



Elevating Cell and Gene Therapy Logistics: 7 ways CSafe adds value outside the box

You probably know CSafe for our industry-leading thermal shipping solutions. But you might be surprised to learn that our service offering is what customers rely on us for.

For 46 years, CSafe has been on a mission to ensure that patients worldwide have access to viable, life-enhancing therapies. It's a mission that has given rise to the growing suite of temperature-controlled packaging solutions our customers rely on to protect sensitive materials on their journey from the production facility to the patient. Today, we offer a comprehensive portfolio of industry-leading bulk air cargo solutions, parcel solutions and high-performance dewars tailored to the specific needs of cell and gene therapeutics.

But there is more to CSafe than high-performance packaging. Through decades of close collaboration alongside pharmaceutical companies, regulators, airlines and logistics firms, we possess a deep history of solving complex problems that characterize medical logistics. Our unique blend of expertise and extensive global footprint has made us a trusted partner for the pharmaceutical industry.

In this article, we look at seven ways CSafe offers value beyond the boxes themselves to stakeholders across the pharmaceutical product life cycle.



#1: Supporting early-stage Cell and Gene Therapy startups

Advances in the development and commercialization of cell and gene therapeutics are reshaping patient care and pharmaceutical innovation. While major pharmaceutical brands continue to dominate the development of common therapeutics, the vast majority of cell and gene therapies stem from academic research labs and early-stage startups. This shift brings new needs. Researchers may have a clear view of their end-goal, but are unsure of how to get there. At CSafe, we have accompanied numerous early-stage startups on this journey, guiding them around the logistical hurdles that can prevent even the most promising discoveries from translating to effective and economically viable therapies.

#2: Qualifying the distribution process

Discovering a promising product is the first step towards developing breakthrough cell and gene therapies. But without a clear grasp of the logistical hurdles, clearing clinical trials and achieving commercialization can become potentially overwhelming, leading to obstacles. How do you ensure that couriers are allowed to board commercial planes carrying temperature-sensitive treatments? What packaging and paperwork are required to clear security without breaking the cold chain and potentially contaminating its contents? With our vast experience in thermal and distribution testing, as well as supporting clients with package selection, regulatory requirements and data collection to demonstrate that the logistical operations defined will deliver treatments to their recipients uncompromised.

#3: Future-focused strategic scaling

At CSafe, we design supply chain solutions with strategic foresight, paving the way for scalability. As a service solutions provider with a comprehensive packaging portfolio, we assist pharmaceutical companies in planning strategies to launch their operations, with the goal of simplifying delivery. This helps control costs of logistics, ensuring financial viability and laying a solid foundation for future endeavors.

#4: Navigating regulatory pathways for seamless compliance

Cell and gene therapies need to comply with regulations set by the FDA, the EMA and other regulatory authorities. Our experts collaborate closely with clients to ensure that they fully understand all the requirements and have the necessary data and documentation to expedite the filing process. This includes selection of appropriate packaging to provide product quality assurance during transit, addressing shipping labeling requirements and providing real time tracking visibility, ultimately establishing a secure chain of custody to mitigate risk.

#5: Vast network of logistics partners

CSafe's 45 years in temperature-controlled packaging business has equipped us with a vast network of logistics partners globally. With over 70 locations, our global network provides access



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to key markets. We understand local regulations and have close partnerships with the necessary logistics providers experienced in transporting highly critical temperature-sensitive therapies. Through our service offering, we leverage our global service network relationships to accelerate the distribution process.

#6: Streamlining Cell and Gene Therapy logistics

At CSafe, we help customers build their ideal distribution plan, optimizing costs and streamlining processes where possible. We leverage our global network of logistics partners and suggest the optimal solution for the specific therapy. Our approach is to guide and make recommendations that will not compromise product quality.

#7: Global emergency scenarios

Global emergency scenarios, from local disease outbreaks to global pandemics, demand rapid scaling to ensure an effective response. As a full-service partner, we ensure that everyone's needs are understood and met. Our industry expertise, a global network and tailored shipping solutions for temperature-sensitive therapies ensures that we are poised to support any global accelerated distribution challenge. A case in point was our rapid scale up of the global COVID-19 vaccine distribution, with all the regulatory challenges that this entailed.

At CSafe, our unique position as a supplier-neutral logistics partner allows us to quickly and effectively build optimal distribution networks tailored to the specifics of each individual project. Offering an assurance through our service, we guide decisions around the distribution process from packaging selection to scaling operations for commercial success.

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

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