How to become CEIV Pharma Certified
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2.0 However, air cargo losing market share to other modes of transportation

3.0 Standards + Regulations: The nature of the industry requires strong cooperation and IATA as a standard setting organization

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5.0 Approach and methodology: Validate knowledge, facilities, as well as processes, train stakeholders and recognize compliance

6.0 CEIV Pharma approach, governance, and organization: A partnership model and approach tailored to the needs of the different stakeholders in the value chain with qualified experts

7.0 Benefits: A win-win opportunity for all stakeholders

8.0 CEIV Pharma: Update of activities
Background: Pharmaceutical Market Development

The global biopharma sales trend is projected to go upwards, with cold chain products growing at 1.8x the rate of non-cold chain products during the 2018 – 2024 period.

- By 2024, world sales of cold-chain drugs and of biologics will likely top $440 billion, in a global biopharma market exceeding $1.58 trillion.

- This data does not include the dramatic shifts that have (or will) occur due to the impact of COVID19.

- Expected impacts from COVID19 include:
  - A noticeable drop on the logistics practices and shipments by air, ground and sea due to limited capacity; and
  - An increase in cold-chain activities with the development of a vaccine.

Source: Pharmaceutical Commerce
Background: Pharmaceutical Market Development
There are currently 250 COVID19 vaccine candidates

Feasibility of In-Country Logistics

• Vaccines typically take 5 to 20 years for development, however given the current pandemic, speed to market is key and thus are most likely to be transported via air.

• Assuming global vaccine coverage of 10 billion doses, it is expected vaccine distribution will require ~200,000 movements by pallet on 15,000 flights.

• Given the current infrastructure, the feasibility to distribute COVID-19 vaccines within destination countries will greatly vary depending on the level of cold storage required (please see graphic on left).

Scenario 1:
Stringent temperature requirements (as low as -80°C) with high feasibility at scale in ~25 countries with total population of ~2.5bn

Scenario 2:
Conventional temperature requirements (+2–8°C or even higher) with high feasibility at scale in ~60 countries with total population of ~5.0bn

Source: DHL / McKinsey / World Bank
Background: Pharmaceutical Market Development
Spending in biopharma logistics will continue to rise to meet demand.

It is estimated cold-chain logistics spending in 2020 will be about $17.2 billion worldwide in a $90.3 billion overall pharma logistics market.

There are three trends:
1. An increased number of container reuse services (which requires a commercially viable returns network);
2. The introduction of more recyclable containers (i.e. can be disposed in municipal waste recycling centers); and
3. Intensified used of electronics to track shipments in terms of conditions and location in real-time.

Source: Pharmaceutical Commerce
Background: Pharmaceutical Market Development
It is estimated the global industry will spend $15 billion on cold chain logistics in 2018, up from $10.1 billion in 2015

Estimated Breakdown of Logistics Spending (2015 vs 2018) ($ Billions)

- It is estimated $10.6 billion will be spent in cold chain transportation
- $4.4 billion will be in specialized tertiary packaging and instrumentation such as:
  - insulated boxes;
  - blankets;
  - phase-change materials;
  - active temperature-control shipping containers; and
  - various temperature sensors and recorders.
- There is a trend towards more spending on devices and systems for controlled room temp (CRT)

Source: Pharmaceutical Commerce
Background: Pharmaceutical Market Development
Out of the USD 10.6B, USD 7.8B of Cold Chain Transport Spending will be spent on Air Freight

Estimated Breakdown of Cold Chain Transport Spending By Mode (2018) ($ Billions)

Source: Pharmaceutical Commerce
Background: Pharmaceuticals Use Air Transport

Pharmaceutical transport by air has shown stronger growth than the air cargo market as a whole.

Long Term Air Trade Growth 2000 - 2016 (% CAGR)

Source: Seabury Global Trade Database (May 2017)
Background: Pharmaceuticals Use Air Transport

The United States is the biggest exporter and importer of pharmaceuticals by air

Pharma Air Trade Destinations JAN-AUG 2017 (Thousand Tonnes)

Export

- USA: 86
- India: 54
- Germany: 33
- China: 20
- France: 19
- UK: 14
- Belgium: 12
- Other: 127

Import

- USA: 73
- China: 23
- Japan: 13
- Germany: 13
- Brazil: 12
- Netherlands: 9
- India: 8
- Other: 214

Source: Seabury Global Trade Database (November 2017)
**Background: Pharmaceuticals Use Air Transport**

Pharmaceuticals represent an important and lucrative sector for air cargo, contributing approximately US$ 1.4 billion to total airline cargo revenue.

Pharmaceutical Trade By Air 2017 Per Volume, Airline Cargo Revenue and Value (%)

<table>
<thead>
<tr>
<th></th>
<th>Volume</th>
<th>Airline Cargo Revenue</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source: Seabury Global Trade Database (November 2017)</td>
<td>1.9%</td>
<td>2.6%</td>
<td>9.4%</td>
</tr>
</tbody>
</table>
Background: Pharmaceuticals Use Air Transport

Pharmaceuticals shipped under CRT, COL or ACT command an average premium of 25-60% above the rate charged for the average air cargo shipment on the same country pair.

Pharma Rates by Handling Code 2017

Source: IATA Economics
Background: Pharmaceuticals Use Air Transport

As a result, pharma air trade growth is based on high value pharma products (> $150/kg) compared to pharma ocean trade growth which relies on low value products (< $15/kg)

Pharma Trade By Product Value: Air vs Ocean 2000 – 2016 (Thousand Tonnes)

Source: Seabury Global Trade Database
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</tbody>
</table>
Background: Air freight has lost “market share” to ocean freight
Over the past 16 years, ocean pharma trade has added significant volumes particularly in the mid-value pharma category

Pharma Share: Air vs Ocean

Global Trade of Pharma, 2016

<table>
<thead>
<tr>
<th>Weight</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCEAN</td>
<td>91%</td>
</tr>
<tr>
<td>AIR</td>
<td>9%</td>
</tr>
</tbody>
</table>

Air Weight Share, 2000 – 2017 (MAR)

Air Share Losing Out to Ocean

Source: Seabury Global Trade Database
Background: Critical Issues Raised by the Shippers

Industry partners in the cold chain need to ensure quality services

Prevent

Vaccines reaching their destination degraded because of incorrect shipping

Avoid

That scrapped pharmaceuticals can be attributed to logistics issues alone

Stop

Damaging temperature-sensitive products during transport due to a broken cold chain

- 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

- Total: USD 34.1B
- 15.20
- 8.60
- 5.65
- 3.65
- 1.00

- Opportunity Labor Costs: 1.3
- Direct Labor Costs: 2.35
- Trial Production Costs: 2
- Clinical Trial Costs: 1.3

- Wasted Logistic Costs: 8.60
- Replacement Costs: 5.65
- Root Cause Analysis: 3.65
- Lost Product Cost: 1.00

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
Air Cargo Industry Concerns and Challenges

Temperature Excursions – Where do they occur?

- Manufacturer
- Truck
- Freight Forwarder
- Airline Cargo Handler
- Airline

- Airline
- Airline Cargo Handler
- Regulatory Authority
- Trucker
- Freight Forwarder
- Truck
- Consignee

Source: Expeditors

Low Risk  Medium Risk  High Risk
Air Cargo Supply Chain Challenges
The process is quite complex and shippers have difficulties to identify stakeholders that meet standards and regulations.

Example of Flow from BRU to SYD

14 milestones from start to end.

HOW CAN YOU MANAGE THIS?
Air Cargo Supply Chain Challenges
Temperature control share of pharma

Temperature management market, 2013-2017
In percentage of total business

• A big share of pharmaceutical shipments in the 15-25°C segment are shipped as general cargo.

• A significant part of pharmaceutical shipments requires temperature controlled transport.

  • 75% of shipments require passive cooling solutions, and
  • 20% require active temperature control.

  • Active temperature control solutions demand a yield premium due to complex requirements.
  • Passive solutions drive volume and are less costly to implement.

Source: Seabury, BRU Cargo
Air Cargo Supply Chain Challenges
From origin to destination pharmaceutical products can be exposed to different climates
Air Cargo Industry Concerns and Challenges

Heavily regulated industry with no global standards and certification for handling of pharmaceutical products

- **Increasing number of regulations** around the world to implement and comply with
- **Increasing number of audits**
- **Airlines, GHAs and forwarders subjected to multiple audits** for handling, transportation and distribution (e.g. WHO Appendix 5, EU 92/25/EEC, IATA PCR Chapter 17 & TCR)
- **No global certification** for handling of pharmaceutical products
Shippers Expectations in Cold Chain

Modal shift is a reality because shippers need products to maintain integrity and efficacy during transportation

- Compliance, standardization, accountability and transparency across the supply chain
- Properly trained stakeholders on regulations and standards
- Adequately equipped facilities throughout the supply chain
- Global certification for handling of pharmaceutical cargo
- Common audit format to minimize the disruptions and increase effectiveness
- Ability to easily search and identify stakeholders that meet requirements
More compliance on the horizon?
Growing regulatory environment, higher business complexity and increased focus on accountability

- Pharmaceutical companies operate in one of the most dynamic environments.
  - Changes in regulations by leading bodies such as US Food and Drug Administration (USFDA) and the European Medicines Agency (EMA) have increased the significance of regulatory compliance management for drug manufacturers.
  - Pharma companies across the globe are compelled to alter their compliance practices to conform to changes in regulations and stringent anti-corruption laws.

- Historically pharmaceutical industry has been dealing with malpractices across the value chain ranging from improper branding to masking safety information and disregarding quality manufacturing standards. This has led to regulators keeping a strict watch on the pharma companies.

- Enforcement agencies the world over have become more active. Any violation of regulatory methods or non-compliance of standards could tarnish a company’s reputation, risking its future.

- According to the 2014 global survey on reputation risk conducted by Deloitte, reputation problems had a severe impact on revenue, loss of brand value and regulatory investigations.
More compliance on the horizon?
In the US and European markets, companies have become increasingly cautious about regulatory compliance

<table>
<thead>
<tr>
<th>Pharma shippers situation</th>
<th>Impact on Air Cargo industry</th>
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<tbody>
<tr>
<td>• Leading pharma companies in these markets have reportedly implemented effective compliance management systems internally.</td>
<td></td>
</tr>
<tr>
<td>• Pharma companies are realigning their quality and compliance structure to conform to the constantly evolving regulatory guidelines.</td>
<td></td>
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<tr>
<td>• With the FDA and other regulators broadening the scope of compliance requirements, it helps if companies have a holistic approach and make regulatory compliance part of their corporate strategy.</td>
<td></td>
</tr>
<tr>
<td>• Compliance is a priority for the air cargo sector.</td>
<td></td>
</tr>
<tr>
<td>• Air cargo sector performance not encouraging and increased regulation will continue to contribute to the compliance challenges facing the industry.</td>
<td></td>
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<tr>
<td>• They will demand the same from their business partners.</td>
<td></td>
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<tr>
<td>• Companies ought to be proactive in setting up stringent internal controls as part of their commitment towards quality and compliance.</td>
<td></td>
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<tr>
<td>• Include effective training, proper timely communication, periodic reviews / follow-up, and support from the top management.</td>
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Will Regulators focus on aligning country-specific regulatory frameworks to global standards enabling harmonization of standards and help companies drive efficiencies?
Introduction: Pharma logistical market growing

However, air cargo losing market share to other modes of transportation

Standards + Regulations: The nature of the industry requires strong cooperation and IATA as a standard setting organization

Objective: CEIV Pharma is a concerted effort to improve the level of competency, operational and technical preparedness

Approach and methodology: Validate knowledge, facilities, as well as processes, train stakeholders and recognize compliance

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Benefits: A win-win opportunity for all stakeholders

CEIV Pharma: Update of activities
IATA a Standard Setting Organization
Implementation and dissemination of standards driven by industry

Step 1: Implementation

Industry feedback driving improvements:

• Need for **standardization** in safety, security, operations, e.g. the handling of pharmaceutical products in air cargo environment
• Need to enhance **partnership and communication**
• Need to ensure **appropriate training in the supply chain**

Step 2: Dissemination

Support Adoption
Prove Concept
Develop Standards

The industry usually asks IATA to address their needs to ensure compliance and quality services
IATA a standard setting organization

IATA adopted a supply chain approach by liaising with all stakeholders…

![Diagram](image-url)
IATA a Standard Setting Organization
…from the health care industry to establish common standards

- **2007**
  - Perishable Cargo Regulations (PCR)
  - *Industry standard*

- **2010**
  - PCR
  - New Chapter 17
  - New T&T Sensitive Label

- **2012**
  - Mandatory T&T Sensitive Label

- **2014**
  - Provides requirements + standards for transporting pharma products

**2008**
**2009**
**2011**
**2013**
**2014**

**Mandatory Standard Checklist**

Must be affixed to all shipments booked as T+T sensitive cargo
IATA a Standard Setting Organization

IATA uses different means to disseminate standards in the industry
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Center of Excellence for Independent Validators for Pharmaceutical Logistics (CEIV Pharma)

Inspired by Shippers, Driven by Industry!
Center of Excellence for Independent Validators (CEIV)
Improve together to protect and grow our industry

The Need
- ... for more safety, security and efficiency
- ... to raise the bar to (re)gain confidence
- ... to improve compliance to standards/regulations
- ... for independent assessments vs. self-assessments
- ... to identify and recognize the best players
- ... to harmonize and reduce the number of audits

The solution
- Develop standards with regulators
- Train industry stakeholders on standards and regulation
- Assess operations against standard check list
- Train independent validators on standards and regulations
- Certify and then register best players on a publicly website
- Get States recognition to ensure audits are valid for all
Center of Excellence for Independent Validators (CEIV)

Approach of the CEIV programs

- Advocate for globally accepted standards and regulations
- Train instructors on behalf of the airlines, cargo and ground handlers
- Manage the pool of qualified instructors
- Train the Independent Validators to a common standard and validation methodology
- Train operational staff
- Run on-site pre-audits to prepare for validation
- Conduct the validations
- Manage the database of Independent validators
- Manage the database of certified companies
Center of Excellence for Independent Validators (CEIV) for Pharma

The CEIV Pharma aims to ensure a higher and more consistent level of pharmaceutical handling through validations with registered independent validators and instructors.

- Advocate for globally accepted standards and regulations
- Establish validation checklist with industry
- Establish industry steering group
- Develop training contents
- Develop assessment criteria for instructors and validators exam
- Train instructors, validators and industry stakeholders
- Manage database of certified instructors and validators
- Develop pre-validation assessment toolkit
- Develop a standard validation methodology and assessment tool
- Manage deployment of validators
- Audit documentation, processes and operations consistently
- Manage quality of validations
- Follow-up
- Award and recognize operators and locations as "CEIV Pharma certified"
- Manage database of validated locations and operators
- Manage re-validation schedule
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 staff competency levels 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

From point of origin to destination

1. Shippers
2. Trucking Companies
3. Origin Ramp/Cargo Handlers
4. Airports
5. Airlines
6. Destination Ramp/Cargo Handlers

Consignee

Freight Forwarders/Pet Shippers
CEIV Pharma Standard
CEIV Pharma standard focuses on global coverage and universality

IATA GUIDELINES

GOOD DISTRIBUTION PRACTICES

LOCAL + REGIONAL GUIDELINES

E.g. Singapore GDP & GDPMDS or FAGG in Belgium

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 Standard

Review, compare against best practice, offer recommendations for change, identify and mitigate risks, develop implementation plan

Criteria applied
- Quality management
- Personnel
- Training
- Documentation
- Infrastructure + equipment
- Operations
- Complaints, returns and counterfeit
- Supplier management
- Self-inspections
- Transportation
- Specific provisions for brokers

Issues tackled
- Content of manuals and guidelines
- Procedures for Audits
- Procedures for describing packaging systems
- Acceptance checklist quality and operating agreements
- Packaging requirements
- Documentation & labeling
- Acceptance & control
- Facilities and equipment
- Staff training requirements
- Training adequacy and currency

Not exhaustive
CEIV Pharma Standard
Compliance vs. non-compliance

IMPORTANT

Non-Conformance Ratings:

**MINOR non-conformance** – minor or less serious non-conformance which is unlikely to pose a risk to product quality;
-> *need to be closed for the CEIV Certification*

**MAJOR non-conformance** – failure to satisfy a key or mandatory requirement and/or one which may pose a risk to product quality;
-> *need to be acted upon for the CEIV Certification.*

*Recommendations are provided as suggestions for potential improvements only and won’t be reviewed for CEIV Certification*
EU GDP – CEIV Pharma Comparison
CEIV Pharma aims at global and consistent assessments specific to air transport

GDP’s are:
- in some cases very region centric
- not consistent and not transparent
- not supported by shippers for air cargo industry
- focused on storage of pharma, not transportation
- not aligning stakeholders in the supply chain
- ignoring transport in areas such as such as ground/tarmac transportation and aircraft (un)loading which are not covered by existing GDPs.

- CEIV Pharma focus is placed on unique handling and storage circumstances that apply to air cargo transport
EU GDP – CEIV Pharma Comparison

CEIV Pharma aims to avoid one of the most “dangerous misunderstandings” of GDP certification

1. Transport companies face strong pressure to be listed in the EudraGMDP Database of companies meeting EU GDP compliance

2. As per EU GDP Guidelines, only competent supervisory authorities can carry out GDP inspections

3. However GDP Competent Authorities do not typically carry out GDP inspections at transport companies (shipping companies) or at airport hubs

4. Gap filled by non-accredited bodies who issue commercial GDP certificates which are not compliant as they are not issued by competent supervisory authority

5. “QP” Certificates from independent consultants are also not valid

SOLUTION?

Source: GDP Group, 14/10/2015
## EU GDP – CEIV Pharma Comparison

GDPs assist wholesale distributors in procuring, holding, supplying or exporting medicinal products, CEIV Pharma focuses on airfreight and temporary storage

<table>
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<th>EU GDP</th>
<th>IATA CEIV Pharma</th>
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<tr>
<td>Wholesale Distribution Authorization</td>
<td>CEIV Certification</td>
</tr>
<tr>
<td>Wholesalers, 3PL’s with storage activities</td>
<td>Supply Chain Stakeholders</td>
</tr>
<tr>
<td>Procuring, holding, supplying or exporting medicinal products</td>
<td>Handling and transporting pharmaceutical products by air</td>
</tr>
<tr>
<td>EU Guidelines</td>
<td>International Regulatory requirements, Regulations and air freight standards</td>
</tr>
<tr>
<td>Encompasses storage and distribution requirements</td>
<td>Focuses on air freight and temporary storage</td>
</tr>
<tr>
<td>Applied interpreted by each Member States (e.g. warehousing rules)</td>
<td>Globally harmonized with consistent requirements</td>
</tr>
<tr>
<td>Accredited service providers will carry out GDP inspections at transport companies or at airport hubs</td>
<td>Validation also on air freight operations (e.g. ground/tarmac transportation and aircraft (un)loading)</td>
</tr>
<tr>
<td>Country specific auditing tools</td>
<td>Same Audit Checklist everywhere</td>
</tr>
<tr>
<td>Considered as a reference globally</td>
<td>Recognition is increasing in the industry</td>
</tr>
</tbody>
</table>
EU GDP – CEIV Pharma Comparison
Which compliance recognition program to choose from?

…The one that best meets your needs and requirements!

• Does your company comply with the required regulations?
• Does your company need a level of recognition?
• Does your company need a WDA (Wholesale Distribution Authorization)?
• Where in the supply chain is your company?
• Are the activities out of Europe, international, global?
• ......?

Keeping in mind that the industry is following the same objective…
EU GDP – CEIV Pharma Comparison
A collaborative approach is vital

...Patient safety...
It is collaborative responsibility!
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8.0 CEIV Pharma: Update of activities
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

2. Training required for certification

3. Assessment
   - On-site (remote) assessment by Independent validator
   - Assessment versus minimum IATA CEIV Pharma Checklist
   - Comparison against best practice
   - Establish findings and offer recommendations for change
   - Develop implementation plan and secure resources

4. Validation
   - On-site (remote) 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

5. Certification

6. Additional Training
Training required for certification

Successful completion of the courses is essential for certification

Successful completion of:
• 2 key personal on the “audit” training (5 days); and
• 2 competent personal on the “handling” training (3 days).
Training
Temperature Controlled Cargo Operations

Key topics:
• The regulatory environment
• Overview of the global pharmaceutical industry
• The differences between “ordinary” perishables and healthcare products
• Packaging Technology
• Documentation and Labelling
• Handling Procedures and Acceptance Control
• Temperature Management in the supply chain
• The critical control points and associated risk factors
• Service Level Agreements (SLAs) and Standard Operational Procedures (SOPs)
• Quality Management

✓ 2 competent personnel per station should be trained on the Classroom course
Training
Audit, Quality + Risk Mgt. for Temperature Controlled Cargo

Key topics:
- The Regulatory framework
- Quality Management System (QMS)
- Audit and Quality Control Principles
- Self assessment and validation
- IATA Time and Temperature Sensitive Audit Checklist
- Effectiveness of risk management control
- Trigger corrective and preventive measures
- Quality Risk Management (QRM)
- Risk assessment, control and management methodology
- Root Cause Analysis and Lean Basics

2 key personnel per station should be trained on the Classroom course
Training required for certification
For both, key personnel vs competent personnel, successful completion of the course is a pre-requisite for certification

Who?

Temperature Controlled Cargo Operations (3 day classroom)

- 2 Competent personnel per station
  - Handling manager
  - Warehouse manager
  - Shift manager for acceptance, handling, ramp and storage of pharmaceutical goods
  - Other staff involve in procession pharmaceutical goods

Audit, Quality and Risk Management for Temperature Controlled Cargo (5 days classroom)

- 2 Key personnel per station
  - QA manager
  - Pharma product manager
  - Station manager
  - Station manager
  - Internal Trainer
  - …
Training Options In-Company vs Training Center

- **Training required for certification**

<table>
<thead>
<tr>
<th></th>
<th>Training Center</th>
<th>In-Company Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>$</td>
<td>$$</td>
</tr>
<tr>
<td>No. of Participants</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Location</td>
<td>Inflexible</td>
<td>Flexible</td>
</tr>
</tbody>
</table>
**Assessment**

Focus is on preparing the organization for validation and creating awareness

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raise awareness</td>
<td>On Pharma handling requirements</td>
</tr>
<tr>
<td>Assess client</td>
<td>To identify potential gaps using the IATA CEIV Pharma checklists</td>
</tr>
<tr>
<td>Conduct on-site (remote) observation</td>
<td>Of facilities, staff, equipment, processes, practices, and systems</td>
</tr>
<tr>
<td>Prepare client</td>
<td>For the subsequent validation exercise</td>
</tr>
<tr>
<td>Capture and convey ‘lessons learned’ and suggest ‘best practice’</td>
<td>To assist client in achieving &quot;CEIV Pharma Certified&quot; status</td>
</tr>
<tr>
<td>Analyze observations and produce report</td>
<td>Highlight findings and provide recommendations</td>
</tr>
<tr>
<td>Collaborative work</td>
<td>Helping creating an action plan and project plan</td>
</tr>
</tbody>
</table>
Validation

Validate to ensure all requirements are in compliance, …

- During the validation, the independent validator will go through the checklist one more time and also review the progress made against recommendations during the assessment phase.

- At the end of validation decision on whether all requirements have been fulfilled.

### Validation

<table>
<thead>
<tr>
<th>Review of progress on action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action Packages</strong></td>
</tr>
<tr>
<td>• Schedule</td>
</tr>
<tr>
<td><strong>Tasks</strong></td>
</tr>
<tr>
<td>1. Flight Ops</td>
</tr>
<tr>
<td>2. Network Mgt.</td>
</tr>
<tr>
<td>3. IT</td>
</tr>
<tr>
<td><strong>Actions</strong></td>
</tr>
<tr>
<td>• Personnel</td>
</tr>
<tr>
<td>• Quantitative</td>
</tr>
<tr>
<td>• Qualitative</td>
</tr>
<tr>
<td><strong>Implementations</strong></td>
</tr>
</tbody>
</table>

Projects running
Internal project teams
Teams supported by IATA
Project management
Validation

…the gaps as well as recommendations have been implemented

- Client agrees to close minor findings identified during the validation process and recorded as open in the final validation report within a timeframe of two (2) months.

- After 2 months IATA reserves the right to request
  - an up-to-date action plan, together with
  - the last Self-Inspection report and associated action plan, as well as
  - the Minutes of the last Management Review.

- If the client does not supply IATA satisfactory information within thirty (30) days of IATA notifying the client, then IATA will withdraw its CEIV Pharma registration certificate with immediate effect.
# Assessment and Validation

## Deliverables

**Step 1: Assessment**

- **Pharma handling criteria checklist.**
- **Report** covering the **findings and recommendations** based on the assessment.
- **Implementation plan.**
- Report and implementation plan will set out assumptions, findings, results, conclusions and recommendations and will specifically:
  - Identify **critical elements** that are not compliant with national and international Regulations and the defined CEIV Pharma Handling criteria (e.g. TCR);
  - Outline the **impact of non-compliance**; and
  - Identify **elements that are inefficient**.
- **Presentation to Senior Management.**

**Step 2: Validation**

- **Progress report** to review the progress made against recommendations during the assessment phase.
- **Implementation plan update.**
- **Recommendation to award certification as "CEIV Pharma certified"** based on satisfactory compliance of CEIV criteria.
- **Presentation** of the validation findings to Senior Management.
Additional Training
Introduction to Time and Temperature Pharmaceutical Products

4-6 hours training. Key topics:
• Pharmaceutical products
• Processes & procedures related to job functions
• Identification and labelling
• Effect of temperature on pharmaceutical products
• Avoidance of counterfeits
• Passive and active packing
• Product security

All personnel involved in handling pharmaceutical products activities per station should be trained on “IATA Introduction to Time and Temperature Pharmaceutical Products course“ (or equivalent) within period of 12 months after the “Certification”
CEIV Pharma: Path to Certification

In a nutshell

Step 1: Preparation
Step 2: Training
Step 3: Assessment
Step 4: Validation
Step 5: CERTIFICATION
Step 6: Training (remaining staff)
Certification Timeline (general approach)
Over the years we have seen companies completing the process within 6-7 months

- **Preparation**: 4-6 weeks
- **Assessment**: 2 days on-site (4 x 0.5 days remotely)
- **Validation**: 2 days on-site (4 x 0.5 days remotely)

**Timeframe depends on results of assessment.**

- **Training required for certification**: 4-12 weeks
  - Ideally completed before assessment.
  - Needs to be completed before validation.

- **Additional Training**: 12 months after certification
Certification Timeline (requirement)
Pharma shippers demanded to impose timelines

Mandatory Trainings: Not more than 6 months between latest training and assessment
Assessment
Validation: Not more than 12 months between assessment + validation

- In case companies pass deadline, key personnel need to take refresher training

Total certification not to last longer than 18 months from last training to certification
CEIV Pharma Caveat

Once a client obtains the CEIV Pharma Certificate, IATA or an IATA representative mandated by IATA will have the right to conduct spot checks to ensure continuing quality of the certification

- Client agrees to close minor findings identified during the validation process and recorded as open in the final validation report within a timeframe of two (2) months. After two (2) months IATA reserves the right to request an up-to-date action plan when minor findings identified during the validation process were still recorded as open in the final validation report, together with the last Self-Inspection report and associated action plan, as well as the Minutes of the last Management Review. If the client does not supply IATA satisfactory information within thirty (30) days of IATA notifying the client, then IATA will withdraw its CEIV Pharma registration certificate with immediate effect.

- In order to determine whether a client and/or station that has received the CEIV Pharma Certificate still meets the criteria, IATA reserves the right to require at any time, submission by the client of all required current documentation and information relating to the certification for IATA’s review and approval. If the client does not supply IATA satisfactory information within thirty (30) days of IATA notifying the client, then IATA will withdraw its CEIV Pharma certificate with immediate effect.

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Recertification

Recertification will take place every three years – includes assessment and one refresher training plus a validation if necessary.

- CEIV Pharma Certified
- 3 years
- Re-assessment
- Max. 2 days
- X Close gaps
- Validation
  - 1 - 2 days

REFRESHER TRAINING

- e.g. update on new regulations, development on new standards, development of new containers, etc.
1.0 Introduction: Pharma logistical market growing

2.0 However, air cargo losing market share to other modes of transportation

3.0 Standards + Regulations: The nature of the industry requires strong cooperation and IATA as a standard setting organization

4.0 Objective: CEIV Pharma is a concerted effort to improve the level of competency, operational and technical preparedness

5.0 Approach and methodology: Validate knowledge, facilities, as well as processes, train stakeholders and recognize compliance

6.0 CEIV Pharma approach, governance, and organization: A partnership model and approach tailored to the needs of the different stakeholders in the value chain with qualified experts

7.0 Benefits: A win-win opportunity for all stakeholders

8.0 CEIV Pharma: Update of activities
### CEIV Pharma Certification Approach

There are different approaches to obtain certification

<table>
<thead>
<tr>
<th>Individual</th>
<th>Community</th>
<th>Coalition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One company decides to get &quot;CEIV Pharma Certified&quot;&lt;br&gt;• One or several stations</td>
<td>• A group of companies at one airport decide to get &quot;CEIV Pharma Certified&quot;&lt;br&gt;• Form a “pharma gateway”&lt;br&gt;• Supply chain approach</td>
<td>• A group of companies decide to get &quot;CEIV Pharma Certified&quot; at several airports to form several “pharma gateways”&lt;br&gt;• Supply chain approach</td>
</tr>
</tbody>
</table>
Project Governance
Everyone in the value chain can participate in the certification process

Project structure - Who is involved and who can participate?

Example (BRU Cargo)

Pharma shippers

Forwarders with pharma focus

Handlers

Truckers

Airlines

Regulators

Facilitators
## Advocacy
Strong emphasis on engaging stakeholder and advocate for endorsement and recognition

### Industry
- IATA Live Animal and Perishable Board (LAPD)
- Time and Temperature Working Group (TTWG)

### Global
- WHO
- FIATA
- TIACA
- Global Shippers Forum (GSF)
- Cool Chain Association
- Pharm.Aero

### Regional
- EU
- Pharmacopeia

### Local
- Local stakeholder associations
  (Shippers, Freight Forwarders, Ground Handlers, Airlines)
- Local BARs

### WHO?
- Approve standards + guidelines
- Approve trainings
- Endorse + recognize standards
- Endorse + recognize trainings
- Endorse + recognize trainings
**CEIV Pharma – Who is auditing/training?**
Qualification and management of independent validators

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ IATA conducts preliminary interview with candidate to pre-qualify candidate for training</td>
<td>▪ IVs are registered in IATA database and available to complete the assessments and validations</td>
</tr>
<tr>
<td>▪ IVs must undergo IATA training</td>
<td>▪ Coordination of IVs is managed by the IATA team for assessments and validations</td>
</tr>
<tr>
<td>▪ IVs need to complete trainings within six months</td>
<td>▪ IV cannot have been in a commercial relationship with entity to be validated 12 months prior to the engagement</td>
</tr>
<tr>
<td>▪ IV’s can also become instructors but need to undergo the IATA Train-the-trainer course (optional)</td>
<td>uplicates and available to complete the assessments and validations</td>
</tr>
</tbody>
</table>

IVs cannot have been in a commercial relationship with entity to be validated 12 months prior to the engagement.
Organizational Chart
How is CEIV Pharma organized?

Head
Ronald SCHAEFER

Compliance
Ronald SCHAEFER

Standards
Andrea GRUBER

Training
Yaniv SORANY

Instructors
Person X
Person Y

Validators
Person X
Person Y

QM
Independent Validator

Frederic LEGER
Laurent DELARUE

External

External
1.0 Introduction: Pharma logistical market growing
2.0 However, air cargo losing market share to other modes of transportation
3.0 Standards + Regulations: The nature of the industry requires strong cooperation and IATA as a standard setting organization
4.0 Objective: CEIV Pharma is a concerted effort to improve the level of competency, operational and technical preparedness
5.0 Approach and methodology: Validate knowledge, facilities, as well as processes, train stakeholders and recognize compliance
6.0 CEIV Pharma approach, governance, and organization: A partnership model and approach tailored to the needs of the different stakeholders in the value chain with qualified experts
7.0 **Benefits: A win-win opportunity for all stakeholders**
8.0 CEIV Pharma: Update of activities

**Content**
CEIV Pharma – Key Benefits
CEIV Pharma is a win-win situation for the industry

**Shippers**
- Conduct simpler audits of operators
- Obtain guarantee that products would be handled in line with regulations
- Experience lower rate of damage and loss due to temperature excursions
- Be able to prepare their products ready for acceptance

**Airlines, GHAs, Forwarders, Airports**
- Protect and grow revenues in fastest growing segment of air cargo
- Obtain recognition for operations, facilities and staff after meeting standards
- Experience simpler audits from various organizations
- Promote their best practices to the shipper’s community
- Speak with one voice

**Regulators**
- Ensure safety of pharmaceutical products shipped by air
- Access to structured and consistent training
- Registry of independent validators and certified operators

**IATA**
- Disseminate standards in the industry
- Common audit criteria and global certification
- Promote air transport and so limit the modal shift
Content

1.0 Introduction: Pharma logistical market growing
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4.0 Objective: CEIV Pharma is a concerted effort to improve the level of competency, operational and technical preparedness
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6.0 CEIV Pharma approach, governance, and organization: A partnership model and approach tailored to the needs of the different stakeholders in the value chain with qualified experts
7.0 Benefits: A win-win opportunity for all stakeholders
8.0 CEIV Pharma: Update of activities
CEIV Pharma Development
From Pilot to Launch

**Discussion with SATS about a Pilot**

- Development of CEIV Pharma Standard 1.0

**SATS Pilot**

- Joint development of Community Concept with BRU

Official launch of CEIV Pharma program

- Development of CEIV Pharma Standard 1.1 and 1.2 + Guidelines

Launch of Community Concept at BRU

- Development of CEIV Pharma Standard 1.3 + updated Guidelines

Recertification of CEIV Pharma program

- All companies of the first community will undergo recertification

Unreliable cargo industry loosing pharma industry: IATA sleeping

09/13 11/13 01/14 03/14 05/14 07/14 09/14 11/14 01/15 03/15 11/17
CEIV Pharma Checklist

CEIV Pharma checklist and guidelines will be included in IATA’s Temperature Control Regulations as Annex

CEIV Pharma Audit Checklist

CEIV Pharma Audit Guidelines
Visibility for CEIV Pharma validated entities
Validated entities are visible on IATA’s website
Visibility for CEIV Pharma validated entities
New database combining different IATA certifications under one roof – Coming in 2019

Preliminary layout
CEIV Pharma (Certified Entities)
Certified Pharmaceutical Trade Lanes Development

Locations
- 296 Certifications Completed
- +75 Certifications in Progress (estimate)
- +99 Certifications under discussion *
CEIV Pharma (Community Approach)
Certified Pharmaceutical Trade Lanes Development

Locations

26 Ongoing Communities
6 Communities in Discussion
CEIV Pharma – Locations Certified Worldwide
Certified Pharmaceutical Trade Lanes Development

Locations
296 Certifications Completed
CEIV Pharma (Certified)
North America

Locations
47 Certifications Completed
24 Certifications in Progress

Cities
Atlanta (2X)
Boston
Chicago
Columbus
Dallas
Indianapolis
Kansas City
Lester
Los Angeles
Miami
New York
Philadelphia
Puerto Rico
Saint Louis
San Diego
San Francisco
Tampa

Cities
Chicago
Cincinnati
Los Angeles
Miami
Philadelphia
Puerto Rico

Cities
Atlanta (2X)
Boston
Chicago
Columbus
Dallas
Indianapolis
Kansas City
Lester
Los Angeles
Miami
New York
Philadelphia
Puerto Rico
Santa Louis
San Diego
San Francisco
Tampa
CEIV Pharma (Certified)
United States

Locations

37 Certifications Completed
19 Certifications in Progress

Certifications in Progress

Certifications Completed

Locations:
- Atlanta (2X)
- Boston
- Chicago
- Columbus
- Dallas
- Indianapolis
- Kansas City
- Lester
- Los Angeles
- Miami
- New York
- Philadelphia
- Puerto Rico
- Saint Louis
- San Diego
- San Francisco
- Tampa

Cities:
- Chicago
- Cincinnati
- Los Angeles
- Miami
- Philadelphia
- Puerto Rico
CEIV Pharma (in progress)
United States

Locations

37 Certifications Completed
19 Certifications in Progress
CEIV Pharma (Certified)

Canada

Locations

- 7 Certifications Completed
- 4 Certifications in Progress
CEIV Pharma (in progress)

Canada

Locations

7 Certifications Completed

4 Certifications in Progress
CEIV Pharma (Certified)

Mexico

Locations

- 3 Certifications Completed
- 0 Certification in Progress
CEIV Pharma (Community Approach)
Community Approach Development Europe

Location

133 Stations participating in Community Approach in Europe
CEIV Pharma (Community Approach)
Community Approach Development Europe
CEIV Pharma (Community Approach)
Community Approach Development Europe

Location

133 Stations participating in Community Approach in Europe
CEIV Pharma (Certified)
Spain

Locations

13  Certifications Completed
3   Certifications in Progress
CEIV Pharma (in progress)
Spain

Locations

13 Certifications Completed
3 Certifications in Progress
CEIV Pharma (Certified)
Portugal

Locations

2 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
France

Locations

12 Certifications Completed
8 Certifications in Progress
CEIV Pharma (in progress)

France

Locations

12 Certifications Completed

8 Certifications in Progress
CEIV Pharma (Certified)
Belgium

Locations

15 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
Netherlands

Locations

16 Certifications Completed
3 Certifications in Progress
CEIV Pharma (in progress)
Netherlands

Locations

- 16 Certifications Completed
- 3 Certifications in Progress
CEIV Pharma (Certified)
Germany

Locations

19 Certifications Completed
3 Certifications in Progress
CEIV Pharma (in progress)
Germany

Locations

19 Certifications Completed
3 Certifications in Progress
CEIV Pharma (Certified)
Ireland

Locations

2 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
Italy

Locations

<table>
<thead>
<tr>
<th>15</th>
<th>Certifications Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Certifications in Progress</td>
</tr>
</tbody>
</table>
CEIV Pharma (Certified)

Hungary

Locations

1 Certification Completed
0 Certification in Progress
CEIV Pharma (Certified)
Poland

Locations

2 Certification Completed
3 Certifications in Progress
CEIV Pharma (in progress)
Poland

Locations

- **2** Certification Completed
- **3** Certifications in Progress
CEIV Pharma
Greece

Locations

4 Certifications Completed
4 Certifications in Progress

ATHENS INTERNATIONAL AIRPORT
ELEFTHERIOS VENIZELOS

SkyServ
Goldair Group

swissport

ATHENS INTERNATIONAL AIRPORT
ELEFTHERIOS VENIZELOS

KUEHNE + NAGEL
GAC
Delivering your strategy

DHL
Talos

IATA
CEIV Pharma (Certified)
Switzerland

Locations

10 Certifications Completed
1 Certification in Progress
CEIV Pharma (in progress)
Switzerland

Locations

10 Certifications Completed
1 Certification in Progress
CEIV Pharma (Certified)
Austria

Locations
- 3 Certifications Completed
- 0 Certification in Progress
CEIV Pharma (Certified)
Sweden

Locations

2 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
Denmark

Locations

4 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)

Norway

Locations

2 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
Finland

Locations

- 3 Certifications Completed
- 0 Certification in Progress
CEIV Pharma (Certified)
Russia

Locations

2 Certifications Completed
3 Certifications in Progress
CEIV Pharma (in progress)
Russia

Locations

2 Certifications Completed
3 Certifications in Progress
CEIV Pharma (Certified)
Turkey

Locations

4 Certifications Completed
0 Certification in Progress

Airline + GHA IST + GHA ISL

TURKISH CARGO

KUEHNE + NAGEL
CEIV Pharma (Community Approach)
Community Approach Development Asia

Location

75 Stations participating in Community Approach in Asia and Pacific
CEIV Pharma (Certified)
Asian Communities (ex PR. of China and India)

Locations

- Certifications Completed: 40
- Certification in Progress (1 undisclosed): 1
CEIV Pharma (in progress)
Asian Community (ex PR. of China and India)
CEIV Pharma (Certified)
India

Locations

12
Certifications Completed

1
Certification in Progress
CEIV Pharma (in progress)

India

Locations

12 Certifications Completed
1 Certification in Progress
CEIV Pharma (Certified)
People’s Republic of China & SAR Hong Kong

Locations

24 Certifications Completed
8 Certifications in Progress
CEIV Pharma (in progress)
People’s Republic of China & SAR Hong Kong

Locations

- 24 Certifications Completed
- 8 Certifications in Progress
CEIV Pharma (Certified)
ANZAC Communities

Locations

4 Certifications Completed
1 Certification in Progress
CEIV Pharma (in progress)
ANZAC Community

Locations

4 Certifications Completed
1 Certification in Progress
CEIV Pharma (Certified)
Middle East Communities

Locations

15 Certifications Completed
0 Certification in Progress
CEIV Pharma (Certified)
Latin American Communities

Locations

16 Certifications Completed
2 Certifications in Progress
CEIV Pharma (Certified)
African Communities (excl. Middle East)

Locations

- **6** Certifications Completed
- **3** Certifications in Progress
CEIV Pharma (in progress)
African Communities (excl. Middle East)

Locations

- Certifications Completed: 6
- Certifications in Progress: 3
Endorsement from European Shipping Council

Dear Mr. Minister,

We are pleased to be working cooperatively and constructively with you regarding the development of this important program which will help to deliver higher and internationally recognized standards improving the transportation of pharmaceutical products by air.

In that regard, we are recognizing IATA in developing and delivering a training and accreditation as well as education program that meets the needs of pharmaceutical companies and industry alike.

We are therefore pleased to formally welcome the International Air Transport Association (IATA) to the 

European Shipping Council (ESC) in this regard. We look forward to working closely with the (IATA) in delivering the IATA Pharma program and promoting the program’s merits to wider adopting industries.

In this respect, The European Shipping Council fully appreciates the commitment of IATA to enhancing industry standards, making it easier for our clients to adhere to these industry standards. We will work closely with you and other international organizations, as they are the leading voices in the field of transportation of pharmaceutical products by air.

Yours sincerely,

[Signature]

Nick Beerman
Secretary General – European Shipping Council
Endorsement from Belgian Regulator

On November 25, 2014, the Belgian Regulator FAGG – AFMPS formally endorsed the CEIV Pharma Program

▪ The Belgian regulator, the federal agency for medicines and health products (famhp) is endorsing the IATA CEIV program. It has been involved in the BRUcargo community certification from the start of the program. Famhp Inspectors have also participated in the training sessions and workshops.

▪ Josiane Van der Elst, Director General DG Inspection FAGG says “Although this type of IATA certification is not an authority-issued regulatory document, initiatives of structured control on transport are important and welcomed by famhp DG INSPECTION. The IATA certification gives more confidence that pharmaceutical air freight shipments are handled in accordance with EU GDP guidelines”.

▪ fagg – afmps, November 25, 2014
Testimonials

Holistic/community approach is the competitive advantage vs other program. The fact that the program is industry specific is a key differentiator vs GDP.

Frank van Gelder, Adelantex, Freight Forwarder

'IATA CEIV Pharma is an industry-wide standard that serves as a sign of the commitment we are making not only to our customers but also to the pharma industry and end consumers. It has been a year since AirBridgeCargo Airlines have gained IATA CEIV and we were able to demonstrate our ability to protect quality, integrity and consistency of temperature-sensitive pharma products. Being perceived as an industry benchmark, CEIV raised the bar of our performance, encouraging our customers' level of credibility and increasing our volumes, which constitutes 3% of total cargo carried for 9 months of 2017 – significant twofold increase as a confirmation of our competency and expertise in the pharma sector.'

Fedor Novikov, Pharma Director, Global AirBridgeCargo Airlines

'It is obvious that we in Duesseldorf engaged for this ever increasing vertical and are glad to share this with you. Duesseldorf Airport is situated in one of the most industrialized regions in Europe where Pharmaceutical Manufacturing plays a vital role! Ever since we obtained our certification, we saw an increase of 15% of Pharmaceutical Products going through our facilities.'

Gerton Hulsmann, Managing Director, Duesseldorf Cargo GmbH

This is not an IATA program. It was drawn up by the pharma shippers and ourselves and disseminated by IATA. The criteria are set by the shippers and ignoring this program is ignoring the interests of the pharmaceutical industry.”

Steven Polmans, Head of Cargo, Brussels Airport

'Increasingly, we are seeing more shippers requesting for their pharmaceutical cargo to be routed via IATA CEIV Pharma certified hubs and trade lanes.'

Mr. Lim Ching Kiat, Managing Director, Air Hub Development at Changi Airport Group

The program helps reducing the scope of shipper audits. CEIV is good sales tool to promote our business to clients: it ensures a robust cold chain in every step in the supply chain through the airport for handling the pharma shipper’ temperature sensitive products.

Eric Veeckmans, UTi Brussels, Freight Forwarder
Testimonial Video

https://www.youtube.com/watch?v=7QyKRoHwBFI&feature=youtu.be
Thank you

Ronald SCHAEFER
SchaeferR@iata.org
www.iata.org