Welcome

Frederic Leger, Director, APCS Products, IATA
Introduction

Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA
Presenters / Moderators

Ronald SCHAEFER
Assistant Director, Cargo/Ground Handling and CEIV Consulting
SchaefeR@iata.org

Frederic LÉGER
Director, APCS Products
LegerF@iata.org

Andrea GRUBER
Head, Special Cargo
GruberA@iata.org

Ricardo AITKEN
Manager, CEIV Pharma
AitkenR@iata.org

Yaniv SORANY
Manager, Cargo Training
SoranyY@iata.org
Aim of the Workshop

• Provide an update of the CEIV Pharma program
• Provide an overview of some of the adjustments made to the program,
• Provide an overview of the recertification process
• Provide insight on topics addressed by CEIV Pharma: Temperature Mapping
• Hear from the companies that are undergoing CEIV Pharma Certification or have been certified
• Ask companies participating in the CEIV Pharma program about their experience with the process
• Seek your input and constructive feedback
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>Welcome and introduction</td>
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<tr>
<td></td>
<td>Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA</td>
</tr>
<tr>
<td>09:15</td>
<td>Introduction to the Center of Excellence for Independent Validators (CEIV) in Pharmaceutical Logistics</td>
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<tr>
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<td>Ricardo Aitken, Manager, Cargo/Ground Handling and CEIV Consulting, IATA</td>
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<tr>
<td>09:30</td>
<td>CEIV Pharma: Update</td>
</tr>
<tr>
<td></td>
<td>Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA</td>
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<tr>
<td>10:10</td>
<td>CEIV Pharma Perspective – Three years down the road: Results and recertification</td>
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<td>Nathan de Valck, Cargo Manager, Brussels Airport Company</td>
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<tr>
<td>10:30</td>
<td>Network Coffee Break</td>
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<tr>
<td>Time</td>
<td>Agenda Item</td>
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</tbody>
</table>
| 11:15 – 11:40 | CEIV Pharma: Recertification Process  
Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA  
Yaniv Sorany, Manager, Cargo Training, IATA |
| 11:40 – 12:10 | CEIV Pharma Checklist Hot Topic: Introduction to Temperature Mapping  
Geert Verniers, Independent Validator, 4Advice |
| 12:10 – 12:30 | CEIV Pharma Perspective – Challenges in Latin America  
Bruno Guella, Corporate Director of Cargo, TCU |
<p>| 12:30 – 14:00 | Lunch |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter / Organizer</th>
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<tbody>
<tr>
<td>14:00 – 14:10</td>
<td>CEIV Pharma Perspective – How to integrate operations</td>
<td>Gian Carlo Alessi, Head of Cargo, EuroAirport</td>
</tr>
<tr>
<td>14:10 – 14:20</td>
<td>CEIV Pharma Perspective – A Perspective from a US / LATAM Airline</td>
<td>Rodolfo Marre, LATAM Cargo, Manager</td>
</tr>
<tr>
<td>14:20 – 14:30</td>
<td>CEIV Pharma Perspective – Impact on DUS operations</td>
<td>Gerton Hulsmann, Managing Director, Düsseldorf Cargo GmbH</td>
</tr>
<tr>
<td>14:30 – 14:55</td>
<td>Panel and Interactive Discussion</td>
<td></td>
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<tr>
<td>14:55 – 15:00</td>
<td>Question and Answers / Final remarks</td>
<td>Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA</td>
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<tr>
<td>15:00</td>
<td>End of Session</td>
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</table>
Introduction to the Center of Excellence for Independent Validators (CEIV) in Pharmaceutical Logistics

Ricardo Aitken, Manager, Cargo/Ground Handling and CEIV Pharma, IATA
Background: The impact of mode shift on pharmaceutical logistics

The pharmaceutical industry has relied heavily on the airline industry for its speed and efficiency but air cargo’s share of global pharmaceutical products transport has dropped.

Over the past 10 years, air carriers, handlers and freight forwarders have responded with branded products and services to grab a share of this lucrative and niche market.

Source: Pharmaceutical Commerce
Background: Critical Issues Raised by the Shippers

The use of air-mode transportation is re-considered unless industry partners ensure quality services

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>25%</td>
<td>Of vaccines reach their destination degraded because of incorrect shipping</td>
</tr>
<tr>
<td>30%</td>
<td>Of scrapped pharmaceuticals can be attributed to logistics issues alone</td>
</tr>
<tr>
<td>20%</td>
<td>Of temperature-sensitive products are damaged during transport due to a broken cold chain</td>
</tr>
</tbody>
</table>

- Due to a lack of compliance, standardization, accountability and transparency across the air transport supply chain a majority of all temperature excursions occur while the package is in the hands of airlines/airports
- Temperature deviation denature the product, render it worthless and be harmful to the health of the patient
- Products can be lost, scrapped, returned leading to significant costs
Background: Critical Issues Raised by the Shippers

Looses associated with temperature excursions in healthcare are around a staggering ~USD 35B

Losses associated with temperature excursions

In USD Billion

<table>
<thead>
<tr>
<th>Category</th>
<th>USD Billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wasted Logistic Costs</td>
<td>15.20</td>
</tr>
<tr>
<td>Clinical Trial Costs</td>
<td>5.65</td>
</tr>
<tr>
<td>Direct Labor Costs</td>
<td>2.34</td>
</tr>
<tr>
<td>Replacement Costs</td>
<td>2.34</td>
</tr>
<tr>
<td>Root Cause Analysis</td>
<td>1.3</td>
</tr>
<tr>
<td>Opportunity Labor Costs</td>
<td></td>
</tr>
<tr>
<td>Trial Production Costs</td>
<td></td>
</tr>
</tbody>
</table>

Total: USD 34.1B

The average costs of root cause analysis for each excursion can range from $3K to up to $10K (avg. USD 6.5K per year)

Source: World Health Organization, Parenteral Drug Association, worldpharmaceuticals.net, cargosense.com, other industrial analysis
Background: Critical Issues Raised by the Shippers

Looses associated with temperature excursions in healthcare are around a staggering ~USD 35B

- Maintain the original quality of pharma products
- Meeting the growing number of national & international regulations
  - Common audit format to minimize the disruptions and increase effectiveness
- Temperature excursions happen while in the hands of supply chain partners
- Properly trained stakeholders on regulations and standards
- Adequately equipped facilities throughout the supply chain
- Adequately equipped facilities throughout the supply chain
- Easily search and identify stakeholders that meet requirements

Use of the air-mode is re-considered unless industry partners ensure quality services
Industry’s Call for Action

"Air freight’s share of global pharmaceutical transport has dropped from 17% in 2000 to just 11% today…"

“We need you, IATA, to spearhead the air cargo GDP standard development. It can only be you, and we are waiting for a long time already – way too long, and I don’t know why it is not happening. My question to IATA and the carriers behind IATA is – are you really willing?”

“Unreliable air cargo industry loses pharma traffic to sea, while ‘IATA sleeps’ (Sep. 2013)

“The air cargo industry and IATA need to act urgently to prevent further modal shift of pharmaceutical traffic to sea freight, on the basis of quality rather than price, according to forwarders and shippers.”

“You have various standards and systems out there and it is a nightmare for those that are inside the sandwich, the ground handler, who is forced to enforce various systems and procedures – and it is chaos… IATA is sleeping”
CEIV Pharma
To ensure the integrity of the product throughout the supply chain

OBJECTIVES

Prevent sanitary issues caused by temperature excursions during transportation.

Improve handling of pharmaceutical products and compliance with existing regulations + standards.

Ensure product integrity

Elevate level staff competency through efficient and robust training program.

Create a global and consistent certification that industry can rely on.
CEIV Pharma Targets

Who does CEIV Pharma target? The supply chain
CEIV Pharma Standard
CEIV Pharma standard focuses on global coverage and universality

CEIV Pharma:
- encompasses various regulations and standards e.g. EU GDP.
- covers GDP requirements.
- aims at covering international standards and country-specific requirements.
- aims at reducing the number of audits or simplifying them.
- aims to align air cargo stakeholders needs.
CEIV Pharma Certification Approach and Methodology

IATA will certify companies in several steps:

1. **Preparation**
   - Assemble team
   - Prepare project logistics
   - Send data and information request
   - Send interview request sheet for first visit
   - ~ 4 weeks before assessment

2. **Training required for certification**

3. **Assessment**
   - On-site assessment by Independent validator
   - Assessment versus minimum IATA Temperature Controlled Audit Checklist
   - Comparison against best practice
   - Establish findings and offer recommendations for change
   - Develop implementation plan and secure resources
   - Draft gap analysis report

4. **Validation**
   - On-site visit by an Independent Validator to ensure full compliance with the IATA CEIV Pharma checklist and also review the progress made against recommendations during the assessment phase
   - Drafting of report
   - ~ 6-8 weeks after the assessment

5. **Certification**

**Additional Training**
CEIV Pharma: Status Update

Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA
CEIV Pharma Development
From Pilot to Launch

- Discussion with SATS about a Pilot
- SATS Pilot
- Joint development of Community Concept with BRU
- Development of CEIV Pharma Standard 1.0
- Official launch of CEIV Pharma program
- Development of CEIV Pharma Standard 1.0
- Launch of Community Concept at BRU
- Development of CEIV Pharma Standard 1.1 and 1.2 + Guidelines
- Recertification of CEIV Pharma program
- Development of CEIV Pharma Standard 1.3 + updated Guidelines

Unreliable cargo industry losing pharma industry: IATA sleeping

All companies of the first community will undergo recertification
CEIV Pharma
Certified Pharmaceutical Trade Lanes Development

Locations

- 209 Certification Completed
- +75 Certification in Progress (estimate)
- +99 Certification under discussion *
  * Estimate

12th World Cargo Symposium
13 - 15 March
Dallas, Texas
CEIV Pharma (Community Approach)
Community Approach Development Worldwide

Location
14 Ongoing Communities
8 Communities in Discussion
CEIV Pharma: Update on Administration

Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA
Update on Administration

Topics

Project Assessments

Rules for obtaining / maintaining CEIV Pharma Certificate

ISO

Capability Database
Update on Administration

Topics

Project Assessments

Rules for obtaining / maintaining CEIV Pharma Certificate

ISO

Capability Database
CEIV Pharma – Project Assessment
Evaluation Parameters

- Specialized know-how
- Teamwork / social skills
- Problem Solving
- Organization
- Communication
- Acceptance
Update on Administration

Topics

Project Assessments

Rules for obtaining / maintaining CEIV Pharma Certificate

ISO

Capability Database
CEIV Pharma – Project Assessment
Rules for obtaining / maintaining CEIV Pharma Certificate

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action taken by IATA</th>
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<tbody>
<tr>
<td>Companies need to conduct the assessment no later than 6 months after attending the last of the two mandatory training sessions.</td>
<td>Standard pricing will apply and any discount benefits will be declared void.</td>
</tr>
<tr>
<td>Timeframe between assessment and validation shall not exceed 12 months.</td>
<td>If total timeline between last training and final validation is more than 12 months, Key Personnel need to take the CEIV Pharma Refresher Training before obtaining the CEIV Pharma Certification for its respective stations / company.</td>
</tr>
</tbody>
</table>
## Rules for obtaining / maintaining CEIV Pharma Certificate

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>In order to determine whether a client and/or station that has received</td>
<td>If the client does not supply IATA satisfactory information within thirty (30) days</td>
</tr>
<tr>
<td>the CEIV Pharma Certificate still meets the criteria, IATA reserves the</td>
<td>of IATA notifying the client, then IATA will withdraw its CEIV Pharma certificate</td>
</tr>
<tr>
<td>right to require at any time, submission by the client of all required</td>
<td>with immediate effect.</td>
</tr>
<tr>
<td>current documentation and information relating to the certification for</td>
<td></td>
</tr>
<tr>
<td>IATA’s review and approval.</td>
<td></td>
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</table>
In the event that IATA determines that the client does not meet the CEIV Pharma qualification criteria anymore it will provide the client in writing an explanation as to why the client does not so qualify and what actions will need to be taken.

### Situation

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>If no corrective action plan is submitted IATA within 14 business days of notice:</strong></td>
</tr>
<tr>
<td>1. The client/station temporarily loses all rights, powers and privileges to be associated with the CEIV Pharma program in any form or variant.</td>
</tr>
<tr>
<td>2. The client/station in question will be temporarily unable to use CEIV Pharma Seal in any type of media format (written, video, etc.) and display CEIV Pharma Certificate in its premises.</td>
</tr>
<tr>
<td>3. Station status in CEIV Database shall be changed to “On Hold”</td>
</tr>
<tr>
<td>4. If no corrective action within 30 business days of notice, the entity in question will be considered “Non-Compliant” and CEIV Pharma Certification status of client and/or stations will be changed to “Suspended”.</td>
</tr>
</tbody>
</table>
## CEIV Pharma – Project Assessment
### Rules for obtaining / maintaining CEIV Pharma Certificate (Recertification)

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action taken by IATA</th>
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<tbody>
<tr>
<td>If an entity fails the recertification and does not meet the CEIV Pharma program standards and requirements, they have until the original certificate’s expiration date to close the NCs and comply with the standards and requirements.</td>
<td>Failure to close Non-Conformities and compliance will result in removal from the Registry as well as their certificate being revoked. Certificate will be reinstated once all Non-Conformities have been closed.</td>
</tr>
<tr>
<td>Client agrees that the timeframe between re-assessment and a potential re-validation shall not exceed 12 months.</td>
<td>If total timeline between re-assessment and final re-validation is more than 12 months, Client needs to undergo the full CEIV Pharma Certification process again.</td>
</tr>
</tbody>
</table>
Update on Administration

Topics

Project Assessments

Rules for obtaining / maintaining CEIV Pharma Certificate

ISO

Capability Database
CEIV Pharma – ISO Certification

- Introduction to ISO9001:2015
- ISO9001:2015 Standards walk-through
- Initial Discussion with the training team in GVA.
- Detection of the main strength and weaknesses of the program
- Perform the gap analysis for the activities based in GVA
- Create a Quality Management Manual
- Work on Documentation Management
- Address all gaps identified in both GVA and MIA
- Perform the Risk Assessment for the processes and activities
- Run Mock Audits
- Address any new gaps found
- ISO9001:2015 Certification Audit

December 17  January  February  March  April  May & June  July, August, & September  October  November  December  Q1 19

- Initial Call with the auditor
- Request of quotations
- Perform the initial Assessment for the activities based in GVA
- Create a Platform to log findings
- Perform the initial Assessment and the Gap Analysis for the activities based in MIA
- Start Addressing the findings from GVA gap Analysis
- Prepare Audit schedule and create Audit plan
- Prepare pre-audits checklist and start audit preparations sessions with auditees.
- Certification Pre-Audit with Auditor
- Address the pre-audits findings and recommendations

Delivered by the central quality team in GVA
Update on Administration

Topics

Project Assessments

Rules for obtaining / maintaining CEIV Pharma Certificate

ISO

Capability Database
The CEIV Pharma Capability Database is designed to address the growing industry interest in understanding (and verifying) stakeholder capabilities. The CEIV PCD can serve as a solid basis for conducting risk assessments of air freight trade lanes.

OBJECTIVES

- Provide transparency to the pharma industry
- Provide credibility to stakeholder capability claims
- Prevent modal shift of pharma products

PROCESS

1. Prior to program certification: CEIV PCD distributed via online survey mechanism
2. Completion indicates company agreement for information to be publicly published
3. During validation phase, IV verifies information supplied by candidate
4. Validated data published online on IATA website
CEIV Pharma Capability Database (CEIV PCD) | Process

The Capability Database builds upon the CEIV Pharma Checklist and covers practical information knowledge

SAMPLE AREAS COVERED

- Existing certification (i.e. ISO, ISAGO, GDP, CEIV, etc)
- Standard pharma temperature range capabilities (e.g. FRO, COL, CRT, ERT) throughout different warehouse areas of operations and storage (e.g. Acceptance, BU/BD, Dedicated Cold Stores, etc.)
- Dedicated areas (i.e. physical segregation capabilities) for DG, PIL, PER, AVI, VAL, etc.)
- Avg. tarmac times
- Quantity and type of dedicated vehicles
- ...and much more!
The CEIV Pharma Capability Database is currently in the testing phase. Planned rollout is MAY 2018.

Development of CEIV Pharma Capability Database 1.0
Presentation to TTTF
Official launch of CEIV Pharma Capability Database
Online Debut
CEIV Pharma Perspective: Three years down the road: Results and recertification

Nathan de Valck, Cargo Manager, BRUCargo
Building a Pharma Cargo Community

Three years down the road:
Results and recertification
Are we ready as an industry?
THE CHALLENGE IN AIR CARGO: TEMPERATURE RISKS

ARE WE READY?

ORIGIN
- MANUFACTURER
- TRUCKER
- FREIGHT FORWARDER
- AIRLINE CARGO HANDLER
- AIRLINE

TRANSFER
- AIRLINE
- AIRLINE CARGO HANDLER
- AIRLINE

DESTINATION
- AIRLINE
- AIRLINE CARGO HANDLER
- REGULATORY AUTHORITY
- TRUCKER
- FREIGHT FORWARDER
- TRUCKER
- CONSIGNEE
ARE WE READY?

YES, WHEN IT COMES TO MARKETING...
ARE WE READY?

... NOT ALWAYS WHEN IT COMES TO EXECUTION.
ARE WE READY?

PHARMA MINDSET IS NEEDED!!

AIR CARGO LOGISTICS  PHARMA SHIPPER
ARE WE READY?

DO WE GO FOR THIS??

\[
\text{MARKET SHARE} + \text{TOTAL MARKET} = \text{NET RESULT}
\]
ARE WE READY?

OR THIS ??

MARKET SHARE + TOTAL MARKET = NET RESULT
How did we start?
COMMUNITY

INSTEAD OF ONLY FOCUSING ON THIS...
COMMUNITY

FOCUS ON: -THE ENTIRE COOL CHAIN -THE COMMUNITY

MANUFACTURERS & SHIPPERS

TRUCKER -> FORWARDER -> TRUCKER -> HANDLING AGENT -> AIRLINE

DISTRIBUTORS & CONSIGNEES

AIRLINE -> HANDLING AGENT -> FORWARDER -> TRUCKER
COMMUNITY

NEED FOR A CONSISTENT SERVICE:

- PHARMA MINDSET
- HIGHER QUALITY
- CONSISTENCY
- TRANSPARENCY

ONE STANDARD FOR ALL

- MADE FOR INDUSTRY
- SUPPORTED BY SHIPPERS
CEIV PHARMA CERTIFICATION
Is GDP the answer to our needs?
IS GDP THE ANSWER TO OUR NEEDS?

YES:
→ BASIS AND FOUNDATION FOR ANY PHARMA PROGRAM

NO:
→ STORAGE, NOT TRANSPORTATION
→ NOT CONSISTENT
→ NOT TRANSPARENT
→ NOT SUPPORTED BY SHIPPERS FOR OUR INDUSTRY
→ GDP IS NOT ALIGNING STAKEHOLDERS IN THE CHAIN
Is IATA CEIV the answer to our needs?
IS IATA CEIV THE ANSWER TO OUR NEEDS?

YES:

→ CEIV = GDP++
→ DEVELOPED TOGETHER WITH THE PHARMA SHIPPERS
→ FOCUS ON INFRASTRUCTURE, PROCEDURES AND TRAINING
→ TAILOR MADE FOR THE AIR CARGO INDUSTRY:
   FORWARDERS, TRUCKERS, HANDLERS, AIRLINES
→ ALIGNS PLAYERS IN THE LOGISTICAL CHAIN
→ TRANSPARENT FOR ALL – ONE STANDARD
→ CONSISTENT GLOBALLY
Creating a cargo community

-Lessons learned at BRU-
Building infrastructure for an unbroken cool chain
DEDICATED PHARMA TEMPERATURE CONTROLLED INFRASTRUCTURE

Temp Controlled Infrastructure

Type:
- CRT 15-25°C
- COL 2-8°C
- FRO -20°C

Location:
- First line
- Second line
Aligning and standardizing the cool chain
BRUCARGO PHARMA COMMUNITY CERTIFICATION

**Truckers**
- Jan de Rijk
- FB Logistics
- NinaTrans
- Van Dievel Transport

**Forwarders**
- B.P.L.
- Expeditors
- DSV
- CECODIS Wilson
- Hazgo
- DHL
- Kuehne + Nagel
- Panalpina
- Bollore Logistics

**Handlers**
- Aviapartner
- Swissport Cargo Services
- WFS

**Airlines**
- Brussels Airlines
- Singapore Airlines Cargo
- United Airlines
- Cathay Pacific
- Finnair Cargo
- Meridian International, Inc.
BRUCARGO PHARMA COMMUNITY CERTIFICATION

BENEFITS OF A COMMUNITY APPROACH:

- LOWER COST
- FOCUS ON THE CHAIN AND THE TOTAL COMMUNITY
- BIGGER VISIBILITY TOWARDS OUTSIDE MARKET
- CRITICAL MASS FOR KICK-OFF
- NETWORKING OPPORTUNITY AND EFFECTS
- LEARNING FROM EACH OTHER
BRUCARGO PHARMA COMMUNITY CERTIFICATION

OUTCOME OF THE PROGRAM:

- CLOSED COOL CHAIN
- LOWER RISK PROFILE
- COMMUNITY DYNAMIC
- FOLLOW UP IMPROVEMENT PROJECTS
- PREFERRED EUROPEAN PHARMA GATEWAY
- GROWTH OF PHARMA VOLUMES
## Outcome of the Program:

### Evolution of Bru Pharma Volumes

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Export</th>
<th>Export Flown</th>
<th>Export RFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 vs 2015</td>
<td>119%</td>
<td>138%</td>
<td>107%</td>
</tr>
<tr>
<td>2017 vs 2016</td>
<td>115%</td>
<td>124%</td>
<td>122%</td>
</tr>
</tbody>
</table>

Source: BRU data analysis

### Improved Quality Performance

| Pharma Acceptance Non-Conformities | - 45% |

Source: BRU Pharma Quality Dashboard

### Investments in Pharma Infrastructure

| First & Second Line | + 68% |

Source: handler & forwarder dedicated m² pharma warehouses
BRUCARGO PHARMA COMMUNITY CERTIFICATION

PARTICIPANTS FEEDBACK:

- ALL PARTICIPANTS:
  - ARE POSITIVE ABOUT THE ADDED VALUE OF THE PROGRAM
  - WOULD PARTICIPATE AGAIN
  - RECOMMEND CEIV PHARMA

- “THE PROGRAM IS INDUSTRY SPECIFIC”

- “CEIV IS A GOOD SALES TOOL TO PROMOTE OUR BUSINESS TO CLIENTS”

- “THE COMMUNITY APPROACH BRINGS MANY BENEFITS”

- “THE PROGRAM FOCUSES ON PROCESS AS WELL AS ON OPERATION”

PHARMA SHIPPERS’ FEEDBACK:

- “REDUCED TEMPERATURE RISK PROFILE FOR THE COOL CHAIN THROUGH THE AIRPORT, RESULTING IN SIMPLIFIED AUDITS”
Recertification
CERTIFICATION METHODOLOGY

1. Training: IATA Pharmaceutical Handling Diploma
2. Preparation
3. Assessment
4. Validation

+ 3 years

Certification
Re-Certification
PROJECT MANAGEMENT

COMMUNITY PARTICIPATION:
- All companies up for recertification are participating
- Living the standard → Smooth audit

COORDINATION:
- Clear governance structure
- Strong project management
Is the CEIV Pharma Certification enough?
“a good start”

Foundation for continuous improvement:
1. Listen to the end customer
2. Increase transparency
3. Eliminate risk
WHAT'S NEXT: IMPROVEMENT PROJECTS
Eliminating temperature risk
Eliminating temperature risk

Temperature
• Guaranteed range 5°C – 25°C
• Continuous pre-conditioning

Autonomy
• 36h during summer
• 24h during winter
• Solar Pannels
Eliminating temperature risk

- Low total operating cost
  - Easy, reliable and effective
  - Combination pharma - general cargo
  - Pooled equipment

Lower deck contour
- Aircraft containers
- Aircraft pallets
- Loose cargo
IMPROVEMENT PROJECTS

Data sharing & Transparency
TRANSPARENCY

PHARMA QUALITY DASHBOARD

* sample, based on demo-data
DATA SHARING

Existing Applications
- Pharma Dashboard
- Equipment Booking App
- Statistics App

In development
- Slot Booking App
- External Apps / New Apps

Existing Applications
- Pharma dolly
- BRU RFID
- Weather data
- GPRS tracking data

Single-truth data
One-to-many communication

Single-truth data
One-to-many communication
IMPROVEMENT PROJECTS

End-to-end collaboration
Our vision
Achieve excellence in reliable end-to-end air transportation for pharma shippers.

Our mission
Foster collaboration between Pharma Shippers and CEIV certified airport communities dedicated in developing and leading when it comes to handling pharmaceuticals.
Mr. Glyn Hughes, Global Head of Cargo, IATA:

“IATA congratulates the Pharma.Aero collaborative initiative that unites around the central theme of linking CEIV certified entities and trade lanes to improve industry logistical networks to achieve supply chain excellence.

Such joint program enhances the Air Cargo industry’s value proposition and adoption of global standards in transporting time and temperature sensitive pharmaceuticals.

Ensuring patient safety throughout the logistical journey is a collective responsibility and this is a great demonstration of that ideal.”
Project groups

Shippers Advisory Group & CEIV validation project group

✓ Project Scope
1. The project group will work with the pharmaceutical shippers to validate and endorse the existing IATA CEIV Pharma checklist and audit methodology.
2. CEIV version 2.0: resulting in a shipper endorsed audit format, reducing audit workload and streamlining the audit process by the shippers.

✓ Project Lead: Brussels Airport

✓ Project participants

<table>
<thead>
<tr>
<th>Company</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brussels Airport</td>
<td>Nathan De Valck</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Alexandra Kaempf</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Gino Vleugels</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Pieter Doms</td>
</tr>
<tr>
<td>MSD</td>
<td>Ruud Vander Geer</td>
</tr>
<tr>
<td>MSD</td>
<td>Debby Mattys</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Eddy Weygaerts</td>
</tr>
</tbody>
</table>
Project groups

Airside Pharma Transport benchmark

✓ Project Scope

1. The project group will come up with a framework for airports and their stakeholders to consider when reviewing/investing in airside transport solutions.
2. It will also review all options and solutions that exist to avoid the exposure of pharmaceutical shipments to extreme temperatures.

✓ Project Lead: Miami Airport, Mumbai Airport

✓ Project participants

<table>
<thead>
<tr>
<th>Company</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miami International Airport</td>
<td>Jimmy Nares</td>
</tr>
<tr>
<td>Mumbai International Airport</td>
<td>Manoj Singh</td>
</tr>
<tr>
<td>Brinks</td>
<td>Leandro Moreira</td>
</tr>
<tr>
<td>Brussels Airport</td>
<td>Nathan De Valck</td>
</tr>
<tr>
<td>Changi Airport Group</td>
<td>Jaisey Yip</td>
</tr>
<tr>
<td>Changi Airport Group</td>
<td>Lim Shyan Jun</td>
</tr>
<tr>
<td>Envirotainer</td>
<td>Stephen Maietta</td>
</tr>
<tr>
<td>Expeditors</td>
<td>Peter Van Domburg</td>
</tr>
<tr>
<td>Expeditors</td>
<td>Timothy cop</td>
</tr>
<tr>
<td>MSD</td>
<td>Ruud Vander Geer</td>
</tr>
<tr>
<td>MSD</td>
<td>Debby Mattys</td>
</tr>
<tr>
<td>Mumbai International Airport</td>
<td>Ritesh Mohanty</td>
</tr>
<tr>
<td>Mumbai International Airport</td>
<td>Nandan Kanchan</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Eddy Weygaerts</td>
</tr>
<tr>
<td>Sharjah Airport</td>
<td>Jeremy Mitchell</td>
</tr>
</tbody>
</table>
Project Scope

1. The goal of the project is to establish pharma trade lanes involving “CEIV pharma certified” operators.

2. The project group will also identify common KPIs during the process when the pharmaceutical shipment is being transported from airport to airport and explore technologies to house the KPIs in the form of dashboards.

Project Lead: Pfizer, Changi Airport

Project participants

<table>
<thead>
<tr>
<th>Company</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
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</tr>
<tr>
<td>Brussels Airlines</td>
<td>Reinout Puissant</td>
</tr>
<tr>
<td>Brussels Airport</td>
<td>Nathan De Valck</td>
</tr>
<tr>
<td>DHL Global Forwarding</td>
<td>Dina Bunn</td>
</tr>
<tr>
<td>Envirotainer</td>
<td>Stephen Maletta</td>
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<td>Timothy Cop</td>
</tr>
<tr>
<td>EuroAirport Basel</td>
<td>Gian Carlo Alessi</td>
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</tr>
<tr>
<td>MVD Free Airport</td>
<td>Bruno Guella</td>
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<td>MVD Free Airport</td>
<td>Hans Guiscardo</td>
</tr>
<tr>
<td>Singapore Airlines</td>
<td>Adrian Goh</td>
</tr>
</tbody>
</table>
CEIV Pharma: Recertification Process + Training

Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA
Yaniv Sorany, Manager, Cargo Training, IATA
## QUESTIONS & ANSWERS

### A. General Questions

<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.1</td>
<td>Certification</td>
<td>How long before the CEIV certificate expires should entities begin the recertification process?</td>
<td>In order to ensure continuity, it is recommended the recertification process begin at least 6 months before the expiration of the CEIV certificate. Entities interested in recertification should reach out to the CEIV Pharma team for the latest version of the CEIV Pharma checklist in order to begin the process.</td>
</tr>
<tr>
<td>A.2</td>
<td>Validation</td>
<td>How many days of audit are needed for recertification?</td>
<td>Two (2) days onsite are needed given a full audit takes place during recertification.</td>
</tr>
<tr>
<td>A.3</td>
<td>Validation</td>
<td>Is the checklist used during recertification the same one used during the original assessment?</td>
<td>No. The latest version of the CEIV Pharma checklist will be used.</td>
</tr>
</tbody>
</table>
### QUESTIONS & ANSWERS

#### A. General Questions

<table>
<thead>
<tr>
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<th>Category</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.4</td>
<td>Validation</td>
<td>What happens if major or minor non-conformances (NCs) are identified during recertification?</td>
<td>If minor and major revisions are needed, the entity will have to take the appropriate corrective actions to close the gaps and resubmit the materials and evidence with changes made within one (1) month before the certificate’s expiration date.</td>
</tr>
<tr>
<td>A.5</td>
<td>Validation</td>
<td>If entity fails recertification, how much time do they have to close the NCs?</td>
<td>If an entity fails the recertification audit, they have until the CEIV Pharma certificate’s expiration date to comply.</td>
</tr>
<tr>
<td>A.6</td>
<td>Validation</td>
<td>If entity fails recertification, will their CEIV Pharma certificate be suspended?</td>
<td>The CEIV Pharma certificate will be suspended only if the entity in question does not close the identified NCs before the expiration of the original CEIV certificate.</td>
</tr>
</tbody>
</table>
**QUESTIONS & ANSWERS**

### A. General Questions

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<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.7</td>
<td>Validation</td>
<td>Can entities who fail the recertification audit handle pharmaceuticals while closing the identified NCs?</td>
<td>If an entity fails the recertification audit, they have until the original certificate’s expiration date to comply. Failure to close NCs will result in removal from database as well as revoking of certificate.</td>
</tr>
<tr>
<td>A.8</td>
<td>Validation</td>
<td>Will the recertification audit be done by the same independent validator (IV) who conducted the initial certification?</td>
<td>In most of the cases IATA will send another IV.. A different IV will conduct the recertification audit. However, the IV may be the same one who conducted the initial assessment. In some cases IATA will send the same IV.</td>
</tr>
<tr>
<td>A.9</td>
<td>Validation</td>
<td>What if there is a discrepancy between the original certification and the recertification audits?</td>
<td>The recertification audit utilizes an updated CEIV Pharma checklist which supersedes the checklist used during the original certification. Three years is a long time, as such industry best practices and regulations will have changed.</td>
</tr>
</tbody>
</table>
### QUESTIONS & ANSWERS

#### A. General Questions

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</tr>
</thead>
<tbody>
<tr>
<td>A.10</td>
<td>Training</td>
<td>What is the Training Requirement for the certification?</td>
<td>As a reminder, each entity, in each location, needs to have at least: • 2 qualified key personnel who hold IATA Training certificate on the “Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)”; and • 2 qualified competent personal who hold IATA Training certificate on the “Temperature Controlled Cargo Operations Course (3 days)”.</td>
</tr>
</tbody>
</table>
## QUESTIONS & ANSWERS

### A. General Questions

<table>
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<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.11</td>
<td>Training</td>
<td>Will the recertification include refresher training for key personnel?</td>
<td>Yes, the recertification includes refresher training for key personnel. To obtain the recertification, each entity, in each location, needs to train at least 2 of the qualified key personnel on the “CEIV Pharma Refresher Course for Key Personnel (2 days)”. The key personnel must hold the IATA Training certificate on the “Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)” in order to attend the refresher course.</td>
</tr>
<tr>
<td>A.12</td>
<td>Training</td>
<td>What happen if the key personnel left the company or moved to another job?</td>
<td>In this case the entity needs to qualify new key personnel and he/she need to be trained on the “IATA Audit, Quality and Risk Management for Temperature Controlled Cargo Course (5 days)”</td>
</tr>
</tbody>
</table>
### QUESTIONS & ANSWERS

#### A. General Questions

<table>
<thead>
<tr>
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<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.13</td>
<td>Training</td>
<td>Will the recertification include refresher training for competent personnel?</td>
<td>The recertification does not include IATA refresher training for the competent personnel. However, the company must have at least 2 competent personnel who hold IATA Training certificate on “Temperature Controlled Cargo Operations Course (3 days)”. In addition, it is the responsibility of the entity to have internal training program and record of training, to give refresher and continuing training for competent personnel, as well as for all personnel involved within processing of temperature sensitive and healthcare shipments.</td>
</tr>
<tr>
<td>A.14</td>
<td>Training</td>
<td>What happens if the competent personnel left the company or moved to another job?</td>
<td>In this case the entity needs to qualify new competent personnel and he/she needs to be trained on the “IATA Temperature Controlled Cargo Operations course (3 days)”.</td>
</tr>
</tbody>
</table>
### QUESTIONS & ANSWERS

#### A. General Questions

<table>
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<tr>
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<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.15</td>
<td>Training</td>
<td>What happens if the entity does not have internal training program and record of training for all personnel?</td>
<td>It is in the program standards and requirements for a certified entity to have an internal training program with initial, refresher and continuing training program for all personnel involved within processing of temperature sensitive and healthcare shipments. Nonconformity will be classified as “Major” and must be corrected before the certification expiry date.</td>
</tr>
</tbody>
</table>
CEIV Pharma Perspective: Temperature Mapping

*Geert Verniers*, Independent Validator, 4Advice
CEIV Pharma hot topic:

Introduction to Temperature Mapping

By Geert Verniers

Independent Validator IATA CEIV program

Dallas – 12 March 2018
Who are we?

4Advice is a Belgian Consulting company, located in Mechelen.

- Founded in September 2015
- Support on Time & Temperature Sensitive Supply Chain for Pharma products
- Support on GDP requirements
- Own GDP Training Centre
- Independent Validators IATA CEIV

www.4advice.eu
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
Temperature mapping

Is a documented technical study, ensuring that the required temperature remains stable throughout the year for:

- each specific temperature controlled area
- empty, before use (if possible)
- full, during operations
- its specific HeatingVentilationAircoCooling system
- the effect of extreme seasonal weather conditions
- based upon a carried out Risk Assessment & mapping protocol
Temperature mapping

Are there any official guidelines in which we can find more technical information?

- WHO Temperature mapping of storage areas, Technical supplement Report Series, Nº 961 2011
  
  Annex 9: Model guidance for the storage and transport of time-and temp sensitive pharmaceutical products

- The EU GDP guidelines 2013, chapter 3.2.1

- IATA Temperature Control Regulations, 6th Edition
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
Facts and figures

CEIV stakeholders who have findings on their temperature mappings during their CEIV audits

Source: CEIV audits performed by 4Advice
IATA CEIV Audits performed by 4Advice
Facts and Figures

What are the main reasons?

Source: CEIV audits performed by 4Advice
Facts and Figures

Why are the mappings not performed yet?

Source: CEIV audits performed by 4Advice
Facts and Figures

What makes the carried out mappings incomplete?

Source: CEIV audits performed by 4Advice
Facts and Figures

What needs to be temperature mapped?

- Temperature controlled trucks
- Temperature controlled warehouses
- Cool Units
- Cool Rooms
- Freighters?
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
Temperature mapping

Based upon a carried out Risk Assessment and mapping Protocol the mapping exercise must be carried out.

CEIV Requirements:

- Mapping results must be documented
- Conclusions if the area is fit for healthcare products
- Recommendations for use of each area
- Mapping exercise in empty/full premises
- Monitoring system reviewed based on the mapping results
- Power failure simulation
- Contingency plan (!)
# The IATA CEIV checklist

## 6. Infrastructure and equipment

### 6.3 Mapping

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3.1</td>
<td>Is a temperature mapping used?</td>
</tr>
<tr>
<td>6.3.2</td>
<td>Is the mapping exercise based on a risk assessment?</td>
</tr>
<tr>
<td>6.3.3</td>
<td>How are changes in the warehouse infrastructure dealt with?</td>
</tr>
<tr>
<td>6.3.4</td>
<td>Is the mapping done in the extreme seasons (e.g., summer and winter)?</td>
</tr>
<tr>
<td>6.3.5</td>
<td>Is the mapping done when the storage facility is both empty and full; and when in operations and inactive? Has a power failure test been carried out?</td>
</tr>
<tr>
<td>6.3.6</td>
<td>Are the temperature mapping results documented?</td>
</tr>
<tr>
<td>6.3.7</td>
<td>Is the temperature mapping report used to provide recommendations in the operations?</td>
</tr>
</tbody>
</table>

### 6.4 Monitoring

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4.1</td>
<td>Is it ensured that the storage temperature is always kept within a defined range and controlled according to instructions?</td>
</tr>
<tr>
<td>6.4.2</td>
<td>Is there a monitoring system in place based on the results of the mapping exercise?</td>
</tr>
</tbody>
</table>

Source: IATA CEIV Checklist v1.3
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
OUR ADVICE IS YOUR SUPPORT
Temperature mapping: How to proceed!

1. Risk analysis & the purpose and scope
2. Definitions and abbreviations
3. Winter Mapping Period
4. Equipment and certification
5. Location of the data loggers
6. Positioning of the Data loggers
7. Proposed Scenario test
8. Removing of the Data loggers
10. Sources
11. Attachment

OUR ADVICE IS YOUR SUPPORT
Temperature mapping: How to proceed!

Based upon a carried out Risk Assessment and mapping Protocol the mapping exercise should be carried out.

Key & Risk Factors:

- The size of the temperature controlled area.
- The location(s) of the HVAC system
- Position of the doors
- Use of storage racks & levels
- Position & numbers of the sensors
- External factors
- The operational simulation
- The required temperature range
Temperature mapping: Risk based Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Scenario</th>
<th>Date</th>
<th>Time</th>
<th>Zone A</th>
<th>Zone B</th>
<th>Temperature inside Zone A</th>
<th>Temperature inside Zone B</th>
<th>Start Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preconditioning 2</td>
<td>15/Feb/18</td>
<td>08:00</td>
<td>5°C</td>
<td>20°C</td>
<td>5°C</td>
<td>9°C</td>
<td>2018-02-15 08:00</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Door open 5min</td>
<td>09:00 / 09-05</td>
<td>09:00</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 09:00</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Door open 30min</td>
<td>10:30 / 10-30</td>
<td>10:30</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 10:30</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>No activity</td>
<td>12:00 / 12-00</td>
<td>12:00</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 12:00</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Unloading pallets</td>
<td>12:45 / 12-45</td>
<td>12:45</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 12:45</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Door open 30min</td>
<td>13:30 / 13-30</td>
<td>13:30</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 13:30</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Preconditioning 2</td>
<td>14:15 / 14-15</td>
<td>14:15</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 14:15</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Power failure</td>
<td>15:00 / 15-00</td>
<td>15:00</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 15:00</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Preconditioning 3</td>
<td>15:45 / 15-45</td>
<td>15:45</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 15:45</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Door open 60min</td>
<td>16:30 / 16-30</td>
<td>16:30</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 16:30</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Preconditioning 4</td>
<td>17:15 / 17-15</td>
<td>17:15</td>
<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 17:15</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>No activity</td>
<td>18:00 / 18-00</td>
<td>18:00</td>
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<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 18:00</td>
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<td>14</td>
<td>Stop Scenario 1</td>
<td>18:15 / 18-15</td>
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<td>5°C</td>
<td>20°C</td>
<td>9°C</td>
<td>9°C</td>
<td>2018-02-15 18:15</td>
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</tbody>
</table>

Power Failure Operations (Simulations)

Preconditioning & Setpoint

Total Graphic Temp mapping

Open doors

Study Winter Mapping Report Bi-Temp Trailer: Van Dievel

1. Risk Assessment
2. Mapping Protocol
3. Data loggers
4. Risk based studies
5. Measuring data
6. Analysis
7. Final reporting report
Temperature mapping: Power Failure!

### Study Winter Mapping Report Bi-Temp Trailer: Van Dievel

<table>
<thead>
<tr>
<th>Study</th>
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<th>Date</th>
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<tr>
<td>1</td>
<td>Preconditioning 2</td>
<td>15/02/18</td>
<td>08:00</td>
<td>5°C</td>
<td>20°C</td>
<td>4°C</td>
<td>6°C</td>
<td>15/02/18</td>
<td>10:00</td>
</tr>
<tr>
<td>2</td>
<td>Door open 5 min</td>
<td>09:00</td>
<td>09:00</td>
<td>6°C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Door open 10 min</td>
<td>09:10</td>
<td>09:20</td>
<td></td>
<td>6°C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Loading pallets</td>
<td>09:25</td>
<td>09:35</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>No activity</td>
<td>09:35</td>
<td>10:45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Unloading pallets</td>
<td>10:35</td>
<td>10:45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Preconditioning 2</td>
<td>14:45 / 15-15</td>
<td>9°C</td>
<td>20°C</td>
<td>6°C</td>
<td>8°C</td>
<td></td>
<td>15/02/18</td>
<td>16:45</td>
</tr>
<tr>
<td>9</td>
<td>Power failure</td>
<td>14:45 / 15-15</td>
<td>9°C</td>
<td>20°C</td>
<td>6°C</td>
<td>8°C</td>
<td></td>
<td>15/02/18</td>
<td>16:45</td>
</tr>
<tr>
<td>10</td>
<td>Preconditioning 3</td>
<td>16:00</td>
<td>16:00</td>
<td>9°C</td>
<td>20°C</td>
<td>8°C</td>
<td></td>
<td>15/02/18</td>
<td>16:00</td>
</tr>
<tr>
<td>11</td>
<td>Door open 30 min</td>
<td>16:30</td>
<td>17:00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Preconditioning 4</td>
<td>17:00</td>
<td>17:10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>No activity</td>
<td>18:30</td>
<td>18:30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Stop Scenarios</td>
<td>18:30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
Challenges

When can you carry out a temperature mapping:

- Extreme Winter & Summer weather conditions
- Impact on the operations
- Duration
- Outside temperature
Challenges

Who should perform your temperature mapping:

- External partner: Critical Supplier
- External partner: expert?
- Number of sensors – certified calibration (!)
- Price
- Do I perform the mapping myself?
Challenges

Focus on:

- Contingency plan
- Cold & Hot spots
- Stability Data
- Valid until
- What if?

*The red line shows the outside temperature.*
Introduction to Temperature Mapping

Facts and Figures

CEIV requirements

How to proceed

Challenges

Questions
Questions?
CEIV Pharma
Perspective: Market Outlook + Challenges in Latin America

Bruno Guella, Managing Director, MVD Free Airport
Addressing **Pharma supply chain complexities** in emerging markets
Airfreight in Lat Am – Market Outlook

A challenging context, full of growth opportunities

A need for a change in distribution approaches?

Key takeaways
Airfreight in Lat Am shows signs of recovery

Main drivers:
- GDP growth in Brazilian, Argentine and Colombian economies

However:
- Tendency of increasing air freight rates due to extended seasonal lack of capacity

Chart 4 – International FTK growth by airline region of registration

Sources: IATA Economics, IATA Monthly Statistics
Northbound and Southbound trade are driven by substantially different products

- South America subregion represents 72% of Latin America Cargo
- Northbound traffic overcomes Southbound traffic, driven by commodities
- Pharmaceutical cargo is concentrated on Southbound shipments

Source: Boeing World Air Cargo Forecast – 2016-2017
Brazil and Colombia represent 50% of South American total airfreight

- MIA consolidated as US Cargo Gateway to Lat Am
- Andean countries driven by exports of perishables

Source: Airport websites + IADB Report

Source: MIA Airport Brochure
Big regional volumes are based on commodity exports

<table>
<thead>
<tr>
<th>Country</th>
<th>Airport</th>
<th>IMPO (000 tons)</th>
<th>EXPO (000 tons)</th>
<th>% EXP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecuador</td>
<td>UIO</td>
<td>41</td>
<td>220</td>
<td>84%</td>
</tr>
<tr>
<td>Peru</td>
<td>LIM</td>
<td>110</td>
<td>230</td>
<td>68%</td>
</tr>
<tr>
<td>Chile</td>
<td>SCL</td>
<td>120</td>
<td>200</td>
<td>63%</td>
</tr>
<tr>
<td>Colombia</td>
<td>BOG</td>
<td>254</td>
<td>420</td>
<td>62%</td>
</tr>
<tr>
<td>Ecuador</td>
<td>GYE</td>
<td>21</td>
<td>27</td>
<td>56%</td>
</tr>
<tr>
<td>Brazil</td>
<td>GRU</td>
<td>144</td>
<td>144</td>
<td>50%</td>
</tr>
<tr>
<td>Argentina</td>
<td>EZE</td>
<td>111</td>
<td>105</td>
<td>49%</td>
</tr>
<tr>
<td>Uruguay</td>
<td>MVD</td>
<td>16</td>
<td>13</td>
<td>45%</td>
</tr>
<tr>
<td>Brazil</td>
<td>VCP</td>
<td>130</td>
<td>65</td>
<td>33%</td>
</tr>
<tr>
<td>Paraguay</td>
<td>ASU</td>
<td>12</td>
<td>2</td>
<td>14%</td>
</tr>
</tbody>
</table>

- ECU, PER, CHI and COL main airports driven by outbound cargo
- Balance Inbound/Outbound influences Route Develop and rates

Source: Airport websites + IADB Report
From an inbound perspective...
Quick Facts:

- Lat Am growth of middle class: 73 million in last decade
- Global access to healthcare focuses on generics (65% of pharma sales in Lat Am)
- Healthcare spend likely to exceed GDP due to aging population and increased life expectancy + government policies

Pharmaceutical sales: growing at 12% per year (average) vs. 3% in mature markets (NA, EU and Japan)

Biomaterials: Set to grow at a CAGR of 18.3% between now and 2022 to reach US$5.18 billion after having a value of US$1.89 billion in 2016

Generics expected to represent 70% of total pharma sales

Biosimilars appears to be the main opportunity
Lat Am, a challenging context full of growth opportunities

“Latin America today represents 7% of our global business, 15% of our headaches and 30% of our growth opportunities” 

Senior Vice-President Global Supply Chain
Global Pharmaceutical Company
Mercosur Region drives the pharma business in LATAM

- Brazil is the key emerging growth market for multinational pharmaceutical firms, 6th largest global market to date.
Brazil - Key Growth Market in Lat Am

- Demographic Changes:
  - the aged population will overtake the working population by the year 2030.

- Balanced Approach for Local and Foreign Players:
  - Foreign Direct Investment (FDI)
  - Government Support and focus on widespread healthcare
  - Additional Benefits

- The Untapped Market Potential:
  - mid-sized cities (population range of 20,000 to 500,000) - uneven market penetration
  - McKinsey predictions: 52% of the share of growth coming from these cities.

- Steady Expenditure:
  - 4.5% of country GDP going towards public healthcare, expected to increase to 9-10% over the next five years. (See also: Emerging Markets: Analyzing Brazil's GDP)
Lat Am – Considerable room for improvement

Logistics & Infrastructure
- Integration & Communication amongst SCM players
- Port and Airport infrastructure capacity constraints
- Quick fact: BR: 7.9% ratio of cold storage vs population (Million m3 cold storage/population) vs 35% USA
- Inland Transportation: Paved network: Argentina 24%, Brazil 12%, Colombia 13% vs USA 67% - (IDB data set)

Politics & Regulatory
- Political environment volatile – substantial downside risks to economic growth and policy continuity
- Lack of harmonization (GDP requirements) / Individual country regulatory and bureaucracy issues

Security
- Violence, bribery, corruption
- Counterfeiting up to 30% of drugs

Costs & Connectivity issues:
- Country policies sometimes do not contribute to development of air transport
  “Unreasonable tax and charges policies are prevalent in the region and this affects travel and hinders economic development” – IATA’s director general and CEO, Tony Tyler
- Air Cargo rates inbound to Lat Am up to 20 USD/KG in peak season

<table>
<thead>
<tr>
<th></th>
<th>Brazil</th>
<th>Developed countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>% GDP spent on logistics</td>
<td>15-18 %</td>
<td>4%</td>
</tr>
<tr>
<td>% GDP invested in transport infrastructure</td>
<td>1.5 %</td>
<td>3.8 %</td>
</tr>
</tbody>
</table>

Source: logisticsexecutive.com
Lat Am - A need for a service-oriented culture

Adopt global quality standards
CEIV Pharma - airport status

Most of Lat Am Ports and Airports still considered a black hole

Most shippers are not satisfied with current solution providers

Challenges and trends

- 54.5% consider air shipment to be the most suitable for transporting medication
- 70% think freight costs associated with the shipment modality currently used are still very high
- 57.1% are not satisfied with current solution providers
- 40.9% say that qualification and integration with providers are the greatest challenges in logistics & cold chain processes nowadays

For more details and exclusive online content visit: www.coldchainbrazil.com
So then, where does all this leave the shipper?

- Eager to reap the regional opportunities
- Subject to social and geographic long-term context
- Conditioned by seasonality, lack of appropriate infrastructure and lack of integration amongst players
- Facing the challenge of servicing heterogeneous markets with an integral approach
With all this said, is it time to rethink network designs? Example of a possible approach

**Increasing Capabilities:**
- CEIV Pharma Gateways
- Dedicated Pharma Air routes
- Implement Postponement strategies
- Perform Quality Controls
- Consolidate sea/air products and reduce regional stocks in each country
- “Last mile” efficiencies and lead time reductions
- Validated expedited entry solutions
- Local / regional knowledge
- Access to regional “fast tracks”
Pharma Shippers are already innovating in new solutions

Not just “theory”... ...but REAL success stories!

The problem
- Time to market, mostly due to bureaucracy in imports to Brazil
- Need of network optimization and convenient Sea/Air mix to source Southern Cone

The solution:
- Set up of a Regional Distribution Center for air&sea cargo consolidation
- Source major markets (BR, AR, CH) via truck (use of dry borders instead of ports/airports)

The result:
- “…and coming to the winner...the organization we awarded due to their exemplary comprehensive approach combining several elements, like transport lane, temperature control in routes smartly considering local requirements, based out with their impressive proven results, reducing incredibly lead times, the number of temperature deviations close to zero, increased compliance, and decreased tremendously the cost of transportation while increasing their service level close to 100%..."

…and the award goes to…AstraZeneca for their innovative solution URUGUAY HUB for their distribution to South America…”
Key takeaways

- Lat Am’s recent and projected economic growth and healthcare investments provide tremendous opportunities.

- The region faces structural and contextual complexities that are hard to overcome for shippers with global perspective.

- The challenge reinforces the need to be creative in supply chain design and supplier decisions.

- New Glocalization solutions arise: “think globally, act locally” - How can I acquire local and regional know-how via strategic partner sourcing?

- Should we look into customized, market-specific “Last-mile” execution?
CEIV Pharma
Perspective: How to integrate operations

Gian Carlo Alessi, Head of Cargo, EuroAirport
EuroAirport’s IATA CEIV Pharma Community Approach

Gian Carlo Alessi – Head of Cargo

Dallas, 12th March 2018
Agenda

- About EuroAirport
- Community Approach
- Learning points – Take aways
About EuroAirport

- 3 Countries
- 2 Markets
- 1 Airport
About EuroAirport

Our strategy

1. Infrastructure
2. Quality
3. Added Value Services
4. Network / Frequency
5. Cooperation & Collaboration
6. Sustainability

Why IATA CEIV PHARMA?
Community Approach

Certified 2017!

Certified 2017!

Certified 2017!

Audit performed February 2018

Audit performed February 2018

Planned: Summer 2018
Learning points – Take aways

Challenges:

- Synchronization of interests / priorities / processes / etc.
- Timeline / Duration

What did we profit from:

- Better understanding of the various companies and they way to work
- Adapt processes / infrastructure (see example next page)
A new «Interface» between the warehouse and the aircraft parking position, allows to keep the cargo inside and temperature controlled!

➔ no waiting time anymore on the Tarmac

Learning points – Take aways
Learning points – Take aways

On what to focus next:

- Joint events & communications
  - Spread news within whole Cargo community & shippers

- Exchange workshop
  - Integrate other CEIV Pharma certified companies who went through different processes (example DHL Global Forwarding)
  - Continuous improvement & learning
Thank you
CEIV Pharma Perspective: A perspective from a US / LATAM Arline

Rodolfo Marre, Manager, LATAM Cargo
“First airline in the America’s to be CEIV Pharma certified”

Please join us today to learn more about our CEIV journey…
Zoom into the Cargo Business Unit: Key Facts

- 10 767F
- 1 747F ACMI + PAX fleet
- 17 freighter-only destinations in 11 countries + PAX destinations
- US$ 1.1 billion of revenue in 2017
- 525 K tons transported in 2017
- 3,265 employees*
- 2.5 K Tons Pharmaceuticals transported in 2017

*Updated as of February 2018

Source: Company information. Data as of December 2017
Why CEIV PHARMA?

Latin American industry leaders

Several years transporting pharmaceutical shipments to South America

Shippers and Forwarders request stricter Standards for transporting Pharmaceuticals

Airline freight transportation industry becomes more competitive

MIA Airport aims to become a PHARMA HUB and sponsors the CEIV Pharma certification

Importance of having quality client service and product treatments

One direction..
Early in 2016, we decided to jump into the IATA CEIV initiative!

Here’s what we achieved:

- Airline Certification
- MIA Self-Handler Certification
Early in 2016, we decided to jump into the IATA CEIV initiative!

Here’s what we achieved:

**Airline Certification**
Processes and procedures standardized over the network within the airline responsibility

**MIA Self-Handler Certification**
Early in 2016, we decided to jump into the IATA CEIV initiative!

Here’s what we achieved:

**Airline Certification**

Processes and procedures standardized over the network within the airline responsibility

**MIA Self-Handler Certification**

Handling and storage processes and procedures standardized in our HUB
“Nobody said it was easy…”
Challenges

**Investment requirements**
- Monitoring System
- Preventive Maintenance
- Temperature Mapping
- Cooling facilities

**Task force team**
- Time compliance
- Team commitment
- No centralized control

**Ongoing excellence**
- Ownership and management of the project
“...But it’s worth it!”
Benefits

- International Recognition (+Pioneers)
- Products with high standards and quality
- Supply chain integration under a common language
- Straight forward processes and procedures
- Continuous improvement
Obrigado! GRACIAS! Thank you!
CEIV Pharma
Perspective: Impact on DUS operations

Gerton Hulsmann, Managing Director, Düsseldorf Airport Cargo GmbH
Düsseldorf Airport Cargo

IATA's 12th World Cargo Symposium

13th – 15th March 2018
Dallas, United States
Düsseldorf Airport Cargo was CEIV certified in March 2016 at the first attempt

CEIV certificate was handed over to Düsseldorf Airport Cargo in 2016 at the 10th IATA WCS in Berlin

We were the first German airport, which has received this certificate
Why CEIV?

- CEIV combines different regulations, standards and best practices in order to create a **global high quality standard**.

- Working in a **global environment**, requires **global standards** instead of creating local solutions.

- Standards will become mandatory or at least the basis of handling pharmaceuticals transported by air.

- Community Approach vs. **Single Company Approach**.

- Being the **1st Company on the German Market** - sometimes it needs a first mover to create a change.
Why CEIV?

- 17-20% of all pharmaceutical exports from Germany are originating from the Federal State North Rhine Westphalia (NRW)
- 53 pharmaceutical companies are located in NRW
- Dusseldorf Airport is at the center of these pharmaceutical companies
- Getting pharmaceutical shipments back from sea to air traffic
CEIV has paid off so far

PIL Shipments

Shipments

0 | 1000 | 2000 | 3000 | 4000 | 5000 | 6000 | 7000 | 8000 | 9000

CEIV certification
Pharmaceutical Exports and Imports 2017 in %

NRW exports 2017 (all modalities)
- United Kingdom 15
- France 11,4
- China 8,4
- USA 7
- Netherlands 6,4
- Ireland 3,1
- Belgium 3,9
- Japan 4,4
- Italy 4,5
- Poland 2,6
- Other Countries 33,4

NRW imports 2017 (all modalities)
- USA 18,9
- Switzerland 38,1
- Other Countries 8,5
- Czech Republic 2,8
- France 3,1
- Denmark 5,1
- Belgium 5,1
- Netherlands 6,5
- United Kingdom 8,2
- China 1,8

Source: Außenhandel NRW
Some hurdles

- Freight forwarders
- Ground Handlers
- Airlines

Do they really cooperate?
Some hurdles

Overall quality in documentation and labelling: e.g. especially designed labels are still misused for non-pharmaceutical products…
One emotional reason to go for CEIV!

Every year 18 million people worldwide die!

Mostly in the 3rd world
How to proceed?

- Cooperation
- Transparency
- Trust
- Share experiences
Pharmaceutical facilities

<table>
<thead>
<tr>
<th>Area</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cool Storage (COL) [+2° to +8°C]</td>
<td>450 sqm.</td>
</tr>
<tr>
<td>Controlled Room (CRT) [+15° to +25°C]</td>
<td>120 sqm.</td>
</tr>
<tr>
<td>DUS Pharma Center (DPC) [+2° to +25°C]</td>
<td>800 sqm.</td>
</tr>
</tbody>
</table>

Capabilities

- Thermo Blankets ✓
- Quality Reporting ✓
- Ground Handling ✓
- Cool Dollies ✓
- Temp. Contr. Storage ✓
- Active Containers ✓

Investments

- Hardware
- Software
- Staff (GDP)
Going the extra mile (new investments)

Cooling/Heating

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature Range</td>
<td>-10°C to +35°C</td>
</tr>
<tr>
<td>Internal Temperature Range</td>
<td>+5°C to +25°C</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Sensor based, self-regulating</td>
</tr>
<tr>
<td>Power Supply</td>
<td>Battery 24V Solar panels, Battery monitor System</td>
</tr>
<tr>
<td>Monitoring on distance</td>
<td>By GSE Track Geoloc System</td>
</tr>
</tbody>
</table>

Dimensions

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall length</td>
<td>6699 mm</td>
</tr>
<tr>
<td>Overall width</td>
<td>3043 mm</td>
</tr>
<tr>
<td>Overall height</td>
<td>3216 mm</td>
</tr>
<tr>
<td>Tara weight</td>
<td>+/- 3.300 kg</td>
</tr>
<tr>
<td>Max Load</td>
<td>3.000 kg</td>
</tr>
<tr>
<td>Suitable for</td>
<td>Pharmaceuticals</td>
</tr>
</tbody>
</table>
CEIV in progress

Number of companies assessed
249 till end 2017 ….. *and counting

Number of assessed companies in regions 2013-2016

Europe/CIS 144

Asia/Pacific 35

The Americas 44

North Asia ca 7

Source: IATA

Number of companies assessed 2013-2017:
- 1 in 2013
- 14 in 2014
- 47 in 2015
- 202 in 2016
- 47 in 2017
- Total: 249*
CEIV in progress

CEIV Pharma (Certified Entities)
Certified Pharmaceutical Trade Lanes Development

Source: IATA
Memberships & Initiatives

Since March 2016

Gerton Hulsman
Board Member

Full Member
Thank you for your attention.

Gerton Hulsman
Managing Director Düsseldorf Airport Cargo GmbH
Panel Discussion

**Gian Carlo Alessi**, Head of Cargo, *EuroAirport*

**Nathan de Valck**, Cargo Manager, *BRUCargo*

**Bruno Guella**, Managing Director, *MVD Free Airport*

**Gerton Hulsmann**, Managing Director, *Düsseldorf Airport Cargo GmbH*

**Rodolfo Marre**, Manager, *LATAM Cargo*
Closing Remarks

Ronald Schaefer, Assistant Director, Cargo/Ground Handling and CEIV Consulting, IATA