IATA AirPharma Conference

29 – 31 October 2019, Amsterdam, Netherlands
IATA AirPharma Conference

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Opening Day 3

Andrea Gruber
Head Special Cargo
IATA
IATA Competition Law Compliance

Do not discuss:

- Pricing, including fares, service charges, commissions, etc.
- Bids on contracts or allocation of customers
- Geographic/Product market allocations and marketing plans, including
  - Expanding or withdrawing from markets
  - Group boycotts
  - Your commercial relations with agents, airlines or other third parties

Any discussion aimed at influencing the independent business decisions of your competitors

You will be asked to leave the meeting, and the meeting may be terminated, if the above-mentioned discussions occur.

Remember: All discussions count, even informal ones outside the meeting room!
Thank you to all our sponsors!
Welcome Back Day 3
Chairman Opening Remarks

Maarten van As
Managing Director
Air Cargo Netherlands (ACN)
Keynote Speech
Showcasing how Customs and Industry can work better together

Henriette Bongers
Director
Customs District Schiphol Cargo
Deviation Management challenges and problems within airfreight

Sven Sachsse & Christopher Stein
Transport Experts
Bayer AG
Deviation Management

challenges and problems within airfreight

IATA Air Pharma Conference

2019-10-30 / Sven Sachsse and Christopher Stein / Version 1.0
Why?  
What?  
How?
01 Why?

Air Freight Transport Process – Parties Involved

Pharma-Industry

Airlines
Haulier
Transit Warehouse

Forwarder

Cargo Handling Agent
Tarmac Handling Agent

Producer
Transport Planning
Pre Carriage
Airport-Handling
Main Carriage
Airport-Handling
Post Carriage
Customer
01 Why?

Air Freight Transport Process – Regulatory Requirements

Good Distribution Practices:
WHO TRS 957 Annex 5; EU GDP Guidelines (2013/C 343/01)

/// Scope:
/// All parties involved in the distribution of pharmaceutical products have a responsibility to ensure
/// that the quality of pharmaceutical products and
/// the integrity of the distribution chain is maintained throughout the distribution.
/// (WHO 4.1, EU GDP)

/// Risk Management:
/// Distributors should from time to time conduct risk assessments to assess potential risks to the quality and
/// integrity of pharmaceutical products. (WHO 8.8, EU 1.3)

/// Deviation Management:
/// Deviations from established procedures are documented and investigated. (WHO 13.5-13.7, EU 1.2)
/// Appropriate corrective and preventive actions (commonly known as ‘CAPA’) are taken to correct deviations and
/// prevent them in line with the principles of quality risk management. (EU 1.2)
02 What?
Air Freight Transport Process – Risks / Deviations

Risks

- Damage of goods
- Sabotage / manipulation of goods
- Loss of goods
- Intermixing at the pallet level
- Insufficient quality management or processes

Deviations

- Temperature deviation
- Crushed / destroyed pallets or packaging
- Moldy, moist, smelly pallets or packaging
- Crosslabelling
- Theft
- Counterfeight
02 What?
Air Freight Transport Process – Deviations
02 What?
Air Freight Transport Process – Deviations
02 What?

Air Freight Transport Process – Deviations
02 What?
Air Freight Transport Process – Reasons for Deviations

 Pharma-Industry

 Forwarder

 Airlines
 Haulier
 Transit Warehouse

 Cargo Handling Agent
 Tarmac Handling Agent

 // Nonattention of personnel
 // Missed / delayed flights
 // Strikes
 // Weather impact (e.g. rain, sun)
 // Security / customs check
 // Wrong freight hold temperature
 // Incompliance of services to used mitigations
03 How?
Investigation / CAPA Process Flow

Preventive Action Process
Observation

Corrective Action Process
Deviations / Complaints

Failure Description
Root Cause Analysis
Implementation

Effectiveness Check

Preventive Action

Corrective Action

"action to eliminate the cause of a potential nonconformity or other potential undesirable situation"
(DIN EN ISO 9000, p.57)

"action to eliminate the cause of a nonconformity and to prevent recurrence"
(DIN EN ISO 9000, p.57)

Preventive Action Process

Corrective Action Process

Failure Description
Root Cause Analysis

"action to eliminate a detected nonconformity."
(DIN EN ISO 9000, p.57)
Examples of CAPA reports for temperature deviations:

Standard actions from different airlines (ambiguities are marked in red)

// Preventive Action: Temperature-sensitive goods have to be moved from the temperature-controlled warehouse as late as possible for loading.
// Preventive Action: Immediately after the arrival at the transit or destination airport, the goods have to be taken out of the aircraft and brought to the temperature-controlled warehouse.
// Preventive Action: The people involved in the ramp and ground handling agent are trained again.
// Preventive Action: It is recommended to use an appropriate packaging to endure varying conditions (hot during summer and cold during winter time).
// Preventive Action: We will keep handling times during freight is exposed to ambient temperatures to an absolute minimum.
// Preventive Action: An active packaging solution is usually more sufficient than a passive packaging solution.
03 How?

Challenges and Problems - Perspective of a pharmaceutical producer and wholesaler

- Missing transparency of capabilities
- Missing knowledge pharma wholesaler about the booked service from forwarder by airlines
  - What is in- and outside of the used logistic service?
  - Are there service differences by airport?
- Missing support for investigations by forwarder, airlines and ground handlers
  - lack of awareness regarding distribution of pharmaceutical goods
03 How?

Challenges and Problems - Perspective of a pharmaceutical producer and wholesaler

Not all problems can be solved, but it is our commun responsibility to

// ensure quality of pharmaceutical producs and

// define right mitigation to reduce the accordant risk related to quality and economic aspects.
Deviation Management - challenges and problems within airfreight

Thank you!

Bye-Bye
Networking break 10:30 – 11:00

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Viking
PACKING SPECIALIST

IATA AIRPHARMA CONFERENCE
Amsterdam, Netherlands
29-31 October 2019
The changing DNA of an airline Sales Partner to improve transparency and service all stakeholders in the healthcare & humanitarian relief goods logistics chain

Esther Romar
Business Development Director
Inter Aviation Services
Temperature Excursions: Industry Standard of the Past
A case study

Marrie Groeneveld
CCO
SkyCell AG
SKYCELL

Safest Pharma Containers. Worldwide.
Safest Pharma Containers. Worldwide.

IATA AirPharma Conference 2019

Marrie Groeneveld
Chief Commercial Officer
Temperature Excursions: 
Industry standard of the past

Case Study: 
Hybrid pharma container: 
The new standard
About

SkyCell is the 3rd largest pharma airfreight container provider with the mission to supply the safest pharma containers worldwide. This is achieved through the unique combination of hardware, software and service, enabling our clients to master logistical challenges, eliminate temperature excursions and most of all let more patients have access to medicine.

ISO 9001: 2015  GDP certified
The Global Industry Challenge

Between 2 and 8 % of shipments experiencing excursion during transportation in pharma containers
The Global Industry Challenge

December 2018: Market study

- 7 out of 11 largest pharma companies
- Findings: 5 to 6% excursions
- Globally: at least 4% excursions
- Leaning towards PCM solutions
Challenge:

- Eliminate temperature excursions,
- Reduce total cost,
  and
- Reduce CO2 emissions
SkyCell USPs

How does SkyCell create value?

- Hybrid Pharma Containers
- Robust implementation planning
- High quality standards
- Independent run time of 160h
- Enabling door to door delivery
- Near to real time monitoring
- Easy handling
SkyCell approach

- Dedicated SkyCell team
- Involve all the relevant client teams
- Easy handling, limited training need
- Improve processes
- Seamless implementation
- Superior hardware & software
- Show results
SkyCell - Implementation

Implementation

Hardware & Software

Results
**SkyCell Implementation**

**Milestones**

1. **Validation**
   - Business award
   - Solution design:
     - Process flow mapping
   - Responsibilities identification:
     - Who does what and when?

2. **Integration**
   - Loading tests:
     - Maximize the loading capacity
   - Lane SOP:
     - Volume, origine, destination, airline
   - Lane simulation with risk assessment

3. **Go Live / Launch**
   - Test shipment:
     - Analyse result
Process Management
• Detailed SOP
• Trained Service Centers
• Centralized quality release
• Temperature & energy live monitoring – per container
• Quality released only when optimum level of energy is reached
• Fully traceable and auditable

Benefits
• Predictability
• Reliability
• Transparency
• Quality Control
• Risk Mitigation
The Software (Transport Planner – Lane Simulation)

Steps

1. Choose Hardware
2. Define route
3. Define Logistics Milestones
4. Analysis (Energy Level)
5. Send link

Benefits

- Simulates the individual pharma supply chain
- Shows expected performance through real-life data
- Compare routing options
- Make decisions on risk-based approach and define risk mitigation strategy with 3PL
- Safe and share link
Software

SkyCell Transport Planner

Analysis
The Hardware

Hybrid Pharma Containers

2 x EU-Pal
Tareweight: 650 kg

SkyCell 2500C
+2°C to +8°C

SkyCell 2500CRT
+15°C to +25°C

1 x EU/US-Pal
Tareweight: 497 kg

SkyCell 1500C
+2°C to +8°C

SkyCell 1500CRT
+15°C to +25°C
3th largest pharma container fleet with more than 20,000 pallets capacity.

Largest IoT container fleet in the airfreight industry

Swiss Made containers
SkyCell Container

Easy Handling

SkyCell Container

Easy Handling

Load optimization through maximal load capacity

- Ready to use delivery
- Easy to implement
- No training required
- Easy to audit
The Hardware

Temperature barrier

- 5x more energy than traditional methods
  Automatically recharged in cooling chamber (without any manual input)
- All parts are integrated and fixed
  Completely surrounding the inner chamber for a steady temperature
- No dry ice, no plugs, no manual intervention, no cold-shock
The Hardware
Cutting-edge Technology

Temperature barrier
Insulation
Global monitoring

= Failsafe cooling technology
>up to 160h energy storage
The Hardware

Insulation

All Containers are equipped with high performance insulation technology.

More than 50 man-years of research and development.
> Over 100 patents

Nano coating reflects maximum radiation while minimizing heat conduction.
> Recyclable
The Software (Monitoring)

Largest IoT pharma container fleet in airfreight industry. Near real time monitoring with SkyCell Sensors

2 data loggers track the temperature inside and outside the container. As soon as the loggers connect with a gateway, it is possible to read the temperature data in real time.
The Software

All SkyCell containers are tracked on:

- History
- Documentation
- Milestone
- Specifications
- Temperature
SkyCell - Implementation

Implementation

Hardware & Software

Results
Results:

- Elimination of temperature excursions and collateral costs
- Timely implementation globally (ongoing)
- Exceed expected cost saving
- Reduction of internal handling costs
- Processes optimized
- First big packaging change in over 10 years
- QBR: 100% score
- Annual report on CO2 emission reduction
We only have one Earth!
SkyCell Sustainability

Reducing CO\textsubscript{2} emissions up to 50%
SkyCell Sustainability

How do we achieve that?

**Reliability** of choice of packaging against temperature excursion - if you have to ship more product due to temperature loss, then this has the largest impact

**Reusability** of container – produces significantly less CO₂ and waste than one-way solutions (majority are non recyclable and are incinerated or put in a land fill)

**Low volume weight** to ship 1 US / 1 EU PAL
SkyCell Hybrid Pharma Containers

No Temperature excursions
The new industry standard
Q&A
Thank you
Conference Wrap up & Chairman Closing Remarks

Maarten van As
Managing Director
Air Cargo Netherlands (ACN)
Networking Lunch 12:30 – 14:00

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