



# Scaling Cell and Gene Therapy Logistics

Cell and gene therapies (CGTs) represent a transformative frontier in modern medicine, offering potentially curative solutions for conditions like cancer, genetic disorders, and rare diseases. However, the logistical complexity of delivering these personalized therapies at scale requires advanced, high-performing systems that ensure reliability at every step.

For CGTs to reach their full potential and achieve global accessibility, scalable logistics systems are vital. Below, we delve into the challenges and innovative solutions shaping the scalability of CGT logistics.

## The unique challenges of CGT logistics

CGTs differ significantly from traditional pharmaceuticals, particularly in their personalized nature. Autologous therapies, derived from a patient's own cells, follow a one-to-one model, while allogeneic therapies, made from donor cells, offer a one-to-many approach. Both require tailored logistics, but autologous therapies are especially delicate. Key challenges include:

- 1. Temperature sensitivity:** CGTs often require strict cold chain management. This can include ultra-low (dry ice) conditions at  $-60^{\circ}\text{C}$  or below, and in some cases, cryogenic storage at  $-150^{\circ}\text{C}$  or colder to preserve product viability.
- 2. Time sensitivity:** Autologous therapies operate within tight timeframes to ensure the cells remain viable for reinfusion.
- 3. Regulatory complexity:** Each country or region has unique regulations, requiring meticulous documentation and compliance throughout the supply chain.
- 4. Geographic distribution:** Patients may be located far from manufacturing facilities, making reliable transportation and cross-border coordination key areas of focus.



## Moving with the times

These challenges have historically meant that CGT logistics relies upon personalized ‘white glove’ delivery services to get the product from manufacturer to customer. As CGT becomes more mainstream, with more therapies available to more people to cure more illnesses, ‘white glove’ services may not always be feasible at scale.

To scale CGT logistics efficiently, in an age of an expanding CGT customer base bound to become more mainstream in the future, the following considerations must be front of mind.

### 1. **Automation and digital integration**

Manual processes increase the chance of errors, particularly as volumes increase. Automated systems for tracking, monitoring, and documentation can streamline operations and reduce errors. Digital platforms offering real time, cloud-based visibility over shipping data, alongside item condition, such as tilt and temperature, can enhance transparency and ensure potential disruptions are proactively managed.

### 2. **Cold chain infrastructure expansion**

Expanding cold chain capabilities globally is crucial. This includes investing in specialized packaging, such as cryogenic containers and portable freezers, and ensuring robust last-mile delivery solutions in regions with underdeveloped infrastructure.

### 3. **Regulatory harmonization**

Collaboration between regulatory bodies is necessary to standardize guidelines and reduce complexity for companies operating across borders. Developments here could significantly lower barriers for global scalability.

### 4. **Stakeholder collaboration**

Successful scaling requires coordinated efforts among therapy developers, logistics providers, healthcare facilities, and regulators.

### 5. **Finding the right logistics partner**

Finding a partner who can scale as needed, alongside your business or therapy as it scales, is essential for optimizing your logistics. This means you benefit from economies of scale and the expertise of a reliable partner, while keeping all delivery options on the table depending on your needs.



### Choose a partner, not a provider

Scaling logistics for CGT is easier said than done, but it is essential. It's vital for the biomedical startups looking to scale their products, the patients in need of these life-changing therapies, and for national health services around the globe who want to supply these medicines to patients at the best possible cost.

Central to this endeavor will be choosing the right partner. The evolution of the CGT industry necessitates logistical stakeholders who can do everything, from 'white glove' to large scale distribution.

For smaller startups who may not have the resources or expertise to optimize their logistical strategy, this is particularly important. Early-stage organizations need a supply chain expert they can outsource the process to while they focus on developing therapies, and one that can grow with them to deliver at every stage. Furthermore, these smaller biomedical companies can benefit from an experienced partner's industry knowledge and wealth of data - which may bring vital insight into the development of the therapies itself.

By investing in technology, infrastructure and collaborative ecosystems, the industry can overcome logistical challenges and ensure that CGTs reach patients globally as the field evolves.

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