



Delivering the Future: *Overcoming Shipping Challenges in Cell and Gene Therapy*

The rise of cell and gene therapy (CGT) is revolutionising how we treat complex diseases, offering life-changing treatments for patients in need. However, with these innovations come significant logistical challenges.

Ensuring these highly specialised therapies reach patients on time, without damage, is crucial. As the CGT market expands, logistics must keep pace to protect the integrity of these groundbreaking treatments.

High-Stakes Medicine Meets Outdated Logistics

The CGT industry is growing rapidly, but the logistics supporting it have struggled to keep pace. CGT treatments are personalised, highly sensitive, and time-critical, making their durability and availability incredibly limited. Simply put, these treatments are some of the most expensive and delicate shipments moving around the world right now – and that means the standard supply chain playbook no longer applies.

Reaching upwards of \$4 million per dose, CGT offers life-altering potential at an incredibly high cost. Once manufactured, these therapies must be administered to patients within hours, and they often require ultra-low temperatures during transport. Should any of these treatments be lost, damaged, or delayed in transit, the manufacturing process would

have to start over. For patients waiting to receive these therapies, that's time that they may not survive.

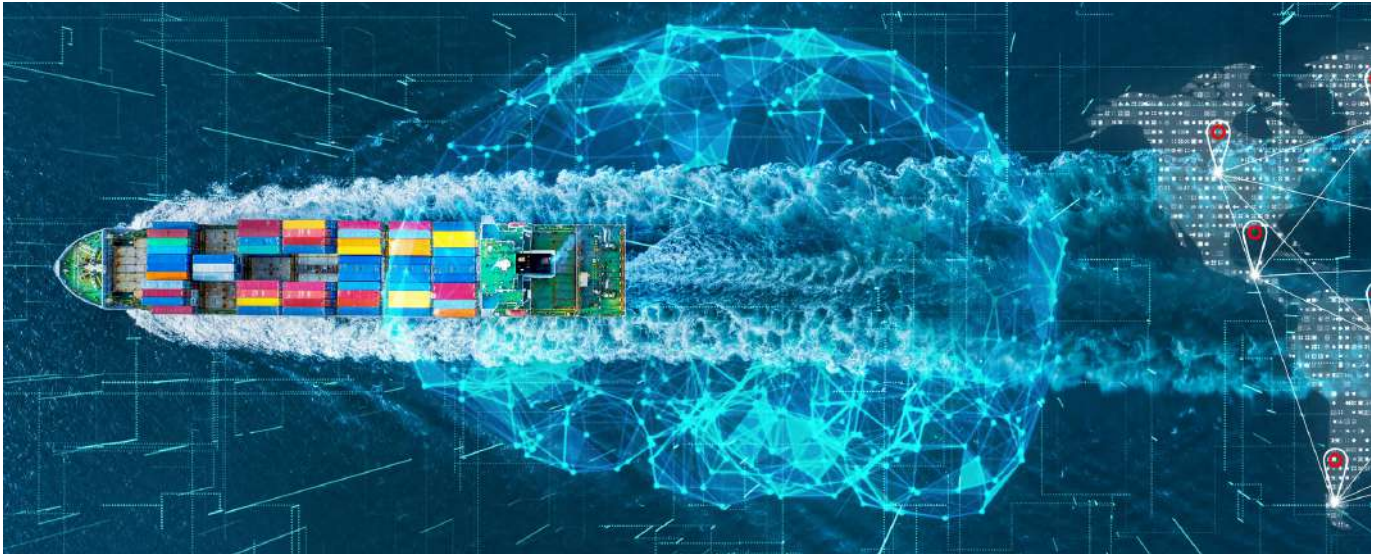
It's no wonder the logistics behind this process are daunting. Not only do logistics teams face the possibility of losing millions of dollars in product, but they are responsible for delivering potentially life-saving treatments. The specific needs of these fragile therapies create a new set of issues that many companies don't fully understand, and therefore, aren't ready to support.

The CGT Cold Chain Challenge

One of the key issues in CGT shipping is outdated cold chain infrastructure. Traditional shipment tracking methods, such as barcode scanning, provide only a snapshot of the shipment's location, leaving teams in the dark about the cargo's real-time condition. Considering how incredibly time-sensitive CGT shipments are, this lack of visibility can be catastrophic.

Additionally, the extreme temperature requirements of CGT products – often needing cryogenic conditions of -150°C or lower – further complicate shipments. If temperature control fails at any point, the entire shipment could be lost. Adding to the strain are stringent regulatory demands. CGT is still a relatively new area of medicine, and additional transport requirements like packaging, surcharges, and restrictions are constantly evolving. This web of intricate cold chain conditions,





regulatory compliance, and constant monitoring needs creates a perfect storm of risk.

The stakes are incredibly high. A single misstep could delay or prevent a patient from receiving treatment, underscoring the dire need for improving the CGT logistics market. As the industry expands, these challenges will only intensify unless there is a significant transformation in how CGT therapies are transported.

Innovative Solutions Transforming CGT Shipments

Fortunately, the logistics industry has begun to develop solutions tailored to the unique needs of CGT. New technologies and approaches are transforming how companies ship these sensitive therapies, providing the precision and reliability that the market demands.

The development of advanced cold chain technology is a critical innovation given the ultra-low temperatures CGT products require. To help maintain treatment integrity, many companies are now leveraging advanced cryogenic packaging that can maintain consistent temperatures over extended periods. When combined with real-time temperature monitoring, these containers can ensure a shipment's condition from origin to destination.

To that end, real-time visibility into shipment location and condition has become essential. GPS-enabled tracking devices offer a live feed of the shipment's status, including temperature, humidity, and even shock events that might compromise the therapy. These devices enable real-time data collection and monitoring, so teams can not only react quickly if something goes wrong but pull from collected data to demonstrate compliance if need be. This visibility not only reduces risk for companies but also provides peace of mind to healthcare providers and patients.

Coupled with real-time visibility, predictive analytics can help not only prevent issues but improve overall operational efficiency. By analysing historical shipping data, weather patterns, and traffic conditions, companies can predict potential delays and proactively reroute shipments. On top of minimising disruptions, these insights can help guide future shipments, helping companies continually optimise their supply chains.

Of course, the importance of close collaboration with experienced logistics service providers (LSPs) cannot be overstated. Specialised LSPs that understand the complexities of CGT regulatory compliance, packaging, and temperature needs, are invaluable in navigating the intricacies of CGT logistics. Their expertise helps reduce the margin for error, ensuring that the product arrives intact and ready for patient administration.

Modernising CGT Supply Chains for Lifesaving Impact

While the challenges of CGT logistics are significant, they are not insurmountable. By embracing innovative cold chain technology, real-time monitoring, and predictive analytics, companies can navigate the complexity of CGT supply chains. These advancements are more than just technical upgrades – they're lifesaving improvements.

The future of cell and gene therapy depends not only on scientific innovation but also on the logistics systems that bring these treatments to life. By adopting an integrated, real-time solutions approach, companies can protect the integrity of their therapies and ensure they reach the patients who need them most.



Alex Guillen

Alex Guillen is an established executive with a proven record in global business and market development, with well-rounded experience in multicultural sales management and brand building. Guillen has extensive experience and expertise in cold chain; as Global SME, Life Science and Pharma at Tive, Guillen leads sales and business development within the company's rapid-growth Life Science division. Previously, Guillen served as a Board Member and leader of Corporate Strategy at SWITRACE S.A, a developer of temperature and humidity data loggers compliant to the Pharma and Biotech industries. Guillen's extensive experience also includes serving as Global Cold Chain Director of Fisher Clinical Services, CEO of Escort Cold Chain Solutions SA and Director for Commercial Operations for Novartis Vaccines.