



Pharma.Aero

Trevor Caswell

Chairman

Milton De La Paz

Advisory Board



Introduction

- Founded 2016
- Pharma.Aero's mission is to achieve excellence in a reliable end-to-end supply chain and in the logistics of Life Sciences sector and Medtech products
- To stay at the forefront of the industry's evolution
- Develop projects and education to explore the emerging Life Science sector





Industry Intelligence Platform

KNOWLEDGE



CONTENT



RESEARCH



INNOVATION



42

publications

13

LMAP

85+

members

4

PLMC

18

projects

5

continents

15

podcasts

6

key partners



OUR MEMBERS



Life Science Manufacturers Advisory Platform

LMAP



Life Science Manufacturers Advisory Platform



of which STRATEGIC (General Assembly and BOD)



Other industry collaborations



TIACA



MoU with The International Air Cargo Association



IATA



MoU with International Air Transportation Association



HLA



MoU with Humanitarian Logistics Association



BSMA



MoU with Bio Supply Management Alliance



neutral
AIR PARTNER



MoU with Neutral Air Partner



COOL CHAIN ASSOCIATION
coolchain.org



MoU with Cool Chain Association





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PHARMA.AERO
PROJECTS



INNOVATION IN MOTION

Harnessing Digital Technology to Predict, Optimize,
and Secure the Pharma Logistics Supply Chain



Pharma.Aero | November 2023

Project team

Samuel Speltdoorn

| Brussels Airport Company | Pharma.Aero Board Liaison

Yue Ming, Liew Zhong Yao, Renee Gan

| Changi Airport Group | Project Lead

Irene S L Lau, Caroline Y W Cheung, Sharon S K Yip

| Hong Kong Airport Authority | Project Lead

**Virginia Domina, Righart Stroobant,
Anne Julie Verhaeghe**

| KPMG | Project Expert, Project Manager

Sara Van Lerberghe

| Pharma.Aero Project Coordinator

Frank Van Gelder

| Pharma.Aero Secretary General



Research Area

1 Identify Challenges Pharmaceutical Logistics

Cold Chain Management and Product Stability
Product Diversity
Regulatory Compliance
Supply Chain Visibility
Real-time Visibility and Technology Limitations
Data Availability and Standardization
Environmental Sustainability
CO2 Emissions
Waste Management

2 Pharmaceutical Logistics Trends & Requirements

Predictive & Prescriptive Analytics and Behaviour Modelling
Standardization and Data Collaboration
End-to-End Visibility and Real-time Tracking
Optimization of Logistics Operations, Costs and Sustainability
Innovations in Medical Treatments
Decentralized clinical trials
Cell & Gene Therapy
Radioactive Medicine at Nano Level

3 Digital Solutions to respond to evolving Trends & Challenges

Achieving End-to-End visibility in Cold Chain with Internet of Things (IoT) and Sensors
Enabling Predictive Risk Mitigation with Artificial Intelligence (AI)
Provide Transparency and Security with Blockchain Technology
Combined Digital Solutions for Sustainability Improvement



Research Area

4 Case Study MSD: Applicability of Next-Gen Digital Technologies

The main goals of MSD's digital logistics program were:



Receive
Real-time
alerts



Implement
interventions
when
necessary



Provide
accurate
customer
ETA advice



Improve
performance
management



Conduct risk
analyses and
drive business
improvement



Enable
strategic
planning

5 Challenges of Implementation & Enablers for Digital Solutions

Infrastructure and Integration
Data Security and Privacy
Regulatory Compliance
Training and Workforce Skills
Rapid Innovations
Precision & Personalized Medicine

6 Exploring Emerging Trends & Transformations

Sectoral Changes Impacting Life Sciences and Pharma in the Next Years
Converging Technologies: Self-driving Supply Chain



Conclusions

Start Small for Quick Wins:

Begin by identifying areas where digital technology can be quickly integrated to improve collaboration, responsiveness, and agility. These early successes can serve as building blocks for broader transformation efforts.

Patient-Centric Transformation:

Shift your operating model from being supply-driven to patient-driven, aligning your strategies with the needs and expectations of your patients.

Data-Driven Decision-Making:

Collect and analyse downstream demand data to enhance forecasting and planning, helping your company make informed, data-driven decisions.

Embrace innovative business models:

It is not just about adopting new technology, but also reimagining new business models, to benefit from the advantages they can offer.

Infrastructure Investment:

A robust and adaptable infrastructure is essential for the successful deployment of digital solutions. Assess your existing infrastructure and invest in the necessary upgrades to support your digitalization strategy effectively.

Workforce Transformation:

Understand that successful digital implementation relies on a skilled and adaptable workforce. Develop comprehensive training programs tailored to different user groups to overcome resistance to change and improve digital literacy.



CELL & GENE THERAPIES Project

Focus on Logistical
Challenges

Results of the White Paper &
follow-up project





WHITE PAPER

CELL & GENE THERAPIES PROJECT

Focus on Logistical Challenges

"Patients can't wait and only have one chance"

FEBRUARY 2023

Project Team

Franck Toussaint

Biolog Consulting and co-founder of BSMA Europe
Project Manager and Expert

Sara Van Lerberghe

Pharma.Aero
Project Coordinator

Milton De La Paz

Dallas Fort Worth International Airport
Project Lead

Trevor Caswell

Edmonton International Airport
Board Liaison

Frank Van Gelder

Pharma.Aero
Secretary General



Methodology

1

WP I: Market opportunity Analysis

2

WP II: Needs Assessment & Gap Analysis

3

WP III: C> Webinar

4

WP IV: Report Publications



1


WP I: Market opportunity Analysis

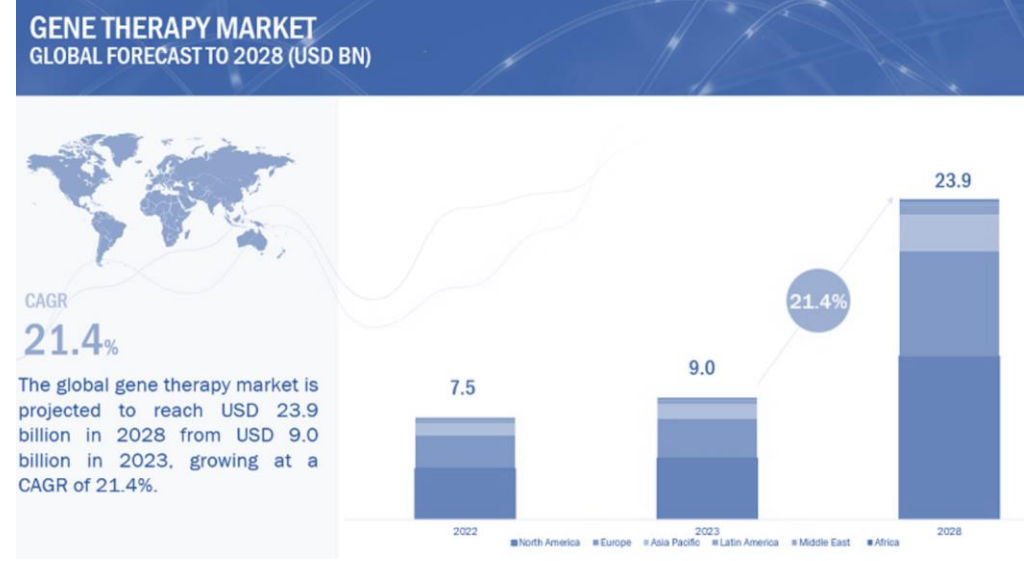
Market activity in 2022:

 **2220**
Active Clinical

 **202**
Trials in Phase 3

 **+100**
Gene Editing Trials

 **1457**
Cell and Gene Therapy Developers Worldwide



Asia Pacific
47% (492)

Europe
17% (244)

North America
47% (686)

Other Regions
2% (35)



2

WP II: Needs Assessment and Gap Analysis

Key differentiators



Starting material from patient



Scarcity of resources / suppliers



No inventories



Timing / scheduling are critical



Less equipment



Each patient is unique



Combining of different temperature ranges



2

WP II: Needs Assessment and Gap Analysis



Product related

The products are unique and have very specific requirements

Process related

Processes related to the CGT industry are also generally more complex

Related to a Specific Stage of the Supply Chain

Specific issues arise in the different stages of the supply chain

Related to Competences and Know How

Specific knowledge is required

Technology related

Technological solutions represent a key element

Business related

This specific industry also generates specific actions and business approaches



2

WP II: Needs Assessment and gap Analysis

Product related



Temperature management



Product stability



Good management of lead time



2

WP II: Needs Assessment and Gap Analysis



Regular quality audits



Lane mapping



Risk Analysis



Labelling



Standardization



2

WP II: Needs Assessment and Gap Analysis



Capacity and availability of flights



Access to road networks, airports / network design



Airport capacity



On site storage



Knowledge of customs & Customs knowledge



Real-time visibility



Natural disasters and environmental issues



Handling capacity



Disruption & risks

Supply Chain Stages



2

WP II: Needs Assessment and Gap Analysis



Externalizing vs Internalizing Logistics: the need to control



Scalability



Sustainability



3

WP III: Webinar Outcomes

Complex and intensive -> high degree of coordination and management

No room from any failure

Scale up the newest available technologies

Need for professional advocacy and international collaboration

Prepare for scalable services in the rapid growing therapy markets

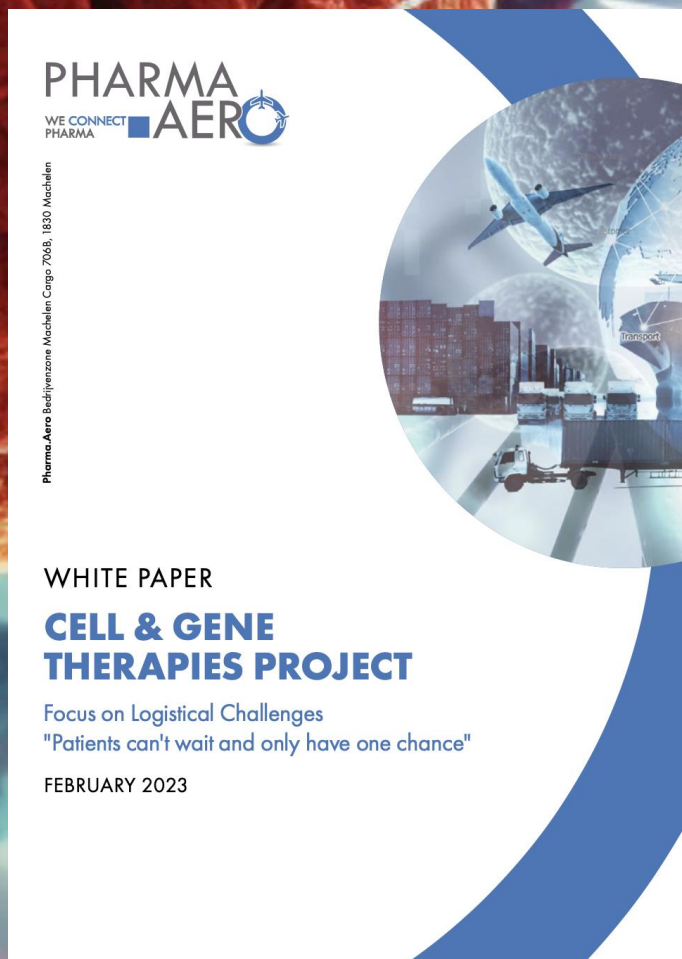
Time, temperature and value are ONE

CONTROL, CONTROL, CONTROL

Chain of custody and chain of identity

Industry standardization





Strengthen the skills of the players in the airfreight sector

The need to strengthen the skills of the airfreight stakeholders emerged from both the survey and the webinar. Participants expressed the need to keep up to date with developments in the sector, but also to increase internal skills. It is also important to be proactive and stay involved, as the rapid evolution of this sector results in continuously evolving needs.



Facilitate the flow of materials and substances

The great complexity of the CGT logistics sector stays in the diversity of its supply chain, involving multiple shipments for one treatment, various temperatures to be controlled, and the criticality of time. This project offers high level information on several key steps where risks arise. The airfreight sector needs to ensure a fluid flow. Also, that the legislative barriers need to be avoided. This also implies an increase in the knowledge of operators and customs officers.



Reduce time/ Eliminate time loss

The time loss can be eliminated through controlled processes, the use of adapted technologies, adequate training and adapted infrastructures. All these represent major elements for ensuring safe, and reliable ATMP logistics.



Identify products as specific to the CGT industry

It is important for the industry to design specific solutions for the CGT/ATMP logistics.



Limit regulatory constraints and upgrade CEIV

Over the years, the industry has been constantly improving its skills and knowledge of the pharmaceutical sector and its specificities. In this sense, the CEIV pharma certification has allowed many players to improve their level of expertise. However, this certification does not seem to be sufficient in view of the specific challenges of the ATMP sector. There is a need to reflect on the certifications and support to be implemented in the industry.

In general, the work on the regulatory elements likely to cause problems in the shipment of samples and products is an element of follow-up to be provided.



Follow-up Project

Based on the current developments, and in continuation of the first ATMP project conducted by Pharma.Aero, we will testcase the potential shipments over a defined transatlantic airport corridor, between two biopharma ATMP bio-incubators

Project aims to canvas all findings over a real lane (March 2024 until November 2024)



Identify key partners

Who are the main drivers in the logistics process both sides the airport gateway



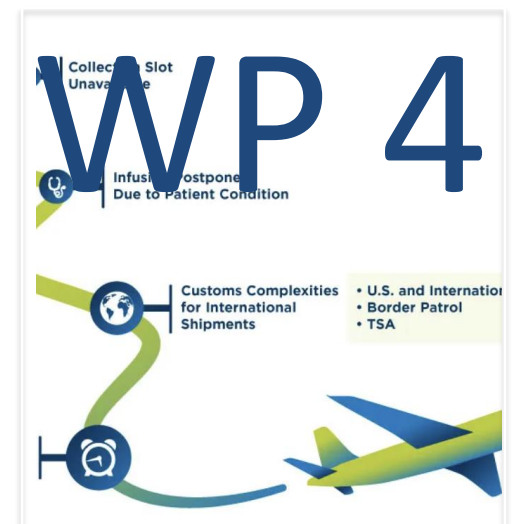
Set-up the test lanes

Identify Pharma.Aero members to be included in the prototype and POC as well as identify the necessary technology specs



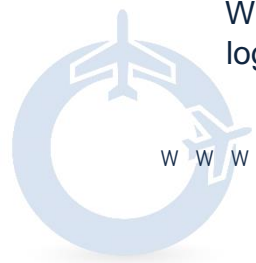
Testing & Analysing

During an identified period, 50 dummy shipments will be physically shipped and analysed on different ATMP KPI's



Future Outlook

Based on analytical reports, we will identify potential threats, shortcomings and working points, to standardise a single strategy of approach



March 2024

April 2024

May 2024

June 2024

July 2024

August 2024

September 2024

October 2024

November 2024

WP 1



WP 2



WP 3



WP 4



BioNTX

DFW

DALLAS FORT WORTH INTERNATIONAL AIRPORT



www.pharma.aero



atmp.logistics Excellence centre



— COLLABORATION —



TEAM WORK



SUPPORT



PARTNERSHIP



CREATIVE



SOLUTION



TRUST



COMMUNICATION



SUCCESS



SEP 29 - 3 OCT
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Thank you

