Managing high value pharma shipments with innovative collaboration between multiple stakeholders

PDA Australia Chapter Cold Chain Distribution Event

Stephen Maietta, Head of Global Key Accounts - Envirotainer
16th February 2016
Brunswick West
Envirotainer°
Who is in attendance today? Where does your accountability start and stop with the product reaching the patient in the expected condition?
Temperature control supply chain drivers

Stakeholder collaboration

Summary

Biomedical innovation framework & market observation
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Temperature control supply chain drivers

Stakeholder collaboration

Summary
This is why we see an increased trend in collaboration across stakeholders

Note: Oncology, 114 B $ in 2018, Anti-diabetics, 61 B $, Anti-Rheumatics, 52 B $, Vaccines, 39 B $

Source: Evaluate Pharma – June 2013
Leading research and innovative countries based on papers and citations

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Source: SJR International Science ranking
Biomedical innovation framework & market observation

Temperature control supply chain drivers

Stakeholder collaboration

Summary
The temperature control supply drivers have remained fairly consistent – only the priority has shifted
Risk assessment for the transportation of a high value pharma and biologics

The market has spoken...“We would like a solution that does the job and is cost effective”

What is the risk profile of the drug?
What is the risk profile of the trade lane?
What is your company’s risk acceptance?

Risk profile
Product life cycle characteristics and requirements
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Summary
Pharma Supply Value Chain

Intermediates
- Commodity Chemicals
- Specialty Chemicals
- Fine Chemicals

Active Ingredient
- Bulk Active Synthesis
- Bulk Biologics

Formulation
- Excipients
- Formulation Oral Solids
- Formulation Steriles
- Formulation Inhalers, etc.

Packaging
- Primary Packaging
- Secondary Packaging

Distribution
The temperature control supply chain is complex but it can be managed through a **Core Team** and measurable KPIs

- Has the temperature sensitive shipments (different types of requirements, according to drugs and routes)
- Either coordinates the whole logistics or pushes the decision to a 3 PL / forwarder

• Picks up the container at the release point (e.g. airport)
• Takes it to the shipper’s own warehouse or manuf. Plant or built up at the 3rd party
• Drives the container back to the airport and stores in its own warehouse - checks
• Takes in to the airline warehouse
• Issues an airway bill

• Takes the container from the airline warehouse
• Transports it on a flight
• Delivers the container back to its airline warehouse or airport warehouse (Pharma)
• (Agrees to fly back the container in case of round trip – or as part of the contract)
• Takes the container from the airline/airport warehouse
• Clear customs
• Takes it to its own warehouse, or directly to the shipper warehouse
• Delivers container to the shipper
• Return container to the station

Quality Agreements, SOPs, partnerships, shared risk & reward
Passive systems

**Skycell’s “770C”**
- 120 hr 2-8°C
- 770 Liters
- Honeycomb structure with nanotechnology
- Reusable, possible rental

**SonocoThermosafe’s “2700 pallet Shipper”**
- 120hr 2-8°C & 15-25°C performance
- PUR

**DS Smith Packaging (Cool Logistics)’s CoolPall**
- 96-120hr 2-8°C & 15-25°C performance
- 1400 to 2900 Liters
- Polystyrene

**Cold Chain Technologies’ “Kooltemp ZX” 2300/4500**
- 120hr 2-8°C & 15-25°C performance
- 45 or 23 Cubic meters
- Extruded Polystyrene

**Topa packaging’s “Climate Box”**
- 80-86 hr 2-8°C & 15-25°C performance
- 210 liters to two pallets
- EPS
- Half PAG pallet built from the inside outwards

**Inmark’s “Flat pack Insulated container”**
- 2-8C; 2/25, 15-25
- One US or EU pallet or half loads
- Polyethurane foam
- Flat pack
Active systems
Example | Transparency for process improvement
Transport Evaluation – Measurable KPIs
Shipper challenged E° recommended load volume with an oversized pallet configuration that exceeds container specifications.
Issue

- Negative impact on container performance – restricts air flow
- Cargo restraint straps cannot be applied due to extended pallet size blocking ‘tie-down’ brackets located on the container floor
Solution

- Proof of Concept
- Secure the pallet from shifting
- Support over-maximized load
Action

• Final product
• “Fixation” bracket
• Durable, lightweight and economical
Example | Market requirement drives service development
Background

Currently have to lease dedicated truck for $17k (SYD-PER) $6k (SYD-MEL).

Limited wide body domestic service

Domestic pharma air cargo service offe
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Summary
Highlights

- Quality Management Systems
- Qualification & Validation
- Planning & Assessments, e.g. partner and technology capabilities
- Quality Agreements
- Measurable KPIs and Process evaluation
- Data collection & reporting
- Core Team
- Regularly scheduled training & education
- Transparency across stakeholders
- Continuous process improvement
Patient focused

Thank you