

WP1 Report - CGT Market  
Analysis: Logistics  
Capabilities, Constraints,  
Challenges

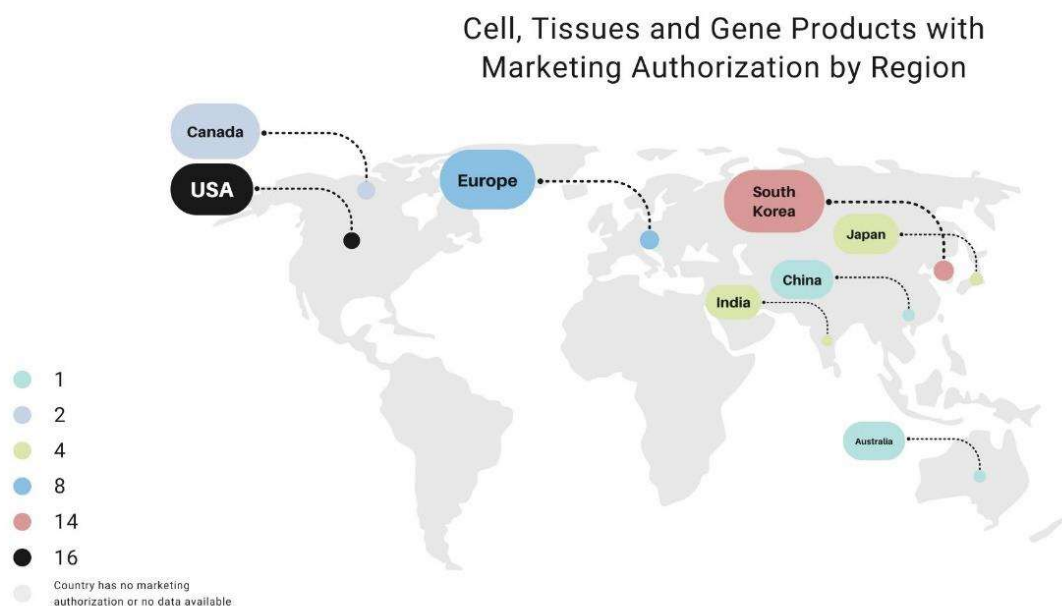
## 1. CGT Market Overview

Clinical research on individualized medicine is currently leaving the pipeline after 20 years of research and the investment of billions of dollars. With more than 900 companies globally focused on such advanced therapy medicinal products (ATMP) and over 1,000 CGT clinical trials underway<sup>1</sup>, the industry could see as many as 10 to 20 new therapies approvals per year starting 2025<sup>2</sup>.

The global cell and gene therapy manufacturing market size was valued at USD 13.1 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 20.3% until 2028<sup>3</sup>.

The CGT sector is most developed in North America with a large share of revenues (47% in 2020), mostly due to strong innovation, a favorable regulatory environment and access to significant investment. Also, 57% of gene therapy clinical trials take place in the US (by 2021).

China is also an important player in the sector, and some European countries have positioned themselves on the global industry map as well (Belgium, United Kingdom, and more recently France).



Due to the fact these therapies are based on genetic cell components and life cells related to complex development pathways, the CGT places significant challenges on the current clinical and commercial supply chain. The logistic sector needs to collaborate directly with researchers and manufacturers to **understand the specific needs, demands of the CGT products**, and define together the solutions for safe and efficient transportation.

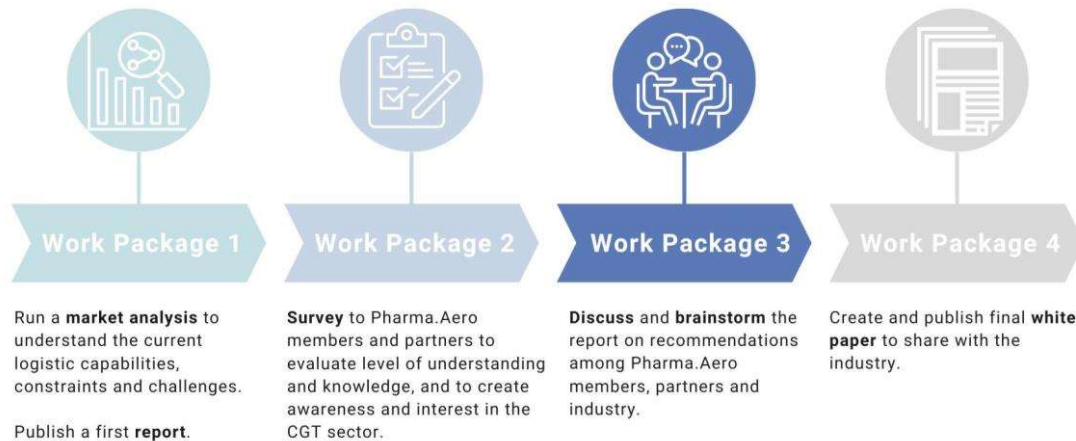
<sup>1</sup>Distribution & Supply Chain Models in the Cell & Gene Therapy, Deloitte, June 2021

<sup>2</sup> FDA Commissioner Scott Gottlieb, M.D.

<sup>3</sup> Cell And Gene Therapy Clinical Trials Market Size, Share & Trends Analysis Report 2021-2028, Grand View Research

Pharma.Aero has initiated the CGT Project to ensure potential adaptations necessary to prepare the air cargo industry to assuring high-quality end-to-end transportation of biopharma and CGT products by identifying its needs, challenges, but also opportunities.

The CGT Project runs in 4 different Work Packages (WPs).



With WP1 now completed, we are sharing the main findings together with relevant aspects that our expert identified as being important in the transportation process (current capabilities, constraints, and challenges). The detailed expert report will be accessible to Pharma.Aero members only.

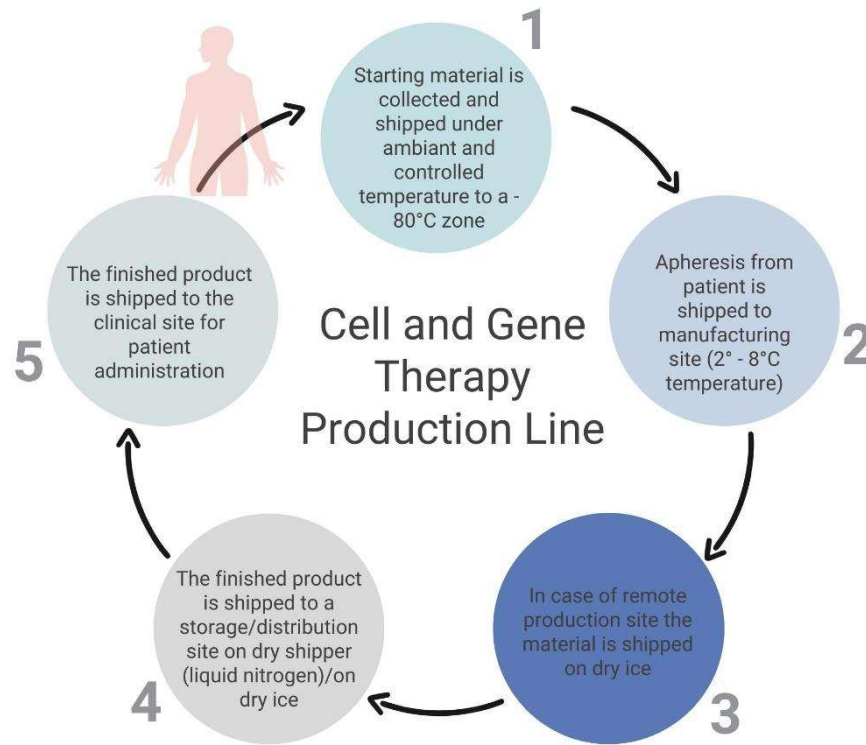
## 2. CGT Logistics and Supply Chain

The personalized nature of the CGT products demands a greater degree of operating model sophistication, pinned to several functions leading up to a "closed loop" supply chain and distribution system. It is key to understand the impact and specificities of the coordination and supply chain of these innovative products.

The CGT sector has some fundamental particularities that have a great influence in determining the logistic solutions:

- ✓ *Starting material*
- ✓ *Scarcity of resources/ suppliers*
- ✓ *Each patient is unique*
- ✓ *No inventories*
- ✓ *Short life span – Timing is critical*
- ✓ *Less equipment*
- ✓ *Combining different temperature ranges*

Figure: Cell and Gene Therapy Production Line



### 3. Key Logistics Challenges

PROCESS	TRACEABILITY	TECHNOLOGY	SAFETY	RISKS
Standardization & Harmonization	Lane Data/ KPI Mapping		Labelling	Risk Analysis
Logistics	Integrated Multi-modal Visibility	Digital Technology (AI, AR, IoT)	Product Stability	Cost/ Risk Balance
Process Control	Basic Tracking Samples/ Shipments	Flexible Technology	Specialized CIE	Quality Audits
Lead Times	Supply Chain Transparency		Education & Training	Disasters/ Disruptions
Supply Chain Planning	Package/ Container/ Vehicle Tracing			Sustainable OPS
Customs Procedures	Access to Carriers Booking & Volume Management			

#### 4. Other Airfreight Specific Challenges



#### 5. Conclusions and Elements for next Work Packages

The CGT sector presents unique complexity in terms of supply chain and logistics flows. Challenges are found in every link of the chain, from planning, procurement to distribution, and require simultaneous shipments at different temperatures. The global challenges of the sector including cost control and industry standardization are subject to a lot of reflection and request significant improvements at the logistics level.

In this context, air transport is an essential link in the logistical chain and represents a key element on which to capitalize to make flows more fluid. It is important to encourage greater collaboration in the industry to facilitate logistical improvements necessary for CGT.

##### Pharma.Aero CGT Project Support and Collaboration:

- ✓ *Pharma.Aero Board liaison and leadership:* Trevor Caswell, Pharma.Aero Chairman (Edmonton Airport) and Frank Van Gelder, Pharma.Aero Secretary General
- ✓ *Project lead:* Milton De la Paz, DFW (Dallas Fort Worth)
- ✓ *Project members:* Pharma.Aero members and partners participating in the survey
- ✓ *External support:* BioNTX (Bio North Texas), GeneTether Therapeutics, Taysha Gene Therapies
- ✓ *Project manager:* Franck Toussaint, BSMA (external consultant)
- ✓ *Project coordination:* Sara Van Lerberghe