How to become CEIV Pharma Certified
<table>
<thead>
<tr>
<th>Section</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
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</tr>
<tr>
<td>2.0</td>
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<td>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</td>
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<td>7.0</td>
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CEIV Pharma: Update of activities
Background: Pharmaceutical Market Development
The global biopharma sales trend is projected to go upwards

- By 2022, **world sales of cold-chain drugs and of biologics will likely top $416 billion**, in a global biopharma market exceeding $1.43 trillion.

- **An expansive future for cold chain logistics is expected (at a 5–6 % growth rate)**, driven by
  - continuing transition to biologically based products;
  - tightening requirements for life sciences shipments;
  - growing internationalization of pharmaceutical trade;
  - continued strong growth in vaccines; and
  - continued expansion of clinical trials logistics
  - broader adoption in underdeveloped economies.

---

**Global Biopharma Sales Trend 2014 - 2022 ($ Billions)**

![Graph showing global biopharma sales trend from 2014 to 2022.](image)

- **Cold Chain (growth +53%)**
- **Non-Cold Chain (growth +26%)**
- **Total (growth +29%)**

*Source: Pharmaceutical Commerce*
**Background: Pharmaceutical Market Development**

Cold chain logistics spending is expected to be fastest in Asia and in North America.

<table>
<thead>
<tr>
<th>Region</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia</td>
<td>$3.8</td>
<td>$4.4</td>
<td>$5.2</td>
<td>$5.9</td>
</tr>
<tr>
<td>Europe</td>
<td>$0.9</td>
<td>$1.1</td>
<td>$1.2</td>
<td>$1.4</td>
</tr>
<tr>
<td>North America</td>
<td>$3.3</td>
<td>$3.7</td>
<td>$4.2</td>
<td>$4.7</td>
</tr>
<tr>
<td>Rest of World</td>
<td>$5.3</td>
<td>$5.8</td>
<td>$6.2</td>
<td>$6.6</td>
</tr>
</tbody>
</table>

- With 20% of world’s population, **Europe and North America consume more than 60% of the total pharmaceutical products** (in dollar terms).

- If Asia and the rest of the world used pharmaceuticals at the same level as Europe and North America, the global market would be **3x as large**.

- **Asia is expected to account for the largest regional share growth** with ~$1.5 billion in cold-chain logistics spending growth between 2018 and 2022.

*Source: Pharmaceutical Commerce*
Background: Pharmaceutical Market Development

Spending in biopharma logistics will continue to rise to meet demand

Global Biopharma Logistics Spending (2016 – 2022) ($ Billions)

- It is estimated cold-chain logistics spending in 2018 will be about $15.0 billion worldwide in a $82.3 billion overall pharma logistics market.

- The year-over-year growth rate is ~8% for cold chain logistics and ~2% for non-cold chain logistics.

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)

- $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)

- Air & Parcel: $62.6
- Sea: $10.6
- Truck & Multi Mode: $4.7
- $0.1

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)

<table>
<thead>
<tr>
<th>Country</th>
<th>Export</th>
<th>Import</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>86</td>
<td>73</td>
</tr>
<tr>
<td>India</td>
<td>54</td>
<td>23</td>
</tr>
<tr>
<td>Germany</td>
<td>33</td>
<td>13</td>
</tr>
<tr>
<td>China</td>
<td>20</td>
<td>13</td>
</tr>
<tr>
<td>France</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>UK</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>Belgium</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Other</td>
<td>127</td>
<td>214</td>
</tr>
</tbody>
</table>

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 (%)

Volume
- 1.9%

Airline Cargo Revenue
- 2.6%

Value
- 9.4%

Source: Seabury Global Trade Database (November 2017)
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

<table>
<thead>
<tr>
<th>Handling Code</th>
<th>Avg. Air Cargo</th>
<th>Avg. PIL</th>
<th>Avg. CRT</th>
<th>Avg. COL</th>
<th>Avg. ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRT</td>
<td>1.5</td>
<td>2.5</td>
<td>3</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>COL</td>
<td>1.5</td>
<td>1.5</td>
<td>2</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>ACT</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
</tr>
</tbody>
</table>

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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CEIV Pharma: Update of activities
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></th>
<th>Weight</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCean</td>
<td>91%</td>
<td>30%</td>
</tr>
<tr>
<td>AIR</td>
<td>9%</td>
<td>70%</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

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

- 25% Of vaccines reach their destination degraded because of incorrect shipping.
- 30% Of scrapped pharmaceuticals can be attributed to logistics issues alone.
- 20% Of temperature-sensitive products are damaged 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

- Wasted Logistic Costs: 15.20
- Replacement Costs: 8.60
- Direct Labor Costs: 5.65
- Lost Product Cost: 3.65
- Opportunity Labor Costs: 1.3
- Clinical Trial Costs: 2
- Root Cause Analysis: 2.35
- Trial Production Costs: 2

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
Air Cargo Industry Concerns and Challenges
Temperature Excursions – Where do they occur?

Source: Expeditors
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

- 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

-10°C  +35°C
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>
</tr>
</thead>
</table>
| • Leading pharma companies in these markets have reportedly implemented effective compliance management systems internally. | • Compliance is a priority for the air cargo sector.  
• Air cargo sector performance not encouraging and increased regulation will continue to contribute to the compliance challenges facing the industry. |
| • Pharma companies are realigning their quality and compliance structure to conform to the constantly evolving regulatory guidelines. | • They will demand the same from their business partners. |
| • 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. | • Companies ought to be proactive in setting up stringent internal controls as part of their commitment towards quality and compliance.  
• Include effective training, proper timely communication, periodic reviews / follow-up, and support from the top management. |

**Challenge**

Will Regulators focus on aligning country-specific regulatory frameworks to global standards enabling harmonization of standards and help companies drive efficiencies?
Content

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8.0 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**

The industry usually asks IATA to address their needs to ensure compliance and quality services.
IATA Cargo Services Conference

CARGO SERVICES CONFERENCE (CSC)

- Dangerous Goods Board (DGB)
- Live Animals and Perishables Board (LAPB)
- Cargo Border Management Board (CBMB)
- Airmail Board (AMB)
- ULD Board (ULDB)
- Cargo Operations and Technology Board (COTB)

- TCR
- DGR
- PCR
- LAR
- AHM
- ULDR
- CIMP & CXML
IATA a standard setting organization

IATA adopted a supply chain approach by liaising with all stakeholders…
IATA a Standard Setting Organization
…from the health care industry to establish common standards

2007
Perishable Cargo Regulations (PCR)
Industry standard

2008
2009
2010
PCR
New Chapter 17
New T&T
Sensitive Label

2011
2012
Mandatory T&T Sensitive Label

2013
Mandatory Standard Checklist

2014
Provides requirements + standards for transporting pharma products

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

<table>
<thead>
<tr>
<th>EXISTING</th>
<th>NEW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards and Regulations</td>
<td>NEW</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Training (Recruent Training)</td>
<td>Assessment</td>
</tr>
</tbody>
</table>

- **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.

**EXISTING**

1. **Standards and Regulations**
   - Advocate for globally accepted standards and regulations
   - Establish validation checklist with industry
   - Establish industry steering group

**NEW**

2. **Training (Recurrent Training)**
   - Develop training contents
   - Develop assessment criteria for instructors and validators exam
   - Train instructors, validators and industry stakeholders
   - Manage database of certified instructors and validators

3. **Assessment**
   - Develop pre-validation assessment toolkit
   - Develop a standard validation methodology and assessment tool

4. **Validation (Audit) & Award**
   - 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"

5. **Re-Validation (Re-Audit)**
   - 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.
- **Elevate staff competency levels** through efficient and robust training program.
- **Create a global and consistent certification** that industry can rely on.

Ensure product integrity
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>
<thead>
<tr>
<th>EU GDP</th>
<th>IATA CEIV Pharma</th>
</tr>
</thead>
<tbody>
<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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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 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
   - 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

5. **Certification**

6. **Additional Training**

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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?

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

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

<table>
<thead>
<tr>
<th></th>
<th>TRAINING CENTER</th>
<th>IN-COMPANY TRAINING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost</strong></td>
<td>$</td>
<td>$$</td>
</tr>
<tr>
<td><strong>No. of Participants</strong></td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>Inflexible</td>
<td>Flexible</td>
</tr>
</tbody>
</table>

Training required for certification
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 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

...and 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

<table>
<thead>
<tr>
<th><strong>Step 1: Assessment</strong></th>
<th><strong>Step 2: Validation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharma handling criteria checklist.</strong></td>
<td><strong>Progress report</strong> to review the progress made against recommendations during the assessment phase.</td>
</tr>
<tr>
<td><strong>Report</strong> covering the <strong>findings and recommendations</strong> based on the assessment.</td>
<td><strong>Implementation plan update.</strong></td>
</tr>
<tr>
<td><strong>Implementation plan.</strong></td>
<td><strong>Recommendation to award certification as &quot;CEIV Pharma certified&quot;</strong> based on satisfactory compliance of CEIV criteria.</td>
</tr>
<tr>
<td>Report and implementation plan will set out assumptions, findings, results, conclusions and recommendations and will specifically:</td>
<td><strong>Presentation</strong> of the validation findings to Senior Management.</td>
</tr>
<tr>
<td>- Identify <strong>critical elements</strong> that are not compliant with national and international Regulations and the defined CEIV Pharma Handling criteria (e.g. TCR);</td>
<td></td>
</tr>
<tr>
<td>- Outline the <strong>impact of non-compliance</strong>; and</td>
<td></td>
</tr>
<tr>
<td>- Identify <strong>elements that are inefficient.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Presentation to Senior Management.</strong></td>
<td></td>
</tr>
</tbody>
</table>
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
- **Validation**: 2 days on-site
- **Training required for certification**: 4-12 weeks
  - Ideally completed before assessment.
  - Needs to be completed before validation.

- **Additional Training**: 12 months after certification

Timeframe depends on results of assessment.
Certification Timeline (requirement)
Pharma shippers demanded to impose timelines

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

  **Refresher Training**
  - 1 - 2 days

  - e.g. update on new regulations, development on new standards, development of new containers, etc.

  **Close gaps**

  **Validation**
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;</td>
<td>• A group of companies at one airport decide to get &quot;CEIV Pharma Certified&quot;</td>
<td>• A group of companies decide to get &quot;CEIV Pharma Certified&quot; at several airports to form several “pharma gateways”</td>
</tr>
<tr>
<td>• One or several stations</td>
<td>• Form a “pharma gateway”</td>
<td>• Supply chain approach</td>
</tr>
<tr>
<td></td>
<td>• Supply chain approach</td>
<td></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)

<table>
<thead>
<tr>
<th>Pharma shippers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer, Actelion, Johnson &amp; Johnson, Janssen, Sanofi, UCB, Alcon, AGFA, Zoeth, Teva, MSD, Baxter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forwarders with pharma focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expeditors, DHL, DB Schenker, red Nine, Bapi, Nippon Express, Schenker, Panalpina, Docks, Kuehne + Nagel, SF Express, Kuehne + Nagel, Lynden International, World Courier</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Handlers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aviapartner, swissport Cargo Services, WFS, Skylink</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Truckers</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHL, H. Essers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Airlines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brussels Airlines Cargo, Finnair, Air Cargo, ACMAB</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fagg, IATA, EASA, TTTF</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airport Academy</td>
</tr>
</tbody>
</table>
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?**

**TASK**
- 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

Qualification

- IATA conducts **preliminary interview** with candidate to pre-qualify candidate for training
- IVs must undergo IATA training
- IVs need to **complete trainings within six months**
- IV’s can also become instructors but need to undergo the IATA **Train-the-trainer course** (optional)

Management

- IVs are **registered** in IATA database and available to complete the assessments and validations
- **Coordination of IVs is managed by the IATA** team for assessments and validations
- **IV 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

Validators
- Person X
- Person Y

Instructors
- Person X
- Person Y

QM
- Independent Validator

Frederic LÉGER
Laurent DELARUE

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
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
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

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

Benefits: A win-win opportunity for all stakeholders

CEIV Pharma: Update of activities
CEIV Pharma Development
From Pilot to Launch

Discussion with SATS about a Pilot

SATS Pilot

Development of CEIV Pharma Standard 1.0

Development of Community Concept with BRU

Launch of Community Concept at BRU

Official launch of CEIV Pharma program

Recertification of CEIV Pharma program

Development of CEIV Pharma Standard 1.3 + updated Guidelines

Unreliable cargo industry loosing pharma industry: IATA sleeping

All companies of the first community will undergo recertification
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

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

* See map for specific locations and certifications.
CEIV Pharma (Community Approach)

Community Approach Development Worldwide

Location

- **20** Ongoing Communities
- **6** Communities in Discussion
CEIV Pharma (Certified)
North American Community

Locations

47 Certification Completed
(2 x LATAM (Airline + MIA Station))

11 Certification in Progress

Cities:
- Atlanta (2X)
- Boston
- Chicago
- Columbus
- Dallas
- Indianapolis
- Kansas City
- Lester
- Los Angeles
- Miami
- New York
- Puerto Rico
- Saint Louis
- San Diego
- San Francisco
- Tampa
CEIV Pharma (Community Approach)
Community Approach Development Europe

Location
80 Stations participating in Community Approach in Europe
CEIV Pharma (Community Approach)

Community Approach Development Europe

Location

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

Location
79 Stations participating in Community Approach in Europe
CEIV Pharma (Community Approach)
Community Approach Development Asia

Location
31 Stations participating in Community Approach in Asia
CEIV Pharma (Certified)
Spain

Locations
14 Certification Completed
5 Certification in Progress
CEIV Pharma (in progress)
Spain

Locations

14 Certification Completed
5 Certification in Progress
CEIV Pharma (Certified)
Portugal

Locations

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

Locations

11 Certification Completed
5 Certification in Progress
CEIV Pharma (in progress)
France

Locations

- 11 Certification Completed
- 5 Certification in Progress
CEIV Pharma (Certified)

Belgium

Locations

21 Certification Completed
0 Certification in Progress
CEIV Pharma (Certified)
Netherlands

Locations

13 Certification Completed
7 Certification in Progress
CEIV Pharma (in progress)
Netherlands

Locations

13 Certification Completed
8 Certification in Progress
CEIV Pharma (Certified)

Germany

Locations

17 Certification Completed
3 Certification in Progress
CEIV Pharma (in progress)
Germany

Locations

17 Certification Completed
3 Certification in Progress
CEIV Pharma (Certified)
Ireland

Locations

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

Locations

- **8** Certification Completed
- **1** Certification in Progress

![Map of Italy](image-url)
CEIV Pharma (in progress)
Italy

Locations

- Certification Completed: 8
- Certification in Progress: 1
CEIV Pharma (Certified)
Hungary

Locations

1 Certification Completed
0 Certification in Progress
CEIV Pharma (in progress)
Greece

Locations
- 2 Certification Completed
- 4 Certification in Progress
CEIV Pharma (Certified)
Switzerland

Locations

<table>
<thead>
<tr>
<th>Certification</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>10</td>
</tr>
<tr>
<td>In Progress</td>
<td>2</td>
</tr>
</tbody>
</table>
CEIV Pharma (in progress)
Switzerland

Locations

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

Locations

4 Certification Completed
0 Certification in Progress
CEIV Pharma (in progress)

Sweden

Locations

1 Certification Completed

0 Certification in Progress
CEIV Pharma (Certified)
Denmark

Locations

3 Certification Completed
1 Certification in Progress
CEIV Pharma (in progress)

Denmark

Locations

3 Certification Completed
1 Certification in Progress
CEIV Pharma (Certified)

Norway

Locations

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

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

Locations

1 Certification Completed
1 Certification in Progress
CEIV Pharma (in progress)

Russia

Locations

1 Certification Completed
1 Certification in Progress
CEIV Pharma (Certified)
Turkey

Locations
- Certification Completed: 3
- Certification in Progress: 0

Airline + GHA IST
KUEHNE + NAGEL
CEIV Pharma (Certified)
Asian Community (ex PR. of China and India)

Locations
19 Certification Completed
12 Certification in Progress (1 undisclosed)
CEIV Pharma (in progress)
Asian Community (ex PR. of China and India)

Locations

19 Certification Completed
12 Certification in Progress (1 undisclosed)
CEIV Pharma (Certified)

India

Locations

5 Certification Completed
6 Certification in Progress
CEIV Pharma (in progress)
India

Locations

5 Certification Completed
6 Certification in Progress
CEIV Pharma (Certified)
People’s Republic of China & SAR Hong Kong

Locations

16 Certification Completed
6 Certification in Progress
CEIV Pharma (in progress)
People’s Republic of China & SAR Hong Kong

Locations
16 Certification Completed
6 Certification in Progress
CEIV Pharma (Certified)
ANZAC Community

Locations

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

Locations

- 4 Certification Completed
- 1 Certification in Progress
CEIV Pharma (Certified)
Middle East Community

Locations

- Certification Completed: 6
- Certification in Progress: 1
CEIV Pharma (Certified)
Latin American Community

Locations

10 Certification Completed
1 Certification in Progress
CEIV Pharma (in progress)
Latin American Community

Locations

10 Certification Completed
1 Certification in Progress
CEIV Pharma (Certified)
North American Community

Locations

Certification Completed
(2 x LATAM (Airline + MIA Station))

Certification in Progress

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

Chicago
Cincinnati
Los Angeles
Miami
Philadelphia
Puerto Rico

Chicago
Cincinnati
Los Angeles
Miami
Philadelphia
Puerto Rico

Atlanta (2X)
Boston
Chicago
Columbus
Dallas
Indianapolis
Kansas City
Lester
Los Angeles
Miami
New York
Puerto Rico
Saint Louis
San Diego
San Francisco
Tampa
CEIV Pharma (in progress)
North American Community

Locations
47 Certification Completed
19 Certification in Progress
CEIV Pharma (Certified)

African Community

Locations

- 3 Certification Completed
- 3 Certification in Progress
CEIV Pharma (in progress)
African Community

Locations
3 Certification Completed
3 Certification in Progress
Endorsement from 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
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 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
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
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7.0 Benefits: A win-win opportunity for all stakeholders
8.0 CEIV Pharma: Update of activities
Thank you

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