# Navigating the Logistics Impact

## Unique Requirements of Cell & Gene Therapies

*Cell and gene therapies (CGTs) present a revolutionary approach to the pharmaceutical industry. CGT is addressing various diseases with personalized and targeted treatments tailored for individuals with various rare diseases that were previously incurable. However, with such innovation, several complexities do arise on a logistical spectrum that diverge from those of traditional pharmaceuticals.*

CGTs, particularly autologous therapies, require specific handling procedures throughout the transportation journey. This involves the transportation of the apheresis sample from the clinic to the manufacturing site and, ultimately, from the manufacturing site back to the clinic as the final product. In some therapies, multiple shipments are conducted for the apheresis sample, which further complicates the logistics requirements and intensifies the overall operations. It is crucial to note that such therapies, whether the apheresis or drug product, are time-sensitive and have unique handling and packaging requirements. Complexities further intensify when clinics and manufacturing sites are across regions with limited connectivity and still have to abide by the zero margin for error.

Pharmaceutical companies encounter diverse challenges in managing their CGTs, with variations arising from factors such as their existing capabilities (both internally and through partnerships), handling and packaging specifications, proximity and connectivity between manufacturing sites and clinics, among other considerations.

However, some of the most prominent challenges are outlined below, each requiring strategic considerations for effective resolution.

- 1. X-ray exemption requirements: Securing X-ray exemptions or optimizing procedures for CGTs is crucial to minimizing disruptions in the supply chain. Delays in inspections or non-compliance with regulations can adversely affect product quality and, ultimately, patient outcomes. Implementing streamlined procedures and maintaining a robust regulatory compliance framework is essential to navigate this challenge successfully.
- 2. Limited logistics service providers with required expertise: The current landscape witnesses a scarcity of logistics providers well-versed in the significance, procedures, regulations, and ecosystem of CGTs. Adapting operations to include the management of the cold chain, real-time tracking, and specialized packaging becomes imperative for logistics providers aiming to support the unique requirements of these therapies. Pharmaceutical companies must proactively seek partnerships with logistics specialists to enhance their supply chain capabilities.
- 3. Limited visibility, especially with local agents: Disparities in reporting systems, language barriers, regulatory variations, and a lack of standardized processes contribute to limited visibility in the logistics chain. This information gap poses operational risks, making real-time monitoring difficult and potentially resulting in delays and challenges in addressing unforeseen issues promptly. Establishing standardized processes, leveraging technology for data integration, and fostering communication can mitigate these challenges.
- 4. Scalability via exploring various transportation modes: The prevalent use of the on-board courier method for transporting apheresis samples may present scalability challenges due to the intricate nature of the process and associated documentation requirements. Exploring and adopting alternative transportation modes that align with the evolving needs of CGTs is crucial for long-term scalability and efficiency.
- 5. Setting contingencies on a single shipping route: Relying on a singular shipping route for transporting CGT components introduces potential challenges in terms of flexibility, adaptability, and responsiveness to unforeseen disruptions. Proactively establishing contingencies for shipping routes and diversifying transportation methods can enhance resilience in the face of evolving logistical landscapes.

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### Tackling the Challenges

To overcome these hurdles, strategic adjustments in logistics operations are paramount. This involves a multifaceted approach encompassing regu-

latory compliance, technological integration, partnerships with logistics providers, and consideration of varied transportation methods. Stakeholder awareness along the value chain is essential for fostering a collective understanding of the intricacies of processes, documentation, and logistics requirements, ultimately ensuring the successful delivery of the final product to the patient.

**Engaging with stakeholders**

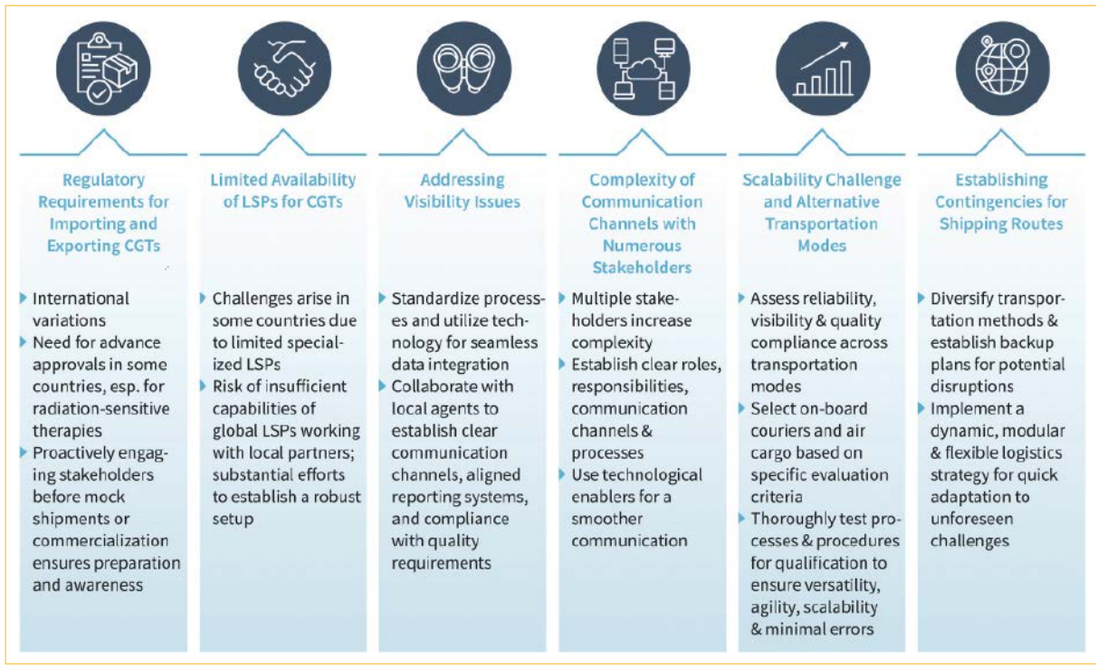
The regulatory requirements for importing and exporting cell and gene therapies vary significantly from one country to another. Some countries demand specific approvals in advance, involving coordination among numerous internal and external stakeholders, particularly for therapies sensitive to radiation that require X-ray exemptions. Consequently, pharmaceutical companies must engage proactively with relevant stakeholders before conducting mock shipments or commercializing therapies. These proactive engagements ensure thorough preparation for all shipment requirements and enhance stakeholder awareness of their responsibilities, thereby ensuring successful and timely shipments.

**Collaborating with multiple LSP**

The limited availability of logistics services providers (LSPs) specializing in CGTs can pose challenges in certain countries due to the restricted footprint of specialized LSPs. Despite LSPs with global pharmaceutical contracts typically establishing local partnerships as an initial solution, the capabilities often fall short of requirements, demanding significant efforts such as training and due diligence to ensure a robust setup.

*"CGTs, particularly autologous therapies, require specific handling procedures throughout the transportation journey."*

In such cases, it is advisable to engage multiple partners to mitigate the risk of courier underperformance or failure to meet set requirements. To enhance the likelihood of success, it is essential to ensure cross-functional collaboration and involve all key stakeholders, checking their current operational capabilities in relation to the specific requirements, such as handling, to further streamline the logistics process for CGTs. This collaborative and comprehensive approach is crucial for meeting the unique and demanding needs of CGTs.




Challenges in CGT logistics. (source: Camelot Management Consultants)

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**Establishing data analytics and communication processes**

Addressing limited visibility issues, especially with local agents, involves implementing standardized processes and leveraging technology for data integration. Pharmaceutical companies can collaborate with local agents to establish clear communication channels, align reporting systems, and ensure compliance with quality requirements. Investing in technologies such as real-time tracking and data analytics enhances visibility throughout the supply chain, enabling proactive decision-making and reducing the risk of operational disruptions.

The involvement of numerous stakeholders, particularly when additional local players such as local agents and distributors are present, elevates the complexity of communication channels and introduces a higher risk of operational issues. To mitigate these challenges, it is crucial to establish clear roles and responsibilities across all stakeholders and ensure the implementation of appropriate communication channels, processes, and procedures. Additionally, leveraging technological enablers is essential to enhance visibility throughout the supply chain, promoting smoother communication and reducing the potential for operational disruptions.

**Diversifying transportation modes**

Addressing the scalability challenge associated with different transportation modes necessitates pharmaceutical companies to evaluate factors such as reliability, visibility, and quality compliance. Currently, on-board couriers and air cargo stand as the two primary transportation modes adopted by pharmaceutical companies, selected based on meeting specific evaluation criteria. However, when opting for the on-board courier, it is imperative for pharmaceutical companies to assess its long-term implications on scalability. To ensure versatility, both transportation modes should be viable options, requiring the establishment of clear processes and procedures that are thoroughly tested for qualification. This strategic approach allows for enhanced agility and scalability and minimizes errors. Decision criteria should prioritize flexibility and adaptability to facilitate future scalability.

*"Implementing a dynamic, modular, and flexible logistics strategy allows for quick adaptations to unforeseen challenges."*

Establishing contingencies for shipping routes involves diversifying transportation methods and creating backup plans for potential disruptions. Implementing a dynamic, modular, and flexible logistics strategy allows for quick adaptations to unforeseen challenges, ensuring the continuous and timely delivery of CGT components. This proactive approach enhances flexibility and minimizes the impact of unexpected events, contributing to the supply chain's reliability for CGTs.

The key in addressing the logistics impact of CGTs lies in the proactive planning of pharmaceutical companies, where effective cross-functional collaboration and learning from trial and error during mock shipments lead to a smooth and successful delivery of CGTs. It is important to highlight the proactive measures taken, including ensuring regulatory compliance, establishing partnerships with logistics specialists, incorporating technology, and maintaining flexibility in transportation methods, to enable scalable therapy in the future.

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