and tampering.

For established pharmaceutical companies, these challenges can be daunting. For first timers and emerging players, they can be insurmountable without proper support.

Tackling challenges ahead of commercialization

Ultimately, the key to slashing distribution costs is neither technological nor infrastructural. It's know-how and experience: working with a process-agnostic partner interested in getting the job done. It's about effectively combining all available solutions, impartially working directly to pharmaceutical companies, carriers, and forwarders, without competing with suppliers.

At CSafe, our offering goes beyond physical dewars to safely distribute cell and gene therapies. Our full wrap-around consultative service supports customers early on in their journey of therapeutic development, testing, and commercialization. By sharing our vast expertise, gathering essential data as it accrues, and addressing internal and external demands, we reduce administrative burden, accelerate filing with regulatory authorities, and ensure that logistical challenges are tackled well ahead of showtime.

Fresh ideas and a trusted partner

Cell and gene therapy, among the fastest-growing fields in medicine, continues to be held back by costly high-touch logistics. To grow its reach and live up to its promise, it will take nothing short of a paradigm shift in how treatments are distributed. While the first wave of development saw companies pay whatever it took to get trials off the ground, the hurdle today is economic viability. Clearing it will require fresh ideas and a trusted partner willing to get into the trenches with you.

To learn more about how you can benefit from CSafe's service offering, get in touch.

Your nearest sales representative is ready to help you maximize the impact of your life-saving therapeutics.

Contact us at: cellandgene@csafeglobal.com