Labeling, Packaging & Logistics – The Achilles Heel of the CGT Delivery

BSMA 2021 Virtual Mini-conference
Commercialization of Cell & Gene Therapy: Advancing Technology and Innovation
August 5, 2021
How can we create healthier futures together?
Therapy efficacy is irrelevant if you cannot connect product to patient

Cell and gene therapies allow for the creation of targeted life extending and potentially curative treatments for patients.

Logistics challenges limit the availability of these therapies for patients.

Consequently, patients have late (or no) access to treatment, with potential catastrophic impact.
# Advantages and challenges of autologous and allogeneic therapies

## Autologous therapies have availability and logistics challenges

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<th>Medical Advantages</th>
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## Allogeneic therapies have logistics challenges too, but bigger potential to scale

### Advantages
- Optimal cells
- Standardized products
- Expansion of dose numbers
- GMP-compliant testing
- Immediate availability
- Eliminated risk of immune response through 2nd generation products

### Medical Challenges
- Risk immune reaction and graft vs host disease

### Logistics Challenges
- Short shelf life
- Expanding shelf life – only possible at -196°C
- Global cryogenic supply chain required
- Traceability (serialization)
The supply chains for autologous and allogeneic therapies differ.

**Autologous Therapy**
- Apheresis/Surgery
- GMP
- Storage
- Autologous ATMP
- LN or 24h
- GMP samples
- LN or 24h

**Allogeneic Therapy**
- Apheresis/Surgery
- GMP
- Storage
- Allogeneic ATMP
- LN
- LN or 24h
- Patient samples
- LN or 24h
- Patient
Three requirements to build a cryogenic logistics platform for allogeneic therapies

1. Storage network
   - Single partner from phase 1-3, to commercialization
   - Global locations

2. Shipping capabilities
   - Specialized packaging
   - Network of charging stations
   - Real-time tracking and monitoring

3. Technology platform
   - Data access, analysis and oversight
We have cryogenic storage capabilities in key locations, with the potential to expand across our global network.

- 01 USA – Reno, NV
- 02 USA – Brooks, KY
- 03 USA – Columbus, OH
- 04 Canada – Milton, ON
- 05 Mexico – Mexico City
- 06 Colombia – Bogotá
- 07 Peru – Lima
- 08 Chile – Santiago
- 09 Argentina – Buenos Aires
- 10 Uruguay – Montevideo (Partner depot)
- 11 Brazil – São Paulo
- 12 Serbia – Belgrade (Partner depot)
- 13 Turkey – Istanbul
- 14 Ukraine – Kiev (Partner depot)
- 15 Russia – Moscow
- 16 Israel – Tel Aviv (Partner depot)
- 17 South Africa – Johannesburg
- 18 India – Bengaluru (also offers a bonded warehouse)
- 19 Singapore – Singapore
- 20 China – Beijing
- 21 Japan – Tokyo
- 22 Australia – Melbourne (also offers order-to-cash and pharmacy dispensing services)

3PL commercial depot*
Clinical & commercial depot
Clinical depot
Cryogenic storage facilities

*Served by 3PL commercial depot
Served by clinical & commercial depot
Served by clinical depot

3PL facilities offer: Commercial full order-to-cash, including storage, pick, pack and ship along with value-added services such as Foreign Trade Zone (FTZ) and serialization.
BioStore™ III
Cryo -190°C
“Vending” System

- Fully automated box/cassette delivery
- Insulating tower protects innocents
- Labware Flexibility – Cryobags or vials
- SW inventory management
- Administer defined access control
- Three-week emergency hold time
- 21-CRF-11 compliant
- Proven Chart/MVE tank technology
- Low operating costs
- Improved ergonomics
Features

- Available in KY
- Ability to commission, thermal print on cartons, inspect and aggregate to Case and Pallets
- Flexible config to meet all Carton sizing requirements and moving the machines to aggregate in cold storage conditions
- EPCIS capability to integrate with all L4 systems
- Validated operational process and system capabilities for preconditioning cryogenic cartons, serialization, Labelling and post storage and integration with 3PL pick, pack and ship
- Experience in supporting labelling and carton testing for text legibility, label adhesion and carton strength

Capabilities

- Manual print, inspect, and aggregation system
- Thermal Inkjet Printer to scribe product variable data and/or serialized code on the carton and inspect
- Black ink on white
- Can print up to 4Lines with 2D code
- Validated lines based on machine capacity
We offer a wide range of cryogenic shipping options

**VIA Capsule**  
Unique LN$_2$ free technology

**SAVSU**  
Inbuilt tracking and able to manage tilt

**Palletized MVE**  
Established, widely used solution
World Courier has global LN$_2$ and VIA Capsule management and charging capability.

- Multiple charge stations strategically positioned throughout the global network.
- Ability to intervene as needed to manage unexpected events and unscheduled delays.
- Driven by a single quality system and underpinned by established SOPs.
- Supporting over 10,000 cryo shipments annually.
Access to data for insight and oversight via technology platforms

- Customer Portal for streamlined order entry and shipment tracking
- Real time tracking for position, temperature and tilt
- Aggregation of storage and logistics cold chain data
- Established APIs to manage systems integration
Create healthier futures through supply chain partnership
Any questions?

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