CEIV
Center of Excellence
for Independent Validators

Pharmaceutical Handling

HOW TO BECOME CEIV PHARMA CERTIFIED

Q1 2016

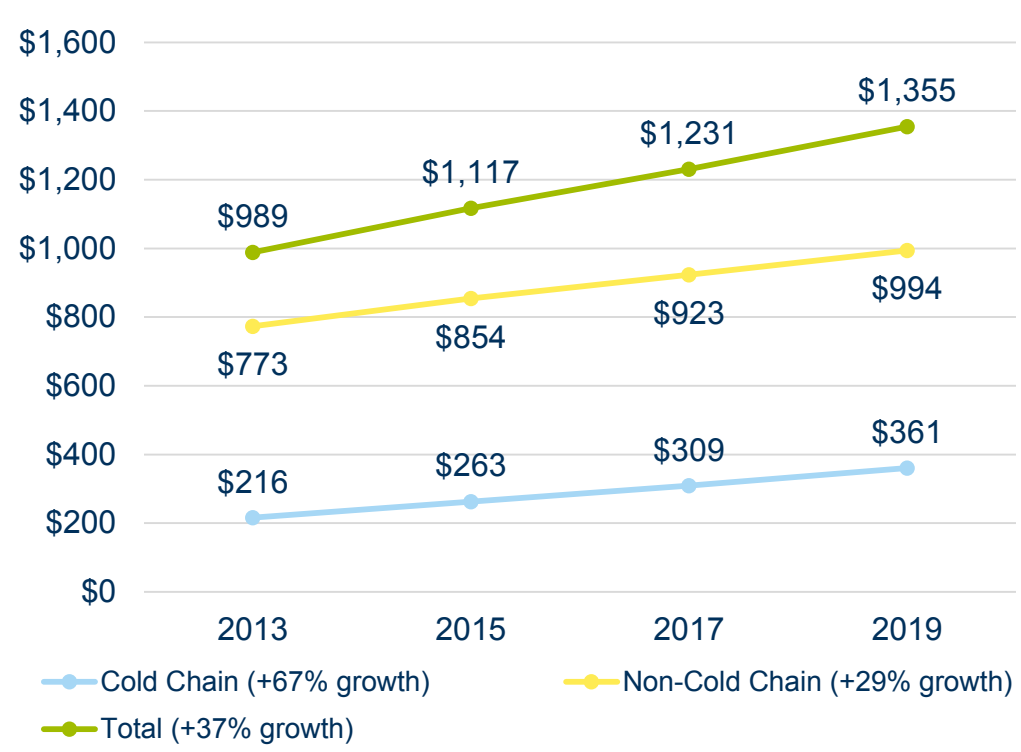
Content

Content

Background: Pharmaceutical Market Development

The global biopharma sales trend is projected to go upwards through 2019: A promising forecast

Global Biopharma Sales Trend 2013 - 2019
($ Billions)



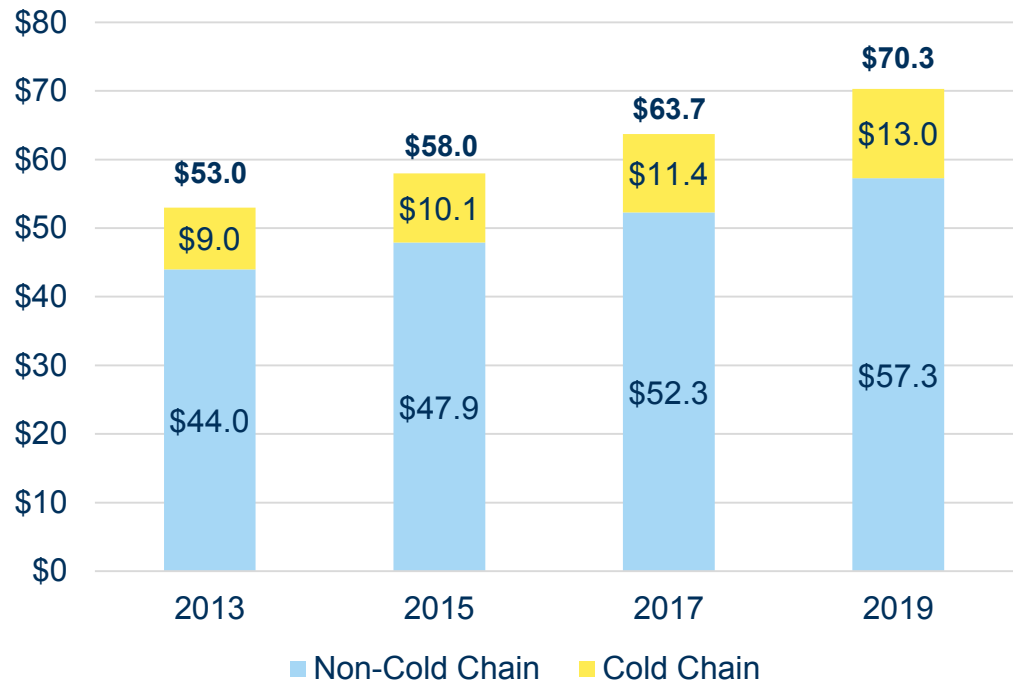
Source: Pharmaceutical Commerce

- The outlook is for continued expansion through 2019, at an average growth rate of about **6% per year**, about the same as the 6% uptrend in the 2012–2018 forecast last year.
- **An expansive future for cold chain logistics is expected**, driven by introductions of new biotech therapies and even more by the expanding usage of cold chain products in developing countries.

Background: Pharmaceutical Market Development

Spending in biopharma logistics will to continue to rise to meet the demand: An encouraging outlook

Global Biopharma Logistics Spending
($ Billions)



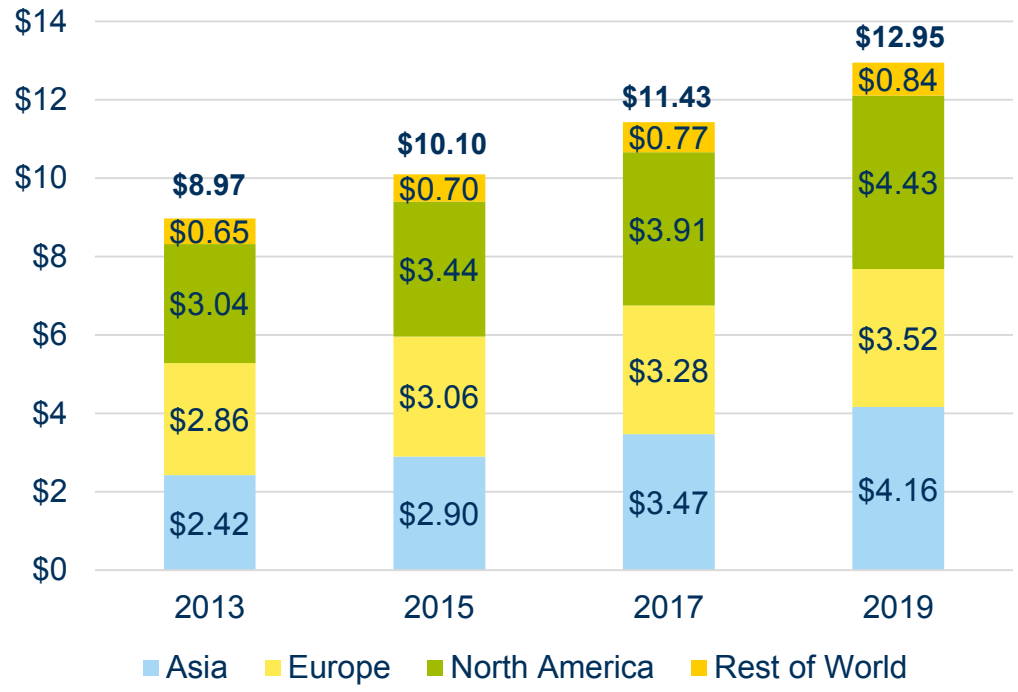
Source: Pharmaceutical Commerce

- **By 2019**, world sales of cold-chain drugs and of biologics such as **vaccines and blood plasma products will likely top $361 billion**, in a **global biopharma market exceeding $1.3 trillion.**
- It is estimated cold-chain logistics spending in 2015 will be about **$10.1 billion worldwide** in a $58 billion overall pharma logistics market.
- Clinical trial logistics, a substantial market for temperature-assured transport, is forecasted to grow at 2.5%/yr

Background: Pharmaceutical Market Development

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

Global Biopharma Sales Trend 2013 - 2019
($ Billions)



Source: Pharmaceutical Commerce

- 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 more than $1.2 billion of cold-chain growth through 2019.

A variety of forces are driving cold-chain spending growth

A sustained advance

DRIVERS

- The biggest drivers of cold-chain logistics over the next few years will be
  - **continued development**;
  - **approval and market penetration of biotechnology-derived drugs**; and
  - expansion in both usage and production of these drugs and other cold-chain products in **emerging markets**.

% GROWTH

- **Unit demand of insulin, the largest cold-chain drug in volume, are growing 6% per year globally** with much faster growth in emerging markets
- A good example is China, which as of 2014 had about one-quarter of the world's diabetic population but used only 6% of the world's insulin.

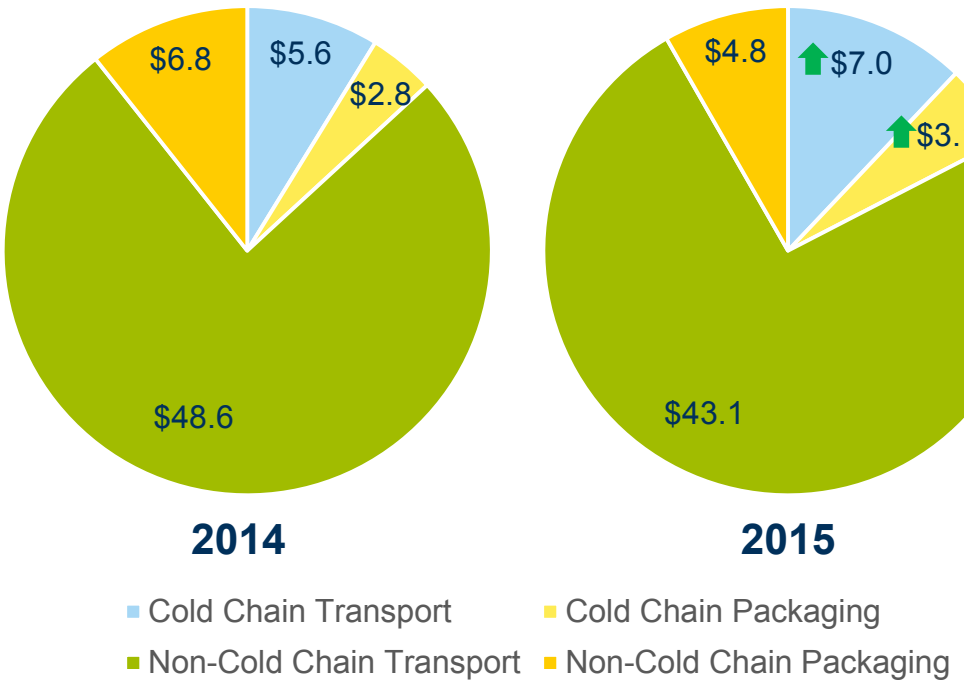
DEVELOPMENT

- Pharma companies and their logistics providers have risen to the task of following all applicable regulations, particularly for high-value cold-chain products.
- They have also taken on challenges of operating efficiently worldwide, aided in some cases by strategic regional investments and acquisitions.

Background: Pharmaceutical Market Development

Global Industry will spend $10.1 billion on cold chain logistics in 2015, up from $8.4 billion in 2014

Estimated Breakdown of Cold-Chain Logistics Costs - 2014 vs 2015
($ Billions)



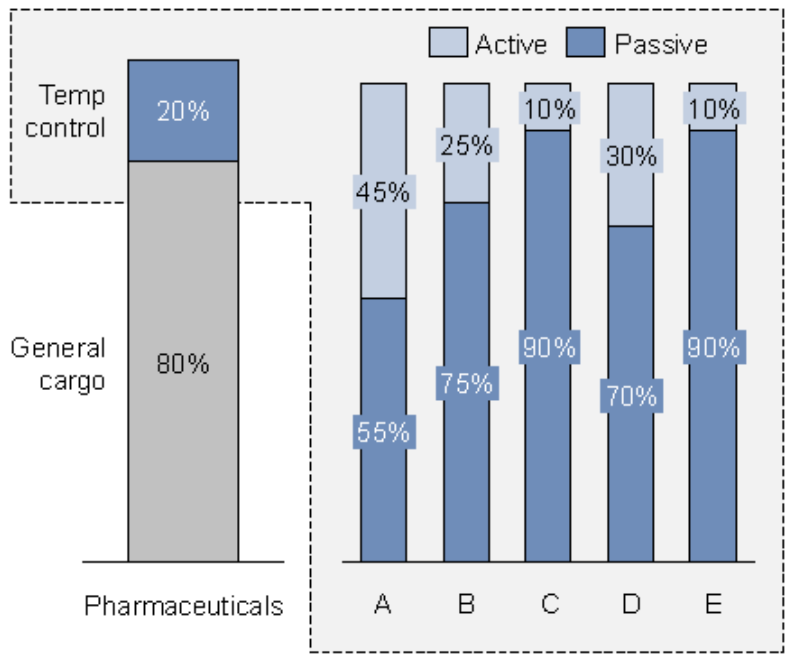
Source: Pharmaceutical Commerce

- **$7.0 billion will be in cold chain transportation**
- $3.1 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.
- Although non-cold chain transport and packaging significantly decreased, **cold chain transport and packaging spending increased by 20%**

Background: Pharmaceutical Product Logistics

Temperature control share of pharma

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

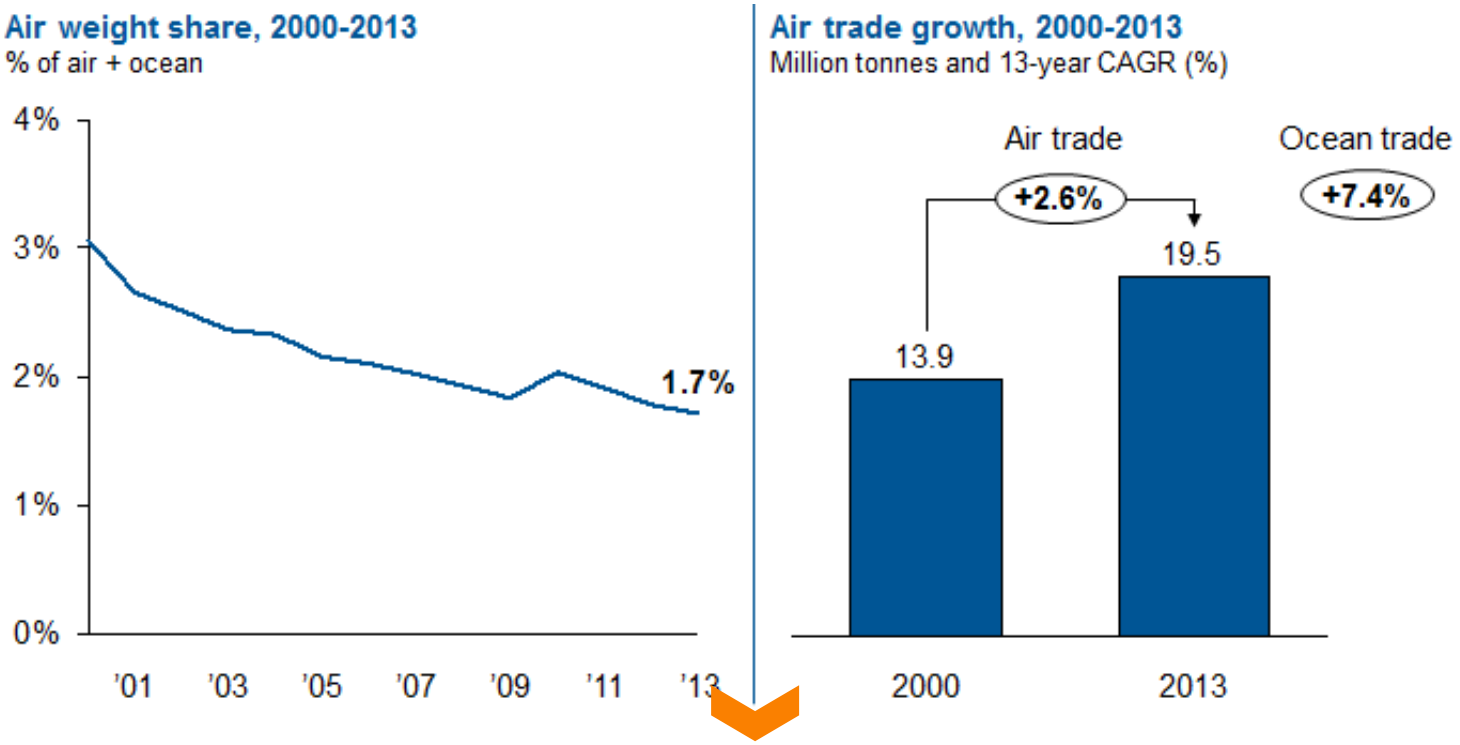


Source: Seabury, BRU Cargo

- 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.

Background: Air freight has lost "market share" to ocean freight

Air trade represents ~1.7% of containerized trade weight, after having lost more than 1 point over the last 13 years; average growth in ocean trade far exceeds expansion in air trade



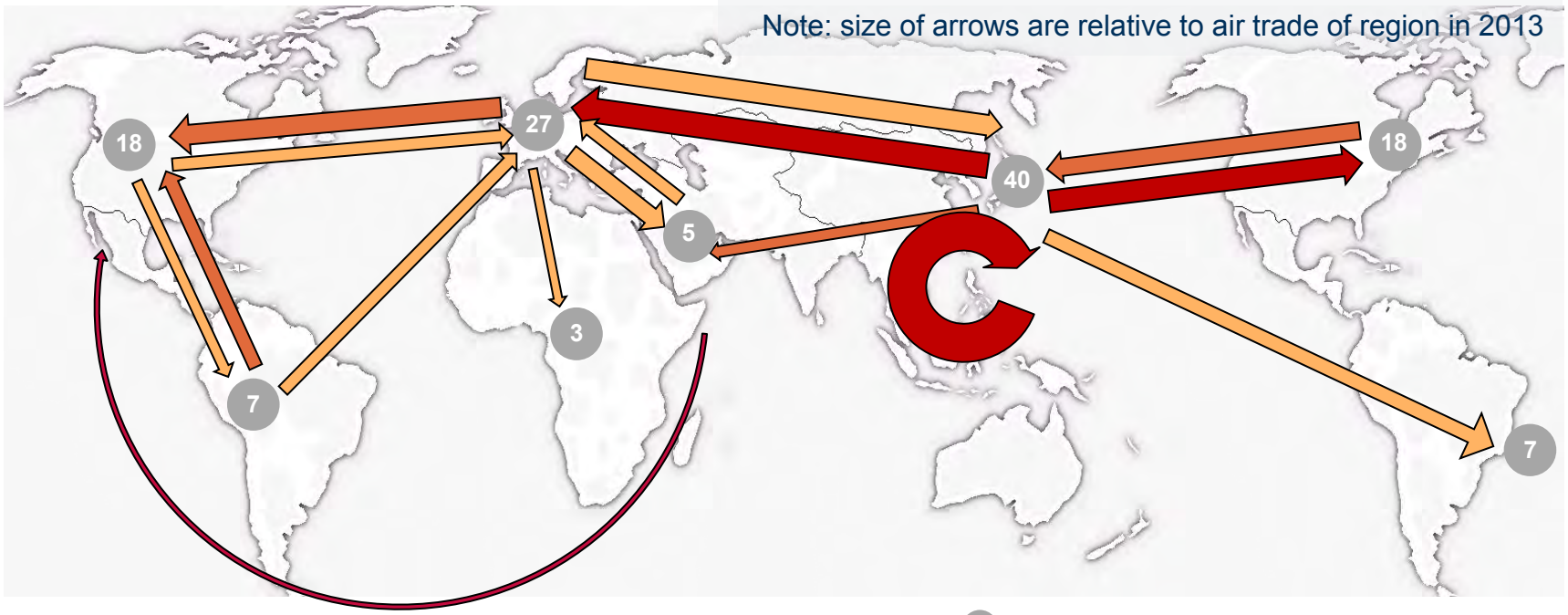
Modal shift of 5.4 million tonnes over 13 years corresponds to an average of ~413,000 tonnes shifting to ocean every year

Source: Seabury Global Trade Database

Background: Trade lanes originating in Asia have seen the strongest shifts

Intra-Asia, Transpacific and Asia-Europe have seen substantial volumes shifting to ocean; emerging trade lanes such as LATAM or M. East & S. Asia are relatively less affected

Total mode shift since 2000 by weight



Intensity of mode shift (average shift per year):

- **Strong shift to Ocean** (More than 400,000 tonnes since 2000)
- **Moderate shift to Ocean** (200,000 to 400,000 tonnes since 2000)
- **Low shift to Ocean** (less than 200,000 tonnes since 2000)

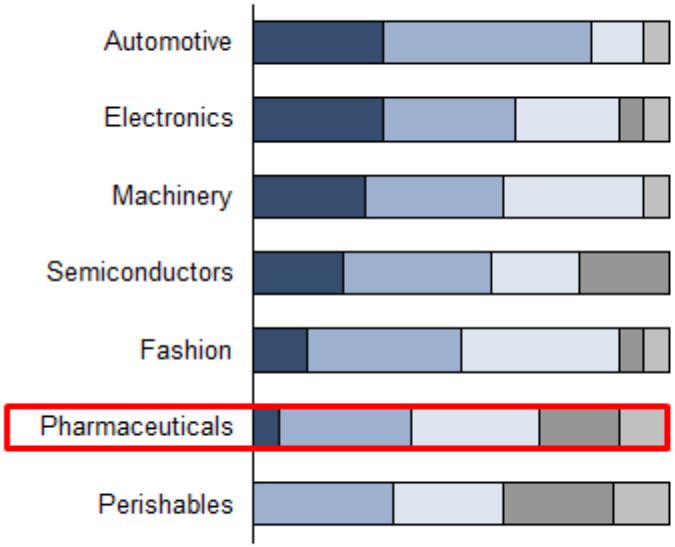
% Regional Share of Total Air Trade

Source: Seabury Global Trade Database

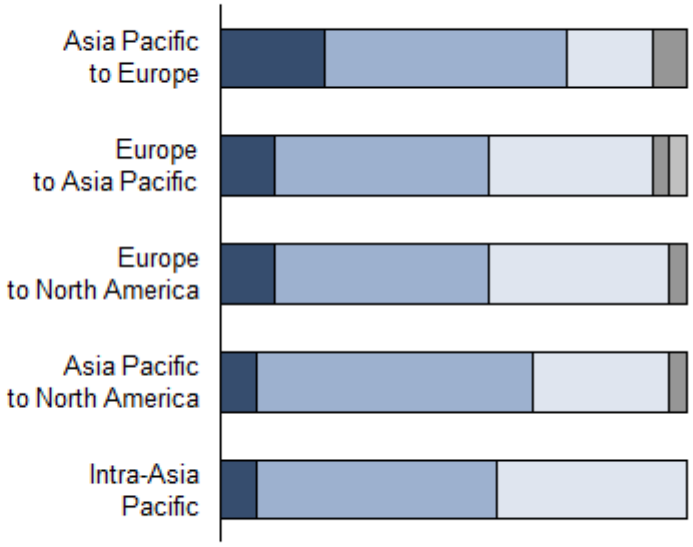
Background: What is the future of mode shift?

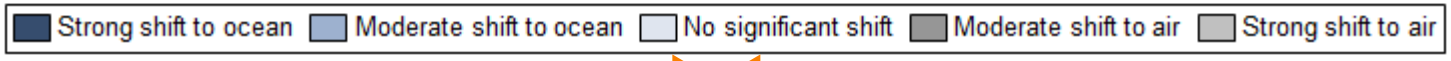
Industry expects a moderate shift to ocean, on no specific trade lane; impact of mode shift is expected to be higher for automotive, electronics and machinery goods

What industries will be impacted by mode shift?
respondents (forwarders)



Where will mode shift occur?
respondents (shippers)



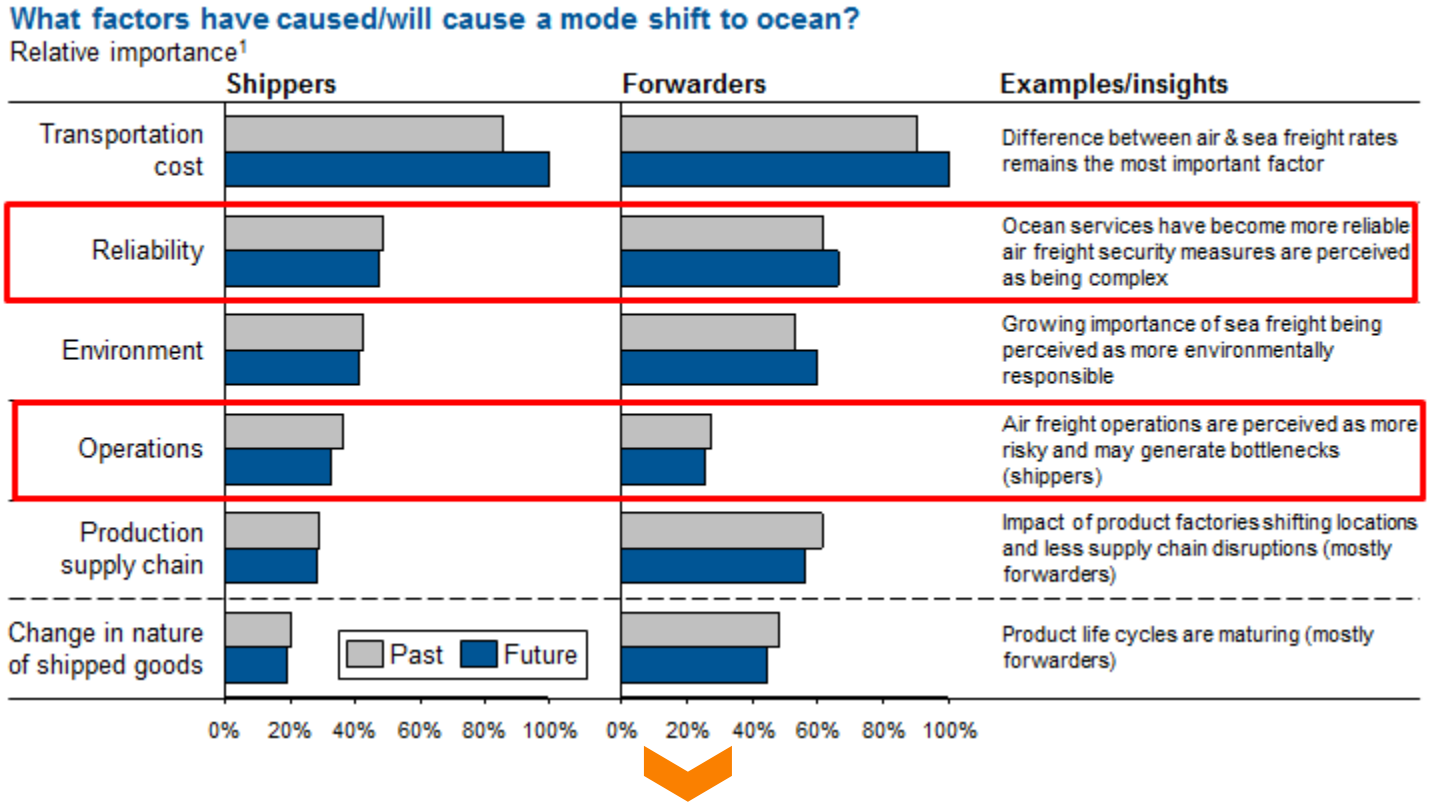


While perishables have largely shifted to Ocean over the past decade, forwarders do not expect this trend to continue but Pharma will

Source: Seabury Global Trade Database

Background: What factors will be driving mode shift?

Industry believes transportation cost has been and will remain the number one factor; shippers and forwarders alike place reliability and environment next in importance

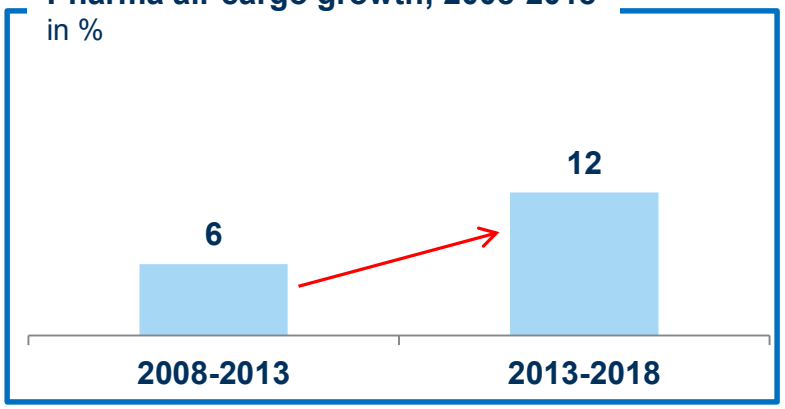


Reliability and Operations becomes two important deciding factors to shift mode after Transportation cost for both shippers and forwarder

Background: The impact of mode shift on pharmaceutical logistics

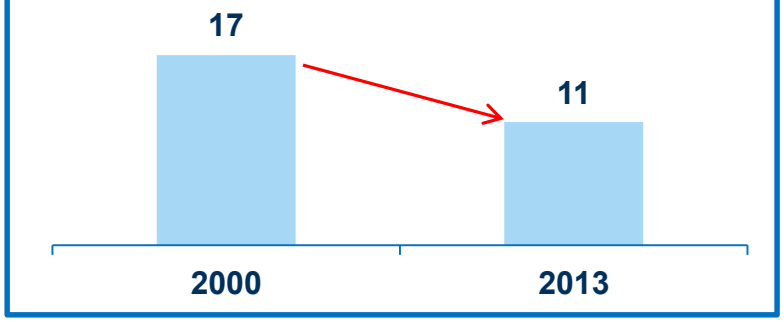
The pharmaceutical industry has relied heavily on the airline industry for its speed and efficiency but air cargo's share of global pharmaceutical products transport has dropped

Pharma air cargo growth; 2008-2018
in %



HOWEVER

Air cargo's share of global pharmaceutical products transport (in %)



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

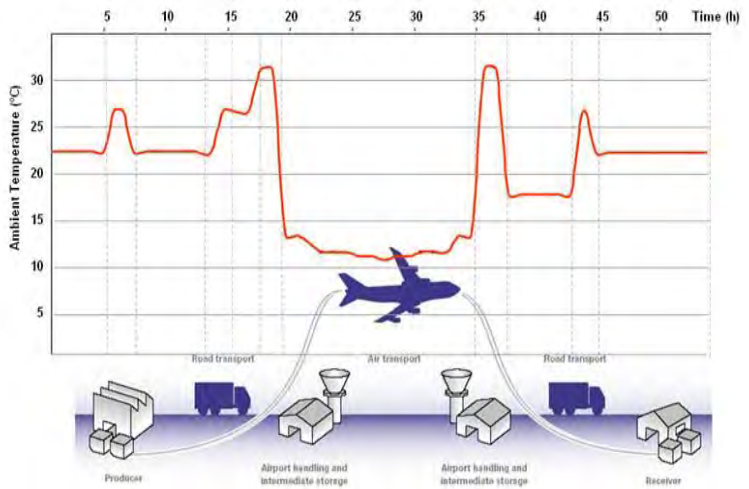
Source: Pharmaceutical Commerce

Background: Critical Issues Raised by the Shippers

Increasing shift in pharmaceuticals transported by sea due to air cargo challenges

- **More than 50% 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

- **Annual product losses between US$2.5-12.5 billion due to various reasons including temperature excursions during transport and shipping.**

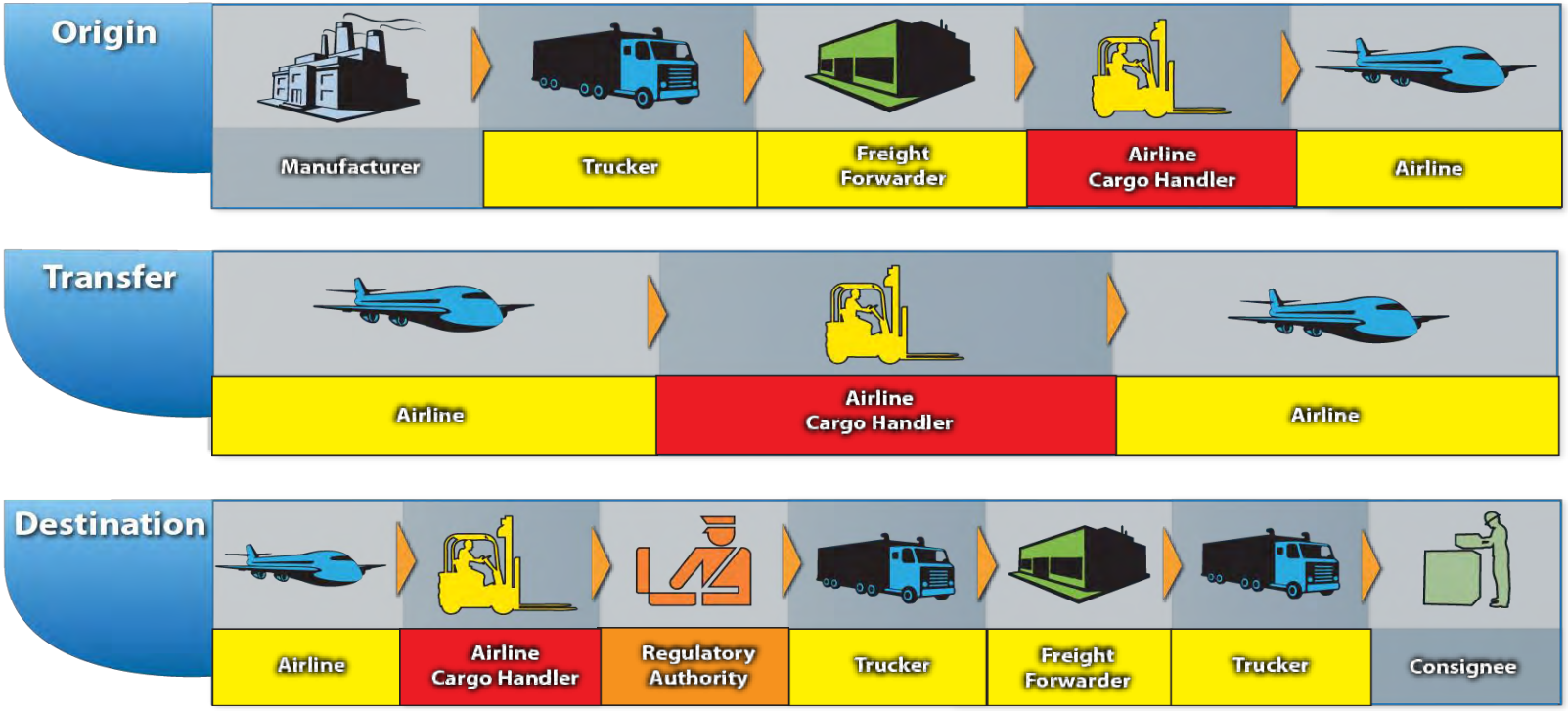


Due to a lack of compliance, standardization, accountability and transparency across the air transport supply chain

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

Background: Air Cargo Industry Concerns and Challenges

Temperature Excursions – Where do they occur?

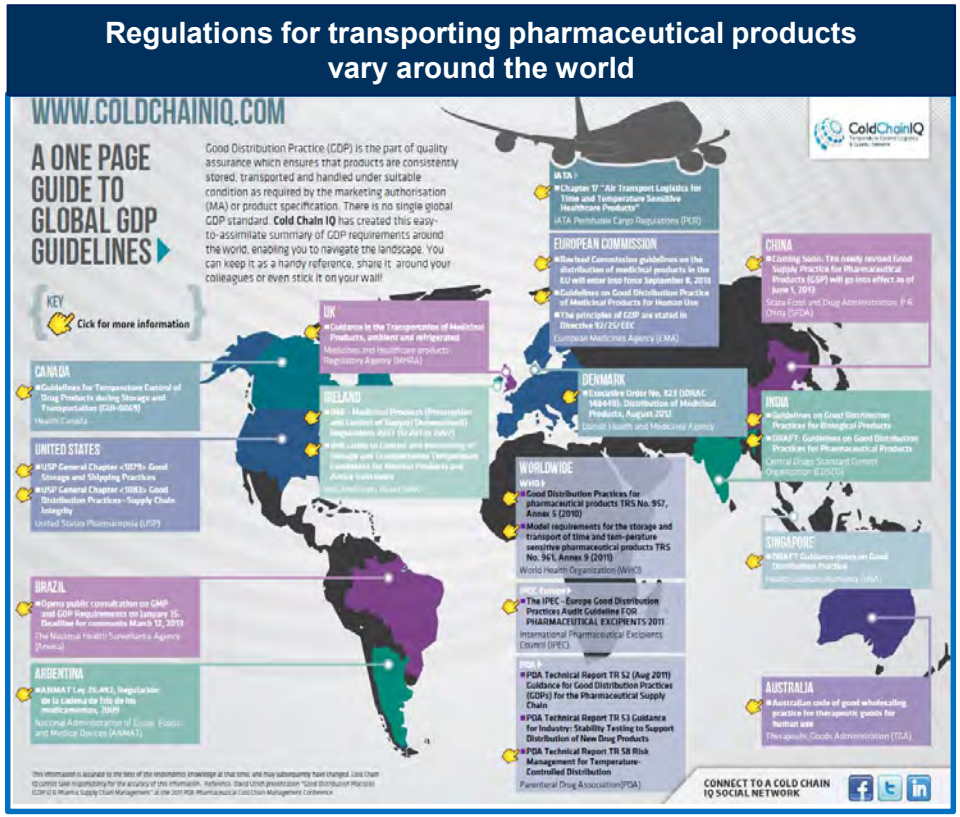


Source: Expeditors

Background: Air Cargo Industry Concerns and Challenges

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

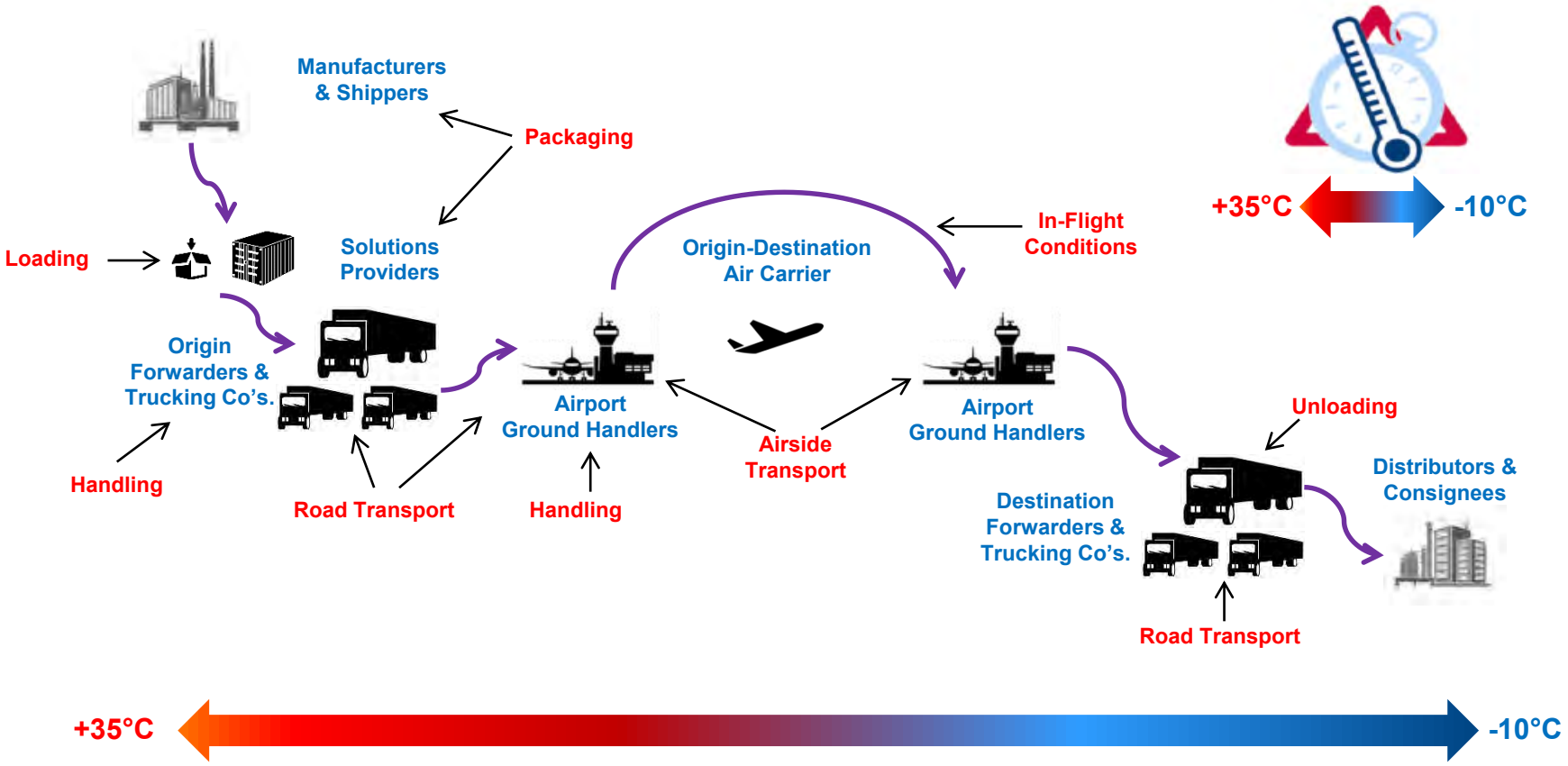
Regulations for transporting pharmaceutical products vary around the world



- **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.

Background: Air Cargo Supply Chain Challenges

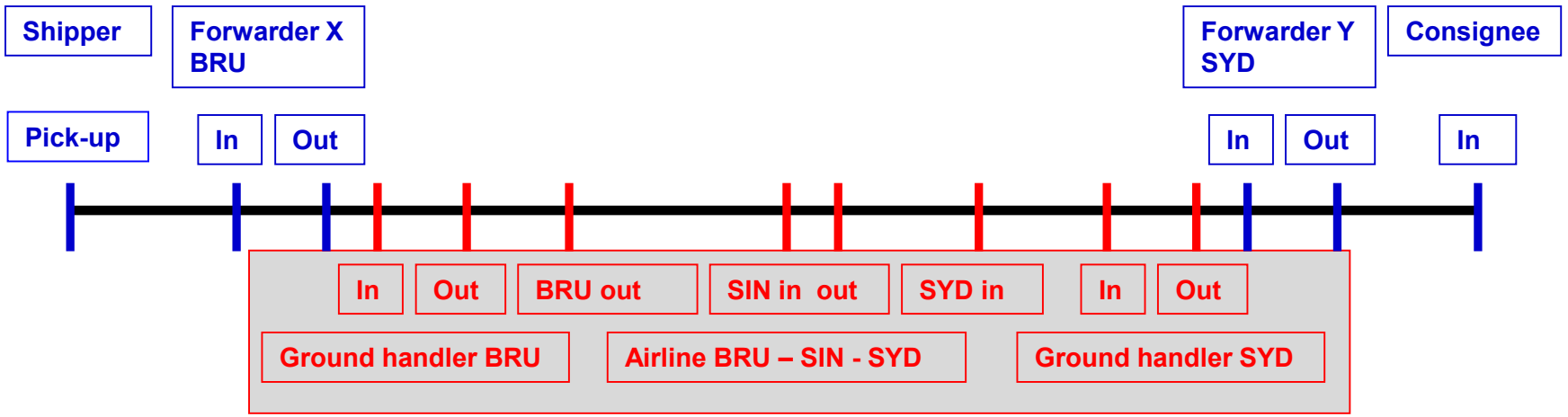
From origin to destination pharmaceutical products can be exposed to different climates



Background: Transparency in pharmaceutical logistics

Shippers have difficulties identifying industry stakeholders that meet standards and regulations at origin and destination

Example of Flow from BRU to SYD



14 milestones from start to end.

HOW CAN YOU MANAGE THIS ?

Source: BRUCargo

Background: Shippers Expectations in Cold Chain

Shippers need service providers that maintain product 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**

Content

1.0 Introduction: Pharma logistical market growing but air cargo losing market share to other modes of transportation

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

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

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

5.0 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

6.0 Benefits: A win-win opportunity for all stakeholders

7.0 CEIV Pharma: Update of activities

Industry Cooperation in Air Cargo

The nature of the business requires strong industry cooperation – Strong stakeholder management is required

Background: Industry Cooperation in Air Cargo

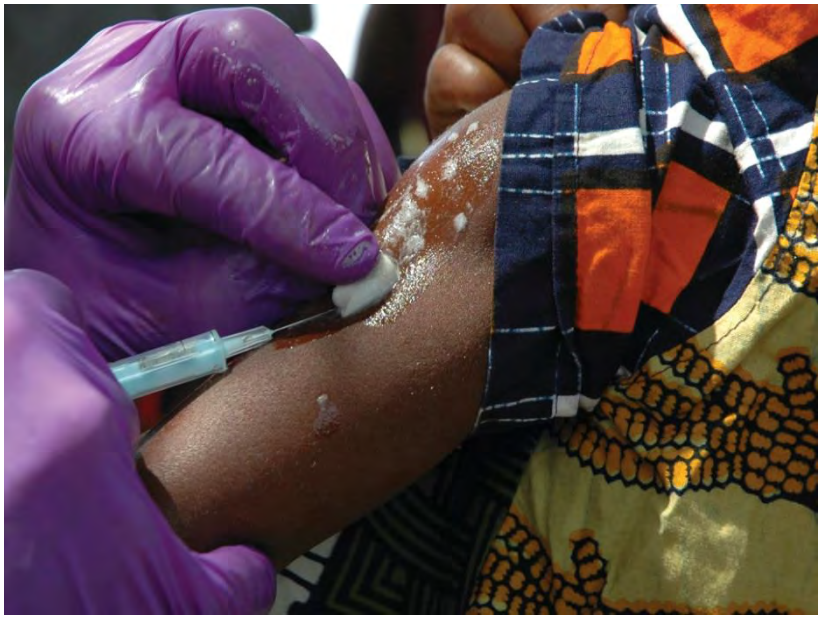
The Time and Temperature sensitive goods play an important role in air cargo

- With the **healthcare market becoming a key engine of the global economy**, pharmaceutical and biomedical industries are facing new challenges in adapting to globalization.
- **Speed to market is** therefore **essential** and the healthcare industry is increasingly dependent upon air cargo.

Background: Industry Cooperation

Why is air cargo so important?

Temperature Sensitive Products



- **Immunization prevents 2.5 million deaths** every year
- **Air cargo is critical** in flying vaccines to their destination in time to be effective.

IATA a Standard Setting Organization

Over the years, IATA has successfully implemented and disseminated of standards

Step 1: Implementation

Industry feedback driving improvements:

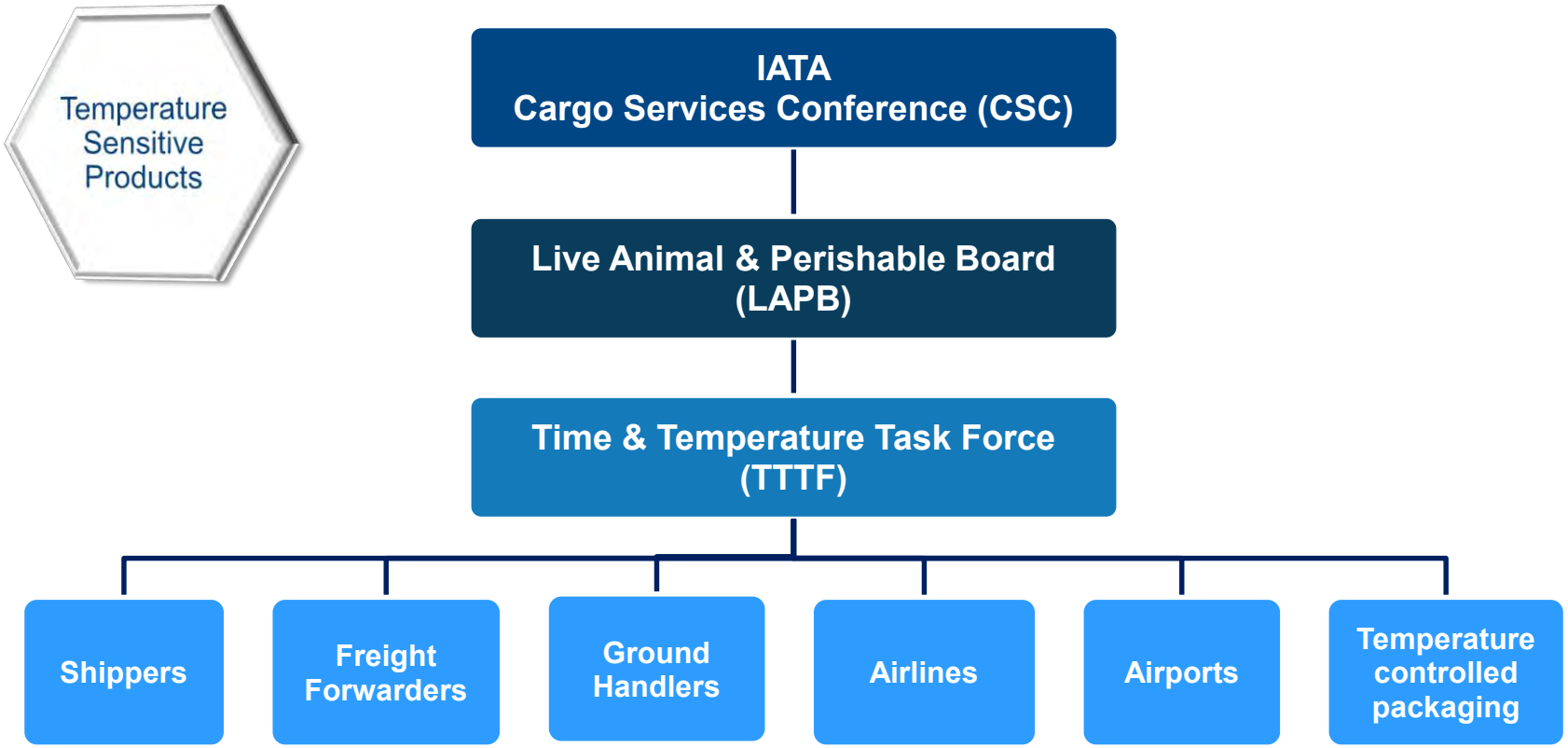
- Need for standardization in the handling of pharmaceutical products in air cargo environment
- Need to enhance partnership and communication
- Need to ensure appropriate training in the supply chain

Step 2: Dissemination

The industry usually asks IATA to address their needs to ensure compliance and quality services

IATA a standard setting organization

IATA uses a supply chain approach for developing and disseminating time and temperature sensitive standards



IATA a Standard Setting Organization

Since 2007 IATA and its industry stakeholders have developed a number of temperature sensitive 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

Must be affixed to all shipments booked as T+T sensitive cargo

2013
Mandatory Standard Checklist

2014

Provides requirements + standards

IATA a Standard Setting Organization

IATA uses different means for dissemination of standards in the industry

Content

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CEIV Pharma

To ensure the integrity of the product throughout the supply chain

OBJECTIVES

Ensure product integrity

Prevent sanitary issues caused by temperature excursions during transportation.

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

Elevate level staff competency through efficient and robust training program.

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

CEIV Pharma targets

Who does CEIV Pharma target? The supply chain

Trucking Companies

Freight Forwarders

Distributors

Ground Handlers

Airlines

Airports

Center of Excellence for Independent Validators

Improve together to protect and grow our industry

IATA | CEIV
Center of Excellence for Independent Validators

The Need

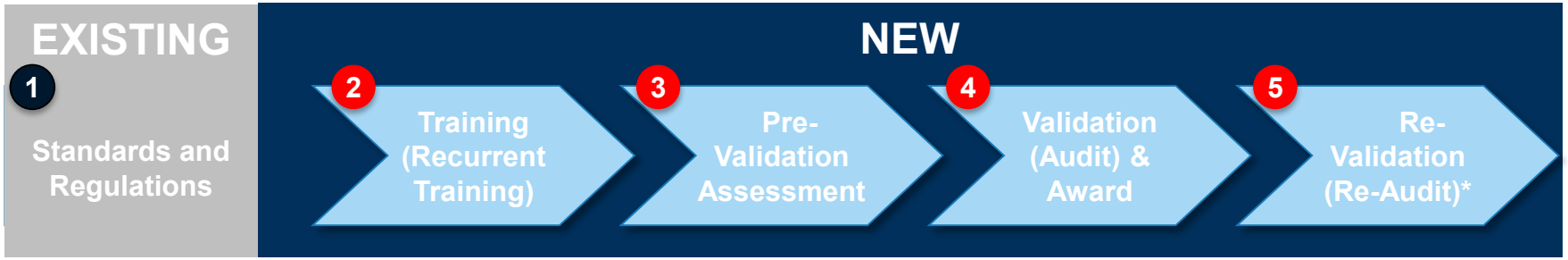
- … for more safety, security and efficiency
- … to raise the bar to (re)gain confidence
- … to improve compliance to standards/regulations
- … for independent assessments vs. self-assessments
- … to identify and recognize the best players
- … to harmonize and reduce the number of audits

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

Approach of the CEIV



- **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**

CEIV ACC3 – Example

All affected air cargo and mail carriers operating into EU and EEA from third countries (ACC3) must obtain an independent validation of their security program

SITUATION

- **July 2014 deadline** for compliance with new EU regulation is fast approaching.
- **Airlines** and other entities (non-EU governments) have **requested** for **assistance**.
- **Some** airlines are **not prepared**.
- **Carriers risk** the **loss of** cargo **revenues**.

IATA RESPONSE

- **IATA** has been **encouraged** by its member airlines and European Regulators **to help prepare air carriers** for the ACC3 EU Security Validation process.
- **Center of Excellence for Independent Validators (CEIV)** to train, advice and support industry stakeholders**.**
- **CEIV offers a comprehensive solution** in an effort to assist both the aviation industry and its regulators.

OBJECTIVES OF CEIV

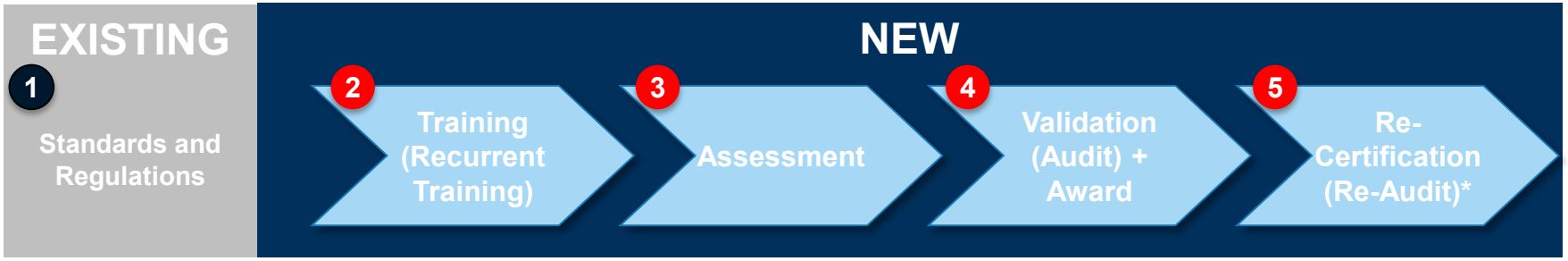
- **Provide** Pre-validation assessment **guidelines.**
- **Provide** standard **validation methodology and** self-assessment **tools.**
- **Scope of countries and stations that need validation.**
- **Training courses** to prepare validators and airlines.
- **EU ACC3 Readiness Workshop.**
- **Aviation Security Independent Validators Training.**

PRE-ASSESSMENT APPROACH

Off-site review of documentation → In-company readiness training workshop → On-site pre-validation assessment → Findings and recommendations

Proposed Solution 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

Objectives of CEIV Pharma Services

Global certification for handling of pharmaceutical products…

Pharmaceutical companies have auditors who audit the industry to ensure that relevant regulations are followed and services rendered according to SLAs

IATA seeks to **improve** the **handling of pharmaceutical cargo** in line with existing regulations and standards:

- **Operations will be audited**, and certified by IATA against regulations and standards.
- **Locations** that complete and pass the validation will be **awarded and recognized as "CEIV Pharma Certified".**

Such a qualification performed by a **neutral organization** is required by the shippers (pharmaceutical companies) that require high standards in quality of their products.

Organizations that undergo such a validation would **simplify the audits** conducted by various pharmaceutical companies and would be in a position to market the receipt of the award.

CEIV Pharma standard

… by applying the newly developed CEIV Pharma standard that focuses on global coverage and universality…

IATA GUIDELINES

+

=

GOOD DISTRIBUTION PRACTICES

European Commission

World Health Organization

+

=

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

Not exhaustive

- 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

CEIV Pharma standard

Snapshot of the IATA Standard Check List

Table of Content

IATA

IATA Change History

IATA Center of Excellence for Independent Validators (CEIV) - Pharmaceutical Handling

IATA Temperature Control Audit Checklist

File Name	Version	Date	Changes	Owner
IATA_TC_Audit_Checklist	5.10	06-Aug-2014	First release	IATA

TABLE OF CONTENT

Example of Questions

Organization	
Party Audited	
Location	
IATA consultants /assessors	
Date	
Contact Name	
Contact Details	

IATA

No.	ITEMS	COMPLIANCE			COMMENTS / OBSERVATIONS	NON COMPLIANCE		POTENTIAL IMPROVEMENTS	RECOMMENDED ACTIONS	CAPA ITEM	RESPONSIBLE FOR ACTION	DUE DATE	STATUS (open, closed, in progress)	Standard or Regulatory Reference				Parties				
		YES	NO	N/A		Major	Minor							IATA	WHO	EU GDP Guideline	SIN	Others	Shipper	Forwarder	Airline	Ground Handling Agents	Road Transport
5.2.28	For container loading/shipment is there a checklist for final inspection?															9.3			Y	Y	Y	Y	Y
6. Infrastructure and equipment																							
6.1	**Premises & Equipment**																						
6.1.1	Are there different temperature controlled storage rooms?															3.2.1			Y	Y	Y	Y	Y
6.1.2	Is there a physical segregated storage area provided for pharmaceutical products?															3.2			Y	N	N	N	N
6.1.3	Are areas where pharmaceutical materials are handled designed and operated in a way to ensure cleanliness, appropriate hygiene and a minimization of cross-contamination risks?															3.2			Y	Y	Y	Y	Y
6.1.4	Are premises well-constructed and in visibly															3.2			Y	Y	Y	Y	Y
6.1.5	Are appropriate laboratory facilities available?															3.2			Y	N	N	N	N
	Has the site implemented security measures to control																						

CEIV Pharma standard

IMPORTANT

Non-Conformance Ratings:

MINOR non-conformance – minor or less serious non-conformance which is unlikely to pose a risk to product quality;

MAJOR non-conformance – failure to satisfy a key or mandatory requirement and/or one which may pose a risk to product quality;

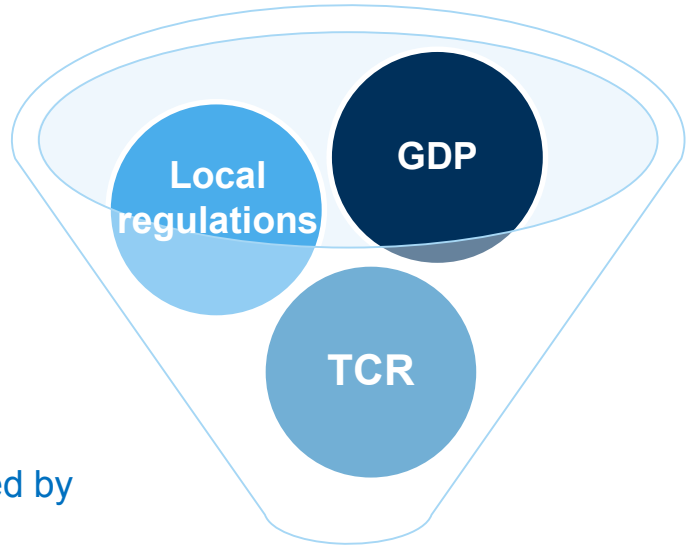
CRITICAL non-conformance – a major non-conformance which poses a risk to users and must be corrected immediately.

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

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

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

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

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?
- 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

Content

1.0 Introduction: Pharma logistical market growing but air cargo losing market share to other modes of transportation

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

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

5.0 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

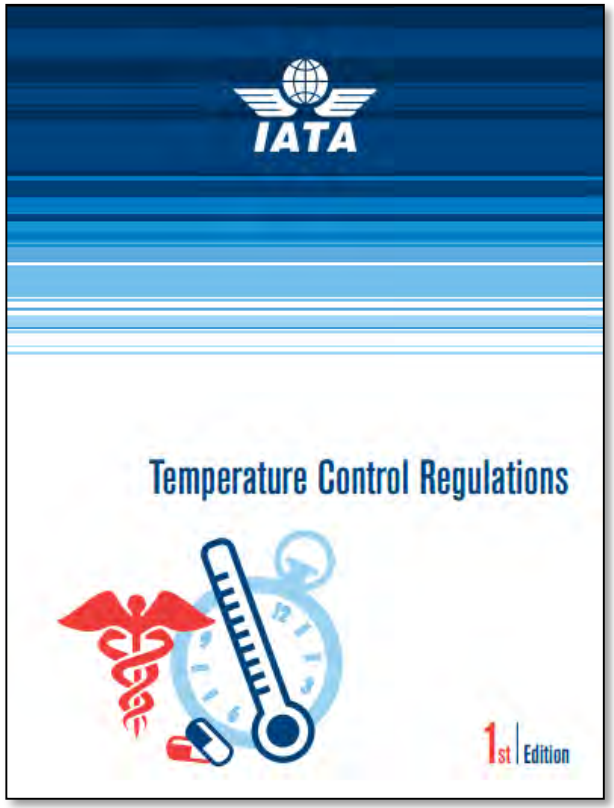
6.0 Benefits: A win-win opportunity for all stakeholders

7.0 CEIV Pharma: Update of activities

Approach of CEIV Pharma Services

The newly established CEIV Pharma offers a comprehensive solution in an effort to assist both the aviation industry and its regulators

- **Pre-validation assessment** guidelines.
- Standard validation methodology and self-assessment tools: to help airlines and other entities test their state of readiness.
- **Training courses** to prepare ground handlers, cargo operators and airlines.



Certification Approach and Methodology

IATA will certify companies in several steps

1 Preparation

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

2 Assessment

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

3 Validation

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

5 Certification

4 Training required for certification

Additional Training

Assessment

Focus is on preparing the organization for validation and creating awareness

Assessment

Raise awareness…	**…on Pharma handling requirements**
Assess client…	**…to identify potential gaps using the IATA CEIV Pharma checklists**
Conduct on-site observation…	**…of facilities, staff, equipment, processes, practices, and systems**
Prepare client…	**…for the subsequent validation exercise**
Capture and convey 'lessons learned' and suggest 'best practice…	**…to assist client in achieving "CEIV Pharma Certified" status**
Analyze observations and produce report…	**…to highlight findings and provide recommendations**
Collaborative work…	**…by helping creating an action plan and project plan**

Validation

Validate to ensure all requirements are in compliance, gaps and recommendations have been implemented

Validation

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

Review of progress on action plan

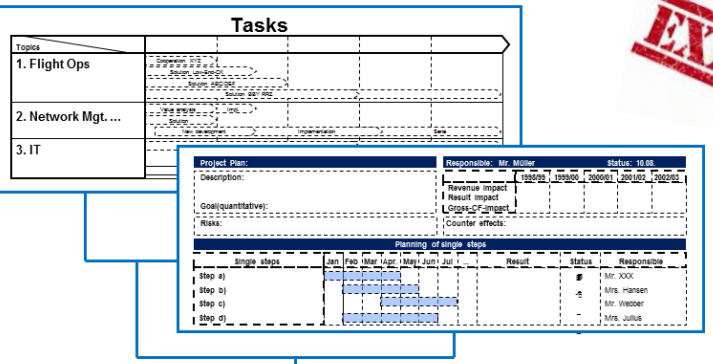
Action Packages

- Schedule

Actions

- Personnel
- Quantitative
- Qualitative

Implementations



Projects running | Internal project teams | Teams supported by IATA

↗ Project management

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

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.

Training

Annex 5: WHO Good Distribution Practices for pharmaceutical products

Training required for certification → **Additional Training**

World Health Organization

Section 6. Organization and Management

- **Section 6.1** "There should be an adequate organizational structure for each entity defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated."
- **Section 6.2** "Duties and responsibilities should be clearly defined and understood by the individual concerned and recorded as written job description. Certain activities may require special attention, such as supervision of performance activities, in accordance with local legislation. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities."

Section 7. Personnel

- **Section 7.1** "All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable."
- **Section 7.2** "Key personnel involved in the distribution of pharmaceutical products should have the ability and experience appropriate to their responsibility for ensuring that pharmaceutical products are distributed property."
- **Section 7.3** "There should be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products in order to ensure that quality of the product is maintained."

Training required for certification

Successful completion of the courses is essential for certification

Training required for certification

Temperature Controlled Cargo Operations (3 day class room)

Temperature Controlled Cargo Operations (Distance Learning)

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

Who?

- **Competent personnel**, e.g.
  - Operations manager
  - Ramp supervisors
  - …

- **Key personnel**, e.g.
  - Quality manager
  - Station manager
  - Trainer
  - …

Training

Temperature Controlled Cargo Operations

Delivery Method(s): Classroom, 3 days and Distance Learning

Training required for certification

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**

✓ **2 key personnel per station should be trained on the Distance Learning course**

Training

Audit, Quality and Risk Management for Temperature Controlled Cargo

Delivery Method(s): Classroom, 5 days

Training required for certification

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

Training required for certification

Who should be trained	Temperature Controlled Cargo Operations	Audit, Quality and Risk Management For Temperature Controlled Cargo
2 key personnel involved in handling pharmaceutical products activities	Distance Learning	Classroom (5 days)
2 competent personnel involved in handling pharmaceutical products activities	Classroom (3 days)	N/A

Training

Two methods of delivery: Classroom and Distance Learning

DISTANCE LEARNING

- Self-study: Manage learning to fit own schedule.
- Study at own pace using a manual, e-book or both
- Write exam at one of IATA's 60 examination locations worldwide.
- E-learning: Get the complete learning experience from your computer. Learn from fun, interactive materials and write your exam online.

CLASSROOM

Training Center

- All classroom courses are developed and delivered by IATA Instructors or staff members.
- At IATA Training Center (scheduled classes
- Class room setting
- Exam at the end of class

In-Company

- IATA Training at workplace. All in-company courses are developed and delivered by IATA Instructors
- Trainings can be customized to fit your company's training needs
- Class room setting
- Exam at the end of class

Training Options

In-Company vs Training Center

TRAINING CENTER		IN-COMPANY TRAINING	
$		$$	Cost
4		12	No. of Participants
Inflexible		Flexible	Location

Additional Training

Introduction to Time and Temperature Pharmaceutical Products

Additional Training

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

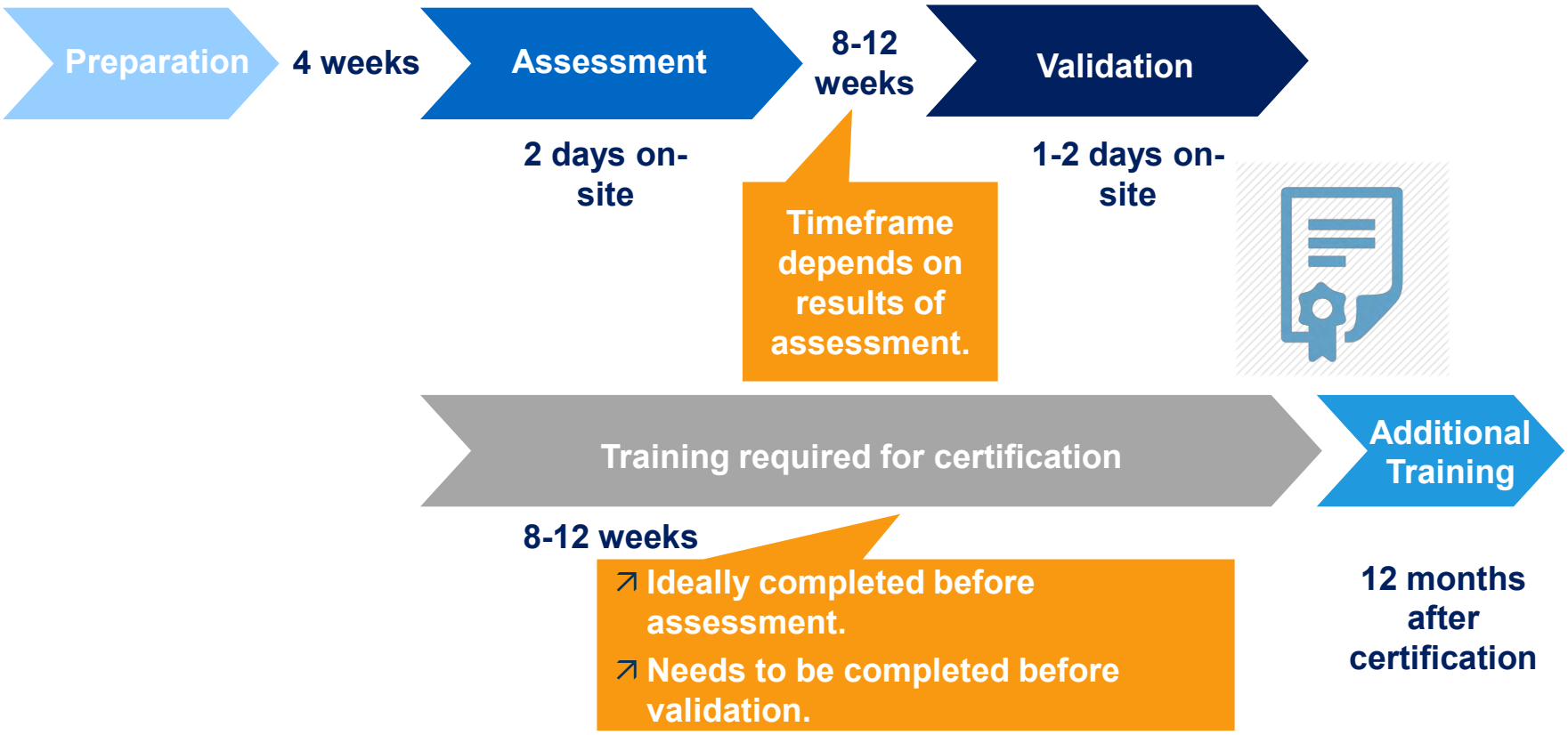
All personnel involved in handling pharmaceutical products activities per station should be trained on "IATA Introduction to Time and Temperature Pharmaceutical Products course" (or equivalent)) within period of 12 months after the "Certification"

Path to certification

In a nutshell

Step 1	Assessment
Step 2	Training
Step 3	Validation
	Certification!!!
Step 4	Training (remaining staff)

Certification Timeline (general approach)



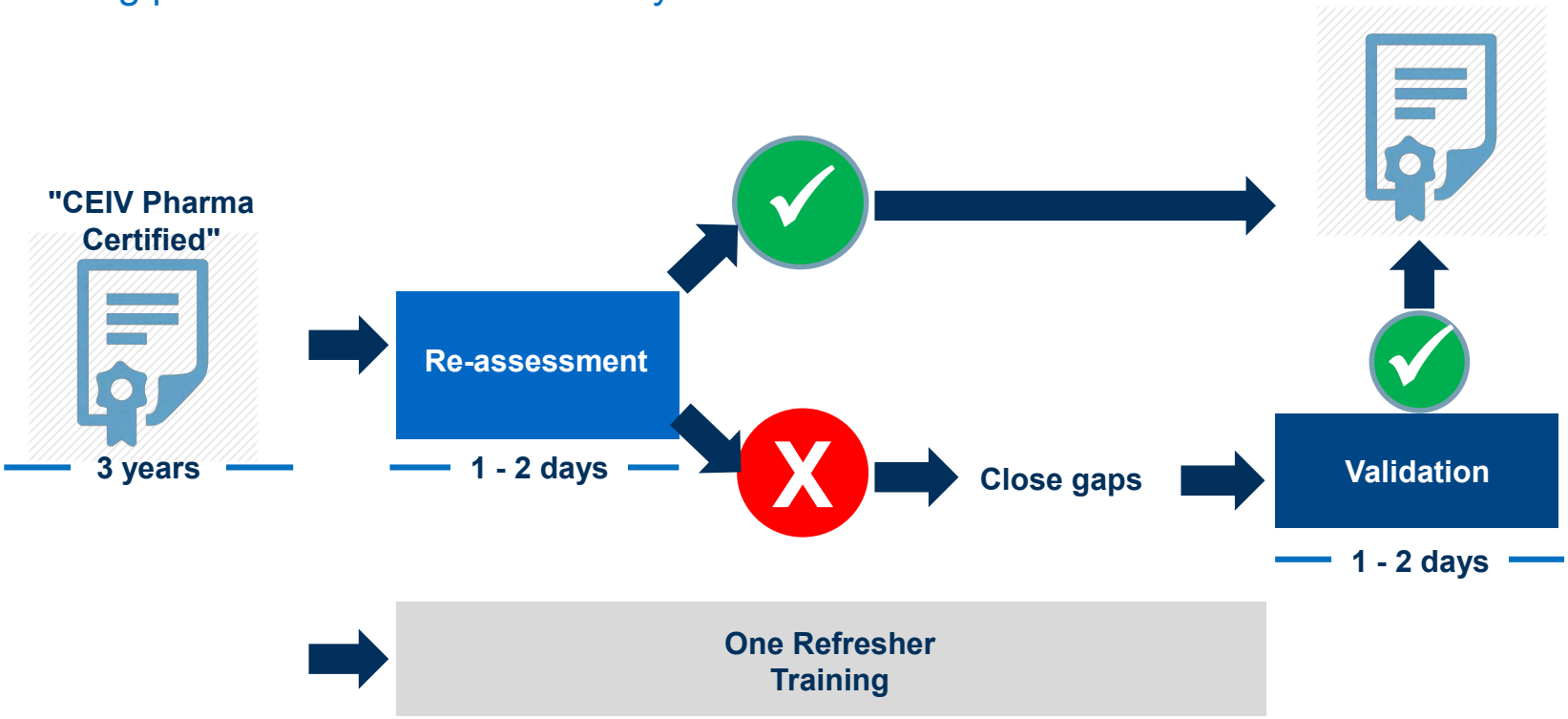
Certification

Award Certificate "CEIV Pharma certified"

Example

Recertification

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



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

Content

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7.0 CEIV Pharma: Update of activities

CEIV Pharma Certification Approach

There are different approaches to obtain certification

Individual

- **One company** decides to get "CEIV Pharma Certified“
- One or several stations

Community

- **A group of companies at one airport** decide to get "CEIV Pharma Certified"
- Form a “pharma gateway”
- Supply chain approach

Coalition

- **A group of companies** decide to get "CEIV Pharma Certified" **at several airports** to form several “pharma gateways”
- Supply chain approach

Advocacy governance

Strong emphasis on engaging stakeholder and advocate for endorsement and recognition

	WHO?	TASK
Industry	Time and Temperature Task Group – CEIV Pharma Steering Group	Approve standards Approve trainings
Global	WHO FIATA TIACA Global Shippers Forum (GSF) Cool Chain Association	
Regional	US GDP EU	Endorse + recognize standards
Local	Local stakeholder associations (Shippers, Freight Forwarders, Ground Handlers, Airlines) Local BARs	Endorse + recognize trainings

Project structure – Who is involved and who can participate?

Everyone in the value chain can participate in the certification process

Example (BRUCargo)

Pharma shippers

Pfizer, GlaxoSmithKline, Johnson & Johnson, Janssen Pharmaceutica, UCB, Alcon, AGFA, Zoetis, Teva, MSD Be well, Baxter

Forwarders with pharma focus

AD Handling, B.P.L., Expeditors, SDV, UTi, DHL Global Forwarding, CEVA, DB Schenker, redline, BAFI, Rhenus Logistics, Nippon Express, Ziegler, Panalpina, Geodis, Kuehne+Nagel, Lynden International, World Courier

Handlers

Aviapartner, swissport cargo services, WFS Worldwide Flight Services, Skylink

Truckers

Jan De Rijk Logistics, H.Essers

Airlines

brussels airlines cargo, Finnair Cargo, Singapore Airlines Cargo, ACMAB

Regulators

fagg, IDA, IATA, CEIV Pharma, TTTF

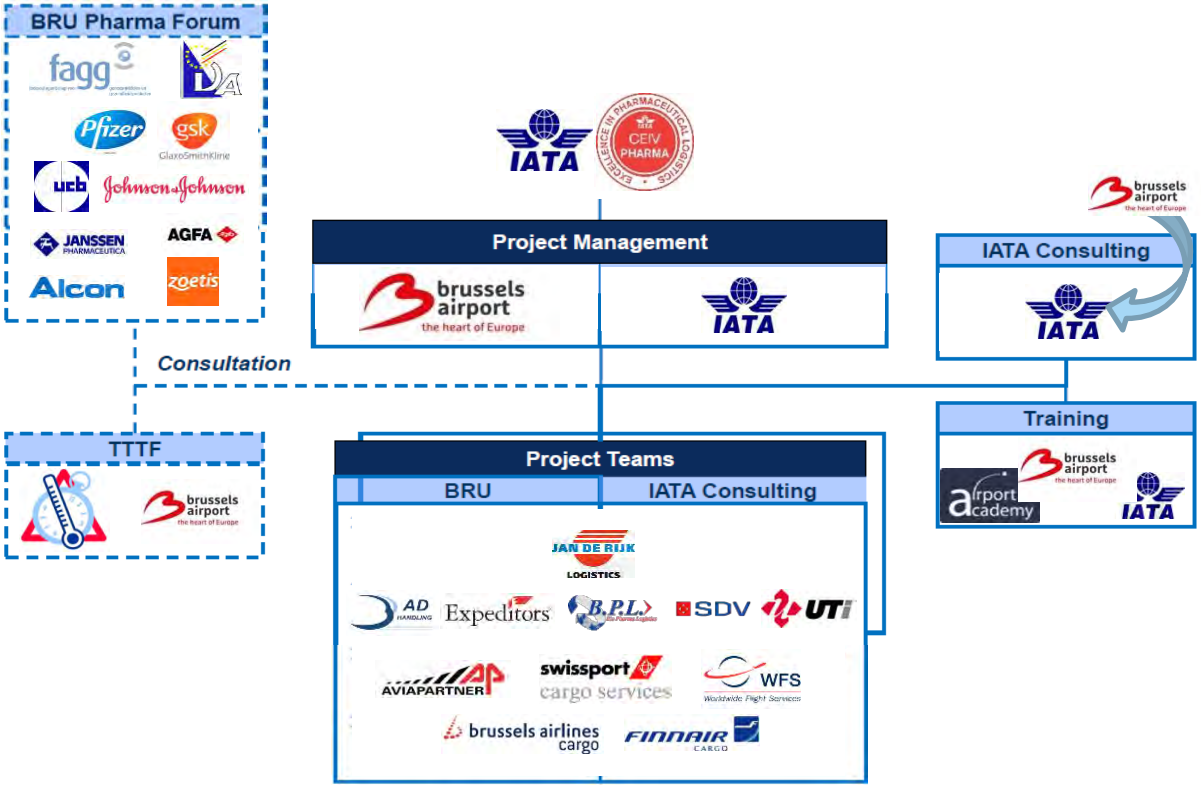
Facilitators

airport academy

Project structure

The project is conducted in close cooperation with relevant stakeholders

Example (BRUCargo)



CEIV Pharma – Who is auditing?

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**

Independent Validator Qualification and Recruitment Process

Pre-qualification

- Pharma and/or Auditing background;
- Cargo experience; or
- Ground handling experience.

Interview

- Motivation;
- Social fit;
- Experience;
- Expectations.

Pharma Training

- TCC Operations;
- Risk, Audit + Quality Management.

On-the-job assessment

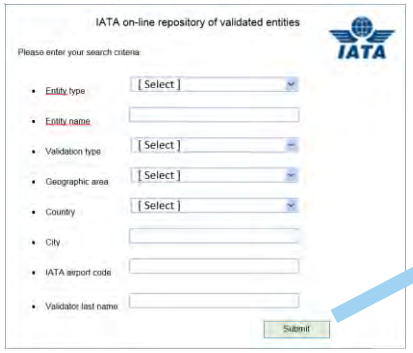
- 1 on-site assessment as a trainee.

Independent Validator

Visibility for CEIV Pharma validated entities

Validated entities will become visible on IATA's website

Search



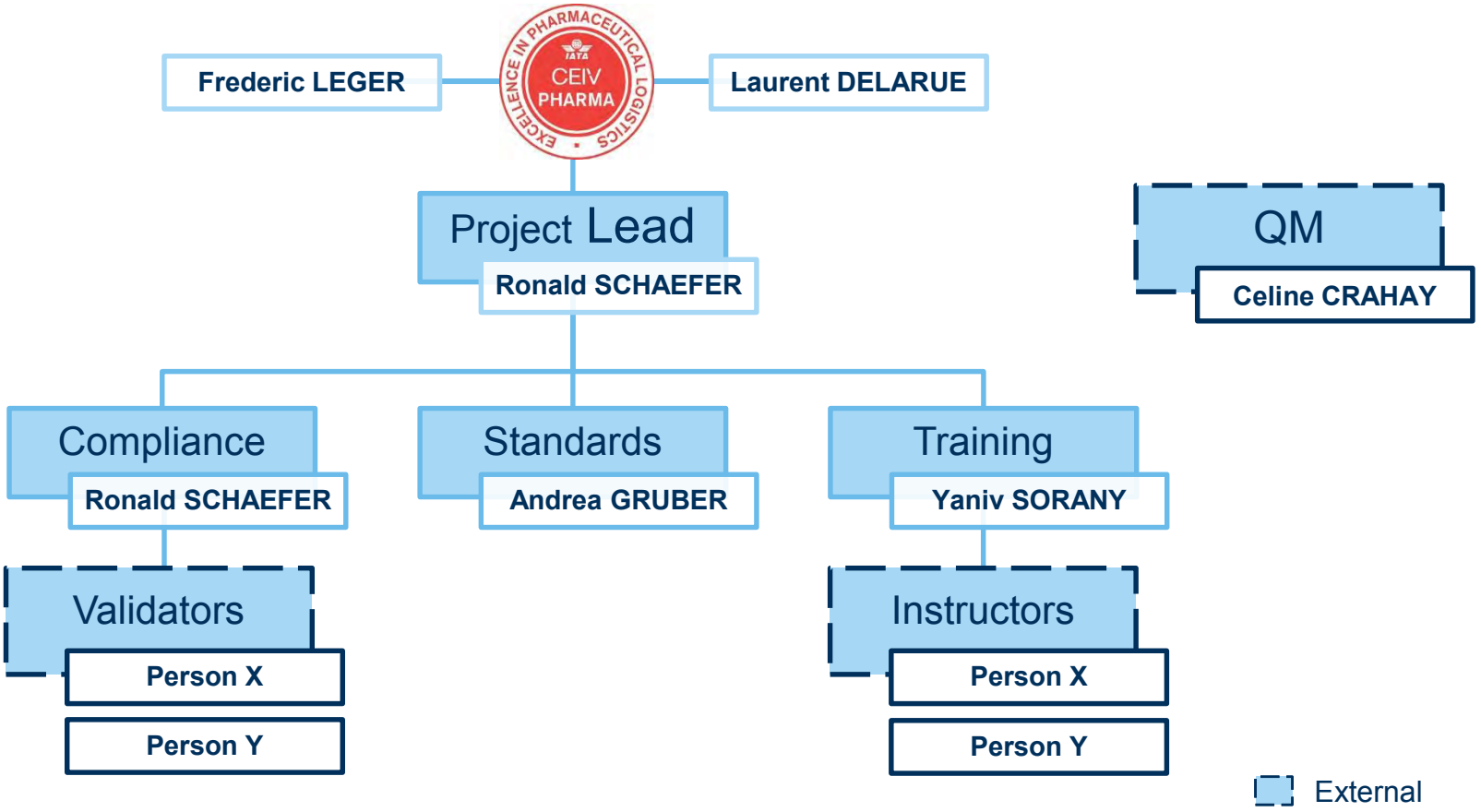
Results

Type	Name	City	Country	IATA Airport Code	End of validity date of audit: EU 185/2010-RA3*	EU 185/2010-KC3*	IATA CEIV Pharma
	Dog screener PLC	MusterCity2	Thailand	SDF	03-Sep-18		
	Easy forwarding	MusterCity3	India	ABC	04-Jan-19		03-Nov-18
	AirlineX	MusterCity5	The Netherland	AMS			05-Aug-18
	AirlineX	MusterCity2	Thailand	BKK			05-Sep-19
	GHA_ABC	MusterCity	Columbia	ABC	15-Jul-19		
	GHA_ABC	MusterCity	Columbia	RTY	04-Jun-19		
	GHA_ABC	MusterCity	Columbia	CBA	04-Jun-19		05-May-18
	Shipping unlimited	MusterCity4	Vietnam	SDG		08-Apr-19	24-Jun-17

Details on a validation

Organizational Chart

How is CEIV Pharma organized



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7.0 CEIV Pharma: Update of activities

CEIV Pharma – Key Benefits

The 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

Regulators

- Assured of safety of pharmaceutical products shipped by air
- Access structured and consistent training and registry of independent validators and assessed operators

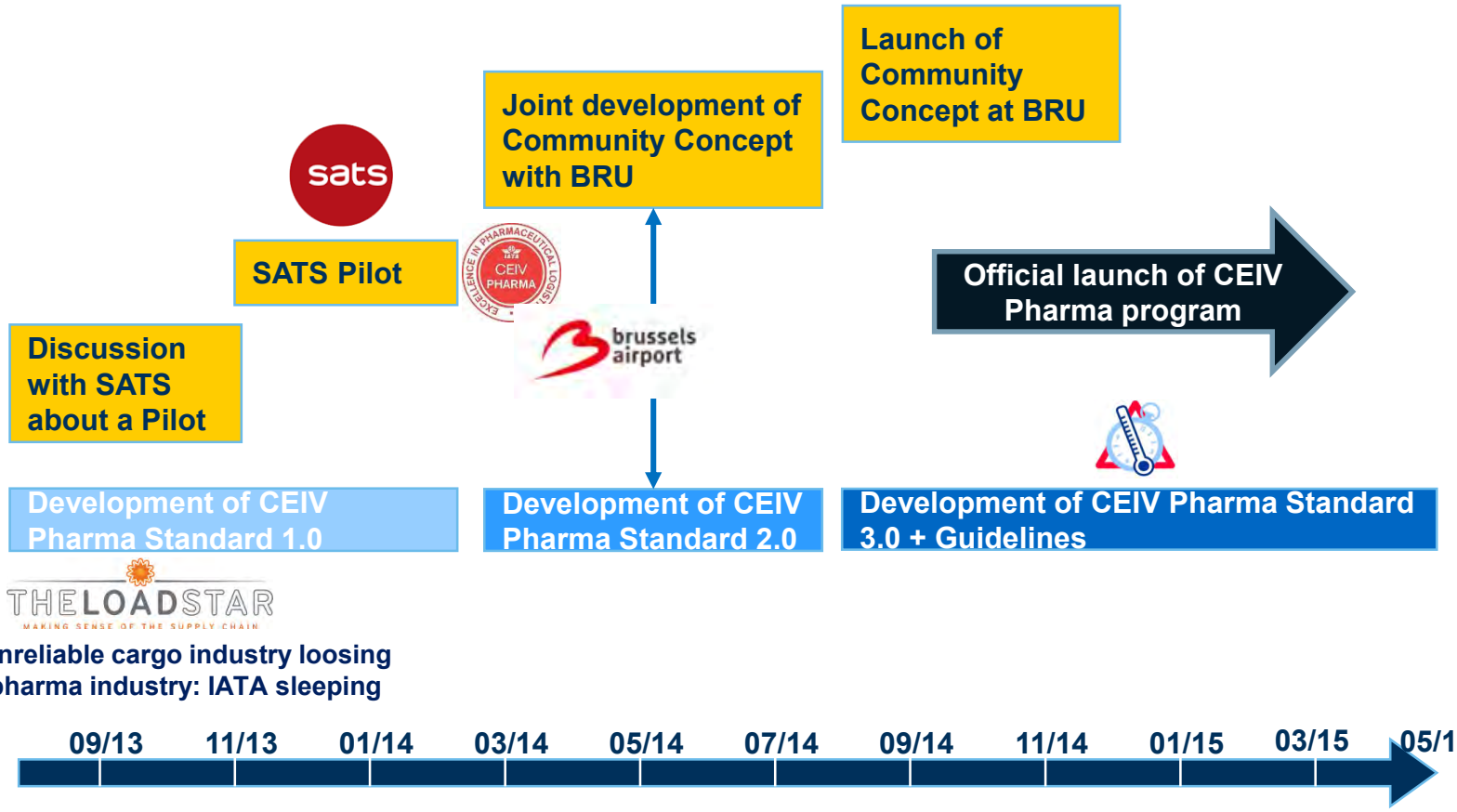
IATA

- Disseminated standards in the industry
- Common audit criteria and global certification
- Promote air transport and so limit the modal shift

Content

CEIV Pharma Development

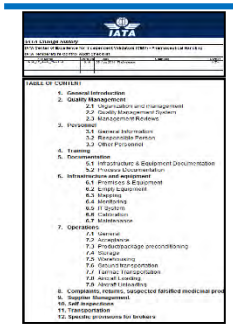
From Pilot to Launch

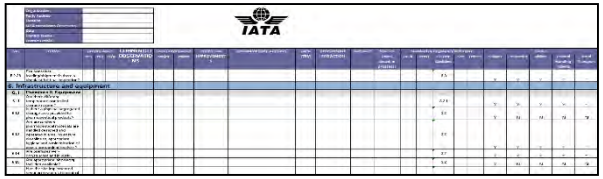


CEIV Pharma Checklist

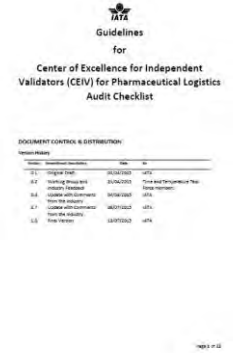
CEIV Pharma checklist and guidelines will be included in IATA's Temperature Control Regulations as Annex

CEIV Pharma Audit Checklist



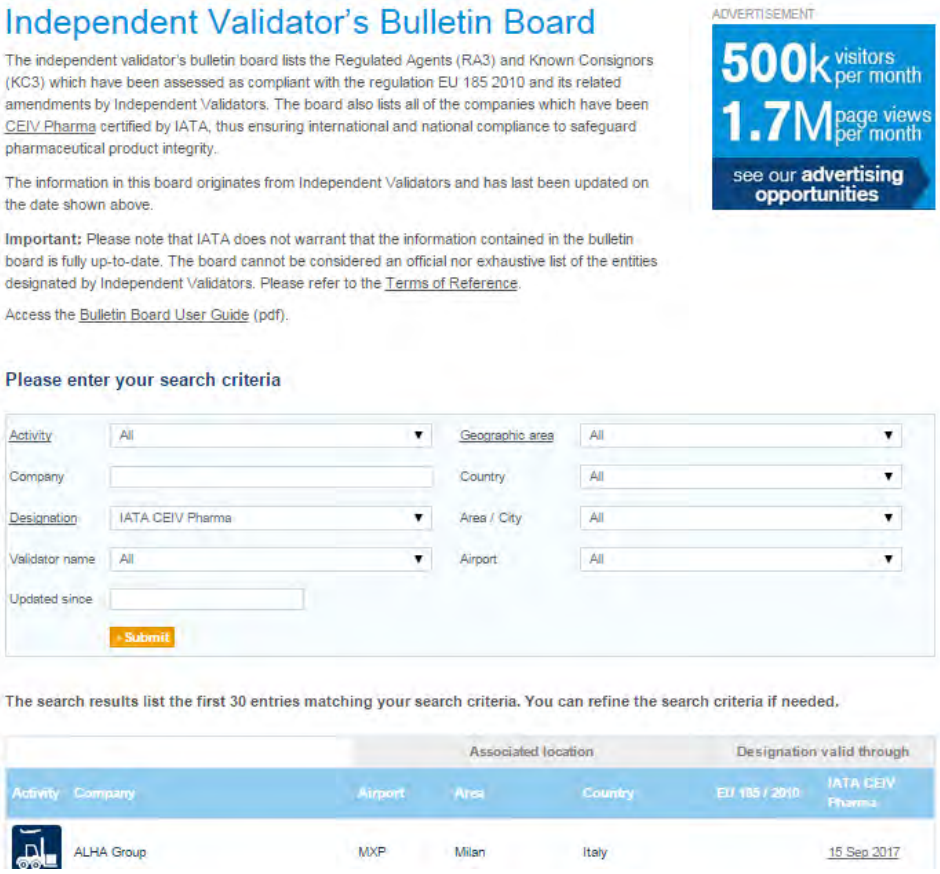


CEIV Pharma Audit Guidelines



CEIV Pharma Database

Launched database to increase transparency for pharma shippers



Independent Validator's Bulletin Board

The independent validator's bulletin board lists the Regulated Agents (RA3) and Known Consignors (KC3) which have been assessed as compliant with the regulation EU 185 2010 and its related amendments by Independent Validators. The board also lists all of the companies which have been CEIV Pharma certified by IATA, thus ensuring international and national compliance to safeguard pharmaceutical product integrity.

The information in this board originates from Independent Validators and has last been updated on the date shown above.

Important: Please note that IATA does not warrant that the information contained in the bulletin board is fully up-to-date. The board cannot be considered an official nor exhaustive list of the entities designated by Independent Validators. Please refer to the Terms of Reference.

Access the Bulletin Board User Guide (pdf).

Please enter your search criteria

Activity	All	Geographic area	All
Company		Country	All
Designation	IATA CEIV Pharma	Area / City	All
Validator name	All	Airport	All
Updated since			

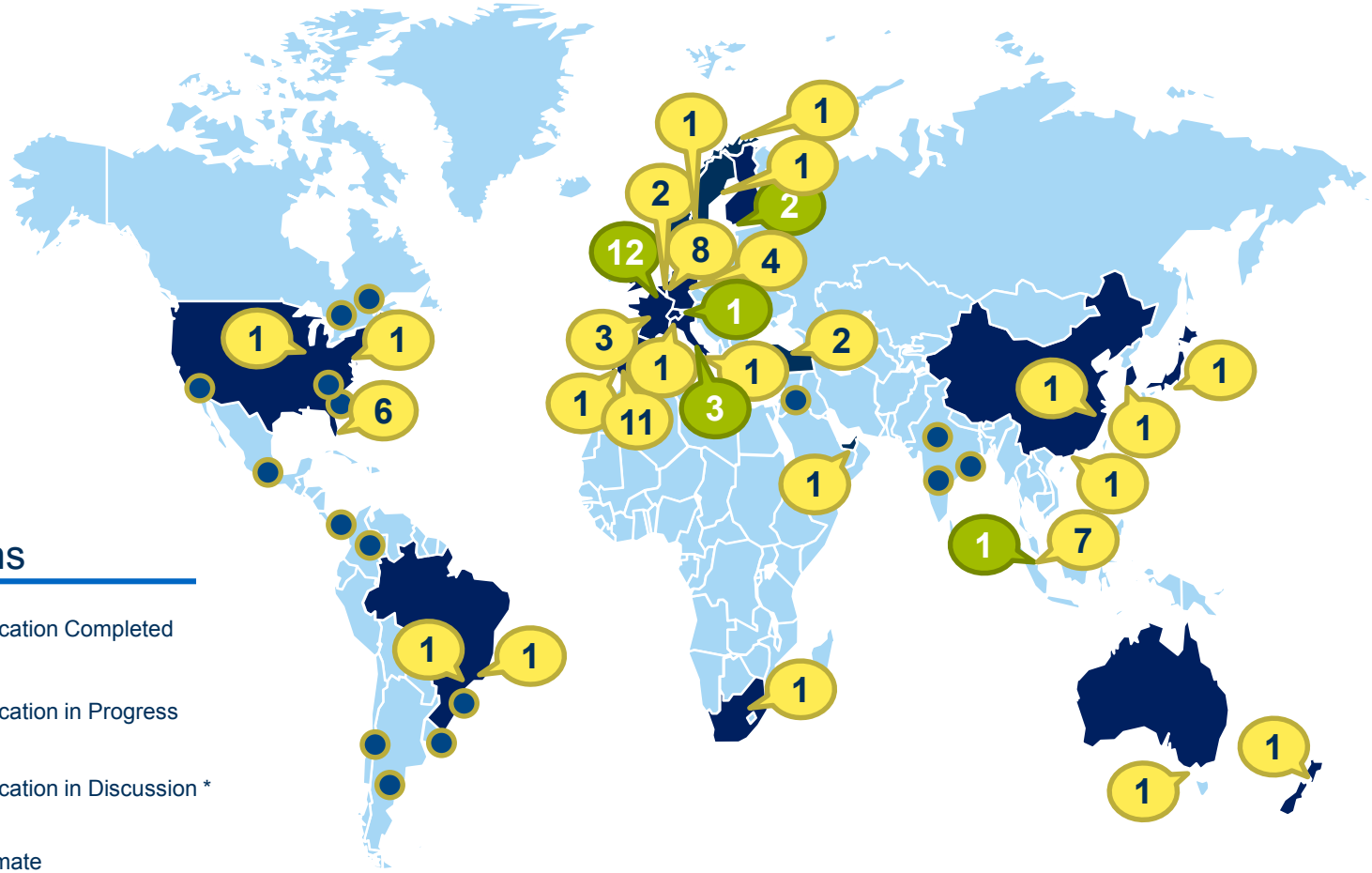
Submit

The search results list the first 30 entries matching your search criteria. You can refine the search criteria if needed.

		Associated location			Designation valid through	
Activity	Company	Airport	Area	Country	EU 185 / 2010	IATA CEIV Pharma
	ALHA Group	MXP	Milan	Italy		15 Sep 2017

CEIV Pharma

Certified Pharmaceutical Trade Lanes Development



Locations

- 19 Certification Completed
- 61 Certification in Progress
- +99 Certification in Discussion *

* Estimate

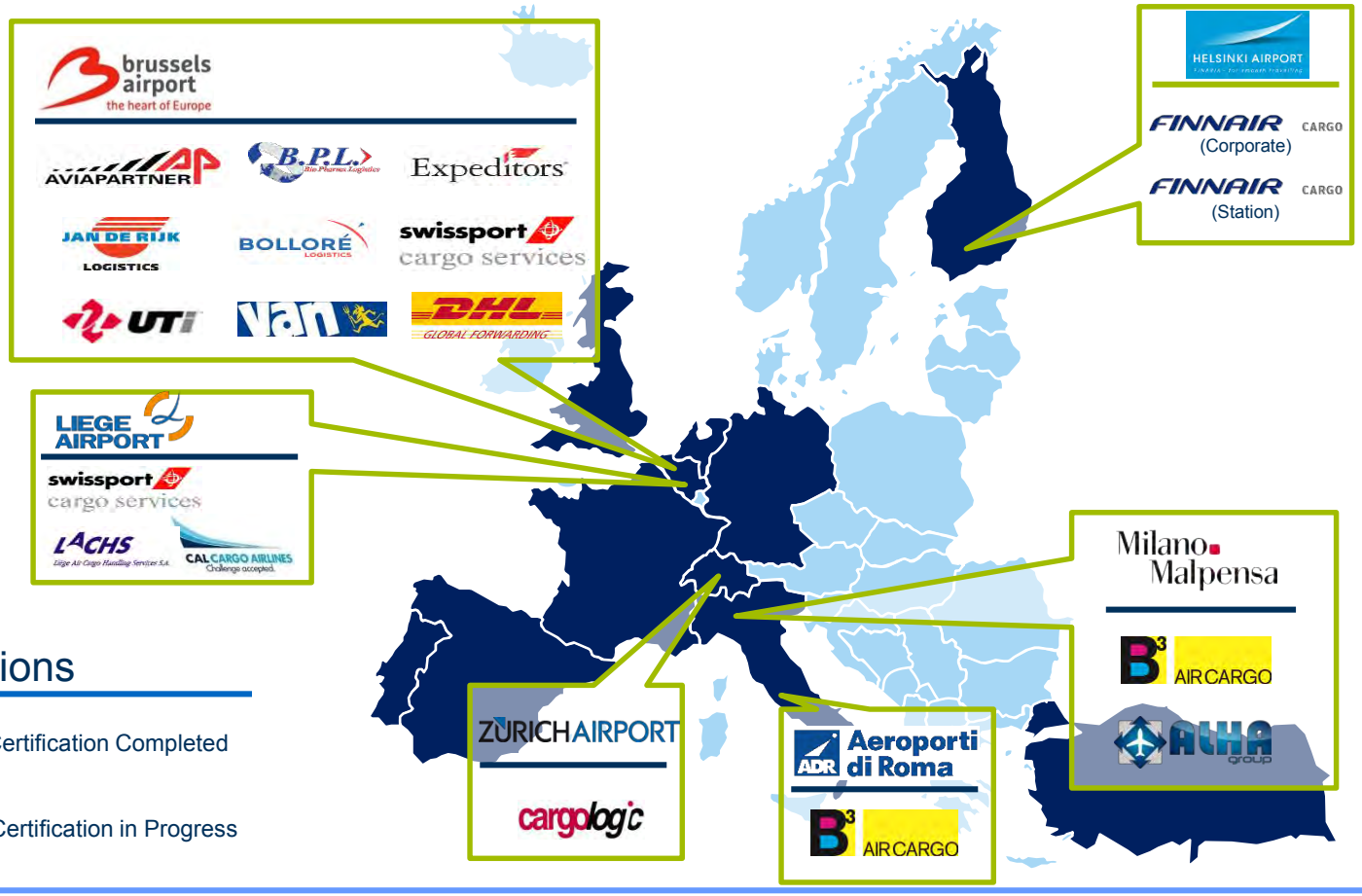
List of companies CEIV Pharma certified

More companies will be added before the end of 2016

Name of the company	Category	Location	Date of Certification	Validity	No. of certificate
SATS Ltd. (Changi Airport)	Ground Handler	Changi Airport (SIN)	21-Nov-14	21-Nov-15	CEIV-PH-14-0002
Aviapartner Belgium NV (Brussels Airport)	Ground Handler	Brussels Airport (BRU)	8-Dec-14	8-Dec-16	CEIV-PH-14-0003
Expeditors International NV (Brussels Airport)	Freight Forwarder	Brussels Airport (BRU)	8-Dec-14	8-Dec-16	CEIV-PH-14-0004
SDV Belgium (Brussels Airport)	Freight Forwarder	Brussels Airport (BRU)	8-Dec-14	8-Dec-16	CEIV-PH-14-0005
UTi Belgium NV - Brussels Airport	Freight Forwarder	Brussels Airport (BRU)	8-Dec-14	8-Dec-16	CEIV-PH-14-0006
Bio Pharma Logistics - Brussels Airport	Freight Forwarder	Brussels Airport (BRU)	8-Dec-14	8-Dec-16	CEIV-PH-14-0007
Jan de Rijk	Transportation	Roosendaal	9-Mar-15	9-Mar-17	CEIV-PH-14-0008
Swissport Cargo - Brussels Airport	Ground Handler	Brussels Airport (BRU)	9-Mar-15	9-Mar-17	CEIV-PH-14-0009
Finnair - Airlines	Airlines	Helsinki HQ	30-Jun-15	30-Jun-17	CEIV-PH-14-0010
Finnair - Helsinki Airport	Ground Handler	Helsinki Airport (HEL)	30-Jun-15	30-Jun-17	CEIV-PH-14-0011
BCUBE - Fiumicino Airport	Ground Handler	Fiumicino Airport (FCO)	22-Jul-15	22-Jul-17	CEIV-PH-14-0012
Cargologic - Zurich Airport	Ground Handler	Zurich Airport (ZRH)	30-Sep-15	30-Sep-17	CEIV-PH-14-0013
CAL Cargo Airlines - Airline	Airlines	Liege Airport (LGG)	30-Sep-15	30-Sep-17	CEIV-PH-14-0014
ALHA Group - MXP Airport	Ground Handler	Milan Malpensa Airport (MXP)	15-Sep-15	15-Sep-17	CEIV-PH-14-0015
BCUBE - MXP Airport	Ground Handler	Milan Malpensa Airport (MXP)	15-Sep-15	15-Sep-17	CEIV-PH-14-0016
LACHS - Liege Airport	Ground Handler	Liege Airport (LGG)	8-Oct-15	30-Sep-17	CEIV-PH-14-0017
Swissport Cargo - Liege Airport	Ground Handler	Liege Airport (LGG)	15-Nov-15	15-Nov-17	CEIV-PH-14-0018
Van Dievel - Brussels Airport	Transportation	Brussels Airport (BRU)	30-Nov-15	30-Nov-17	CEIV-PH-14-0019

CEIV Pharma – Entities Certified

European Community



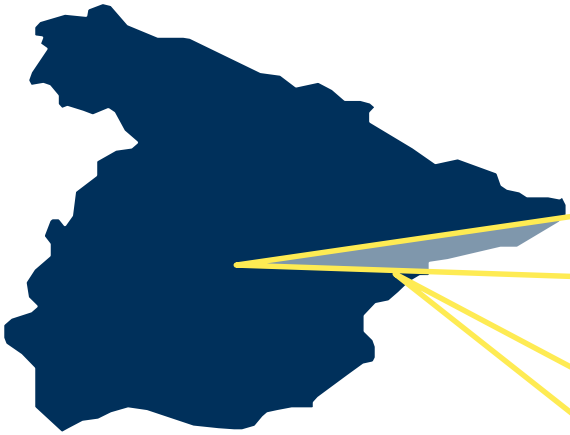
Locations

18 Certification Completed

36 Certification in Progress

CEIV Pharma (in process)

Spain



aena

Aeropuerto Adolfo Suárez Madrid-Barajas

swissport cargo services

Alaire

WFS

DB SCHENKER

Tiba

AIR EXPRESS CARGO

aena

Aeropuerto de Barcelona-El Prat

Aeroport de Barcelona-El Prat

swissport cargo services

Airpharm

DB SCHENKER

WFS

Ibercondor

transportes internacionales y aduanas

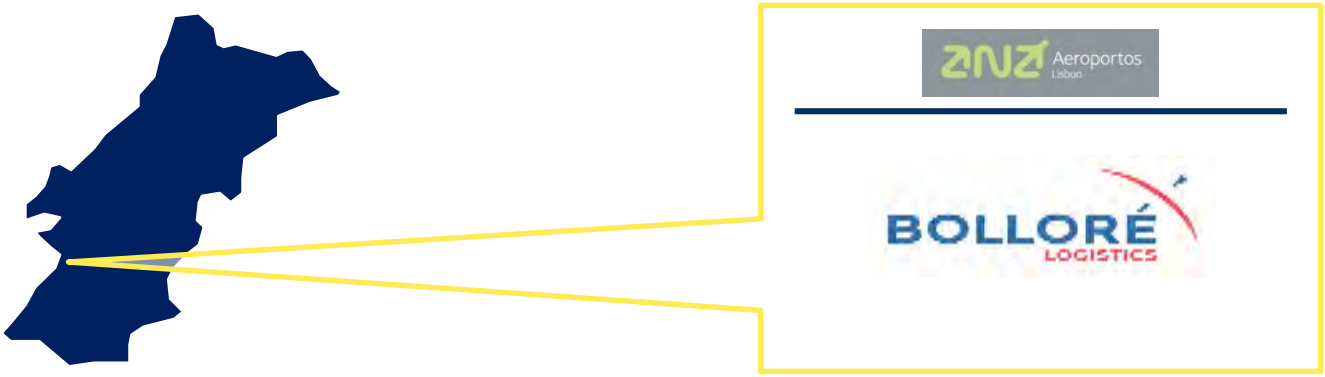
Locations

0 Certification Completed

11 Certification in Progress

CEIV Pharma (in process)

Portugal



Locations

0 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)
France

AÉROPORTS DE PARIS

BOLLORÉ LOGISTICS

AIRFRANCE KLM Martinair CARGO

Locations

0 Certification Completed

3 Certification in Progress: AFKLM Air and Ground)

CEIV Pharma (in process)

Belgium

brussels airport
the heart of Europe

AD HANDLING | brussels airlines cargo | WFS

HAZGO | HB LOGISTICS | GEODIS wilson

NINATRANS

LIEGE AIRPORT

AVIAPARTNER

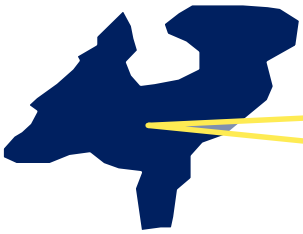
Locations

12 Certification Completed

8 Certification in Progress

CEIV Pharma (in process)

Netherlands



Schiphol Amsterdam Airport

BOLLORÉ LOGISTICS

AIRFRANCE KLM Martinair CARGO

Locations

0 Certification Completed

2 Certification in Progress

CEIV Pharma (in process)

Germany

Düsseldorf Airport DUS

Düsseldorf Airport Cargo DUS

Frankfurt Airport

BOLLORÉ LOGISTICS

Lufthansa Cargo

Locations

0 Certification Completed

4 Certification in Progress (1 undisclosed)

CEIV Pharma (in process)

Italy

Aeroporti di Roma

ALHA group

Locations

3 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)

Switzerland

FLUGHAFENZÜRICH

BOLLORÉ LOGISTICS

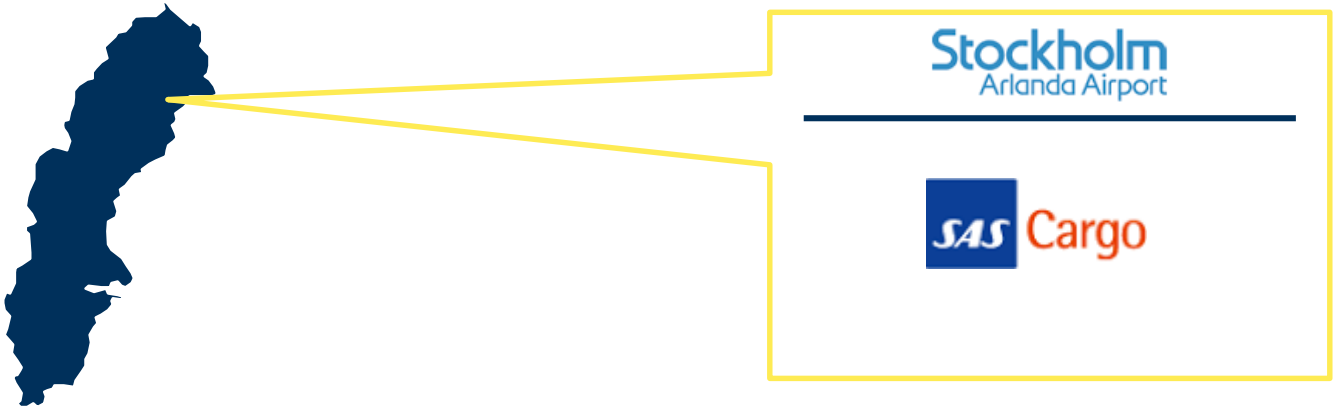
Locations

1 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)

Sweden



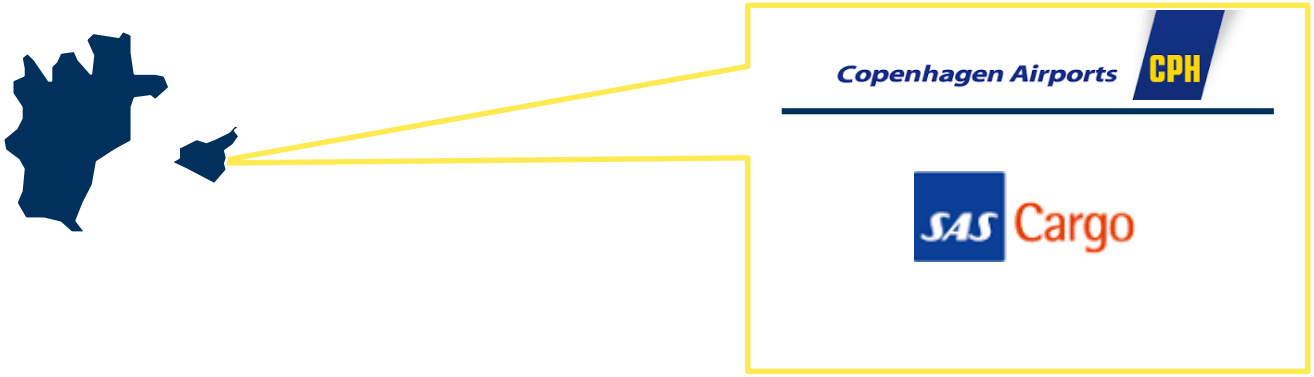
Locations

0 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)

Denmark



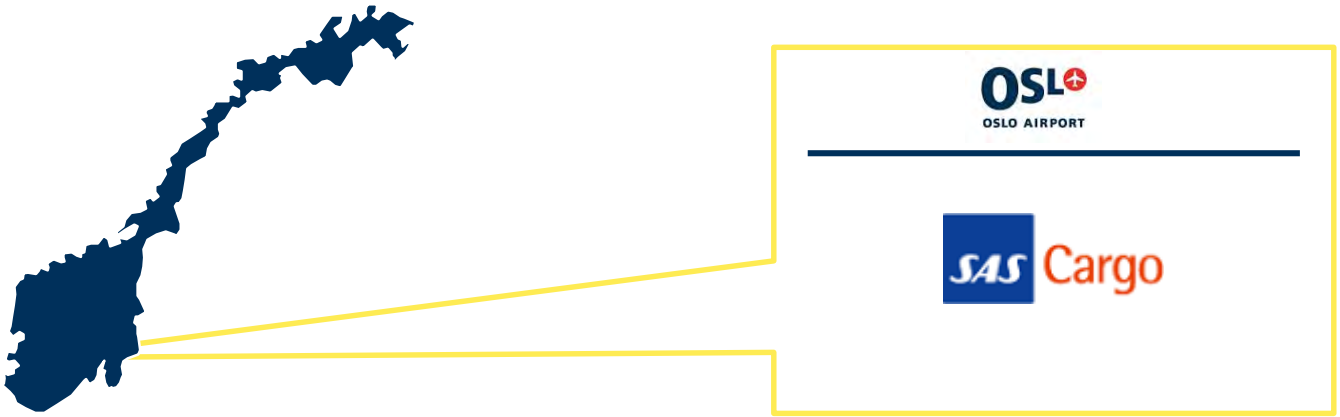
Locations

0 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)

Norway



Locations

0 Certification Completed

1 Certification in Progress

CEIV Pharma (in process)

Turkey

Tepe Akfen TAV Airports

TURKISH CARGO

Locations

0 Certification Completed

2 Certification in Progress

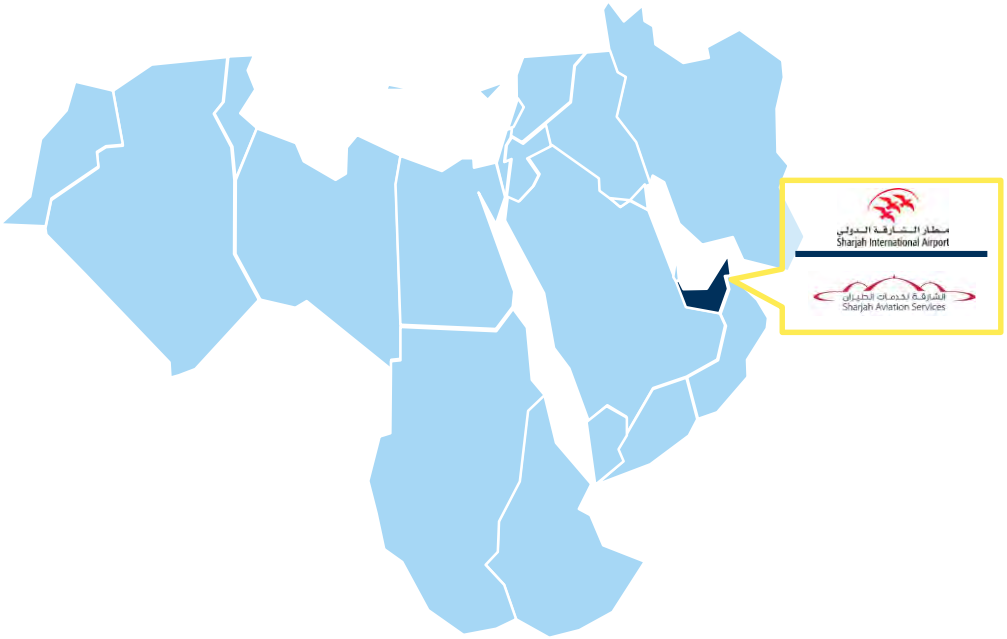
CEIV Pharma
Asian Community

Locations

1 Certification Completed

13 Certification in Progress

CEIV Pharma
Middle East Community



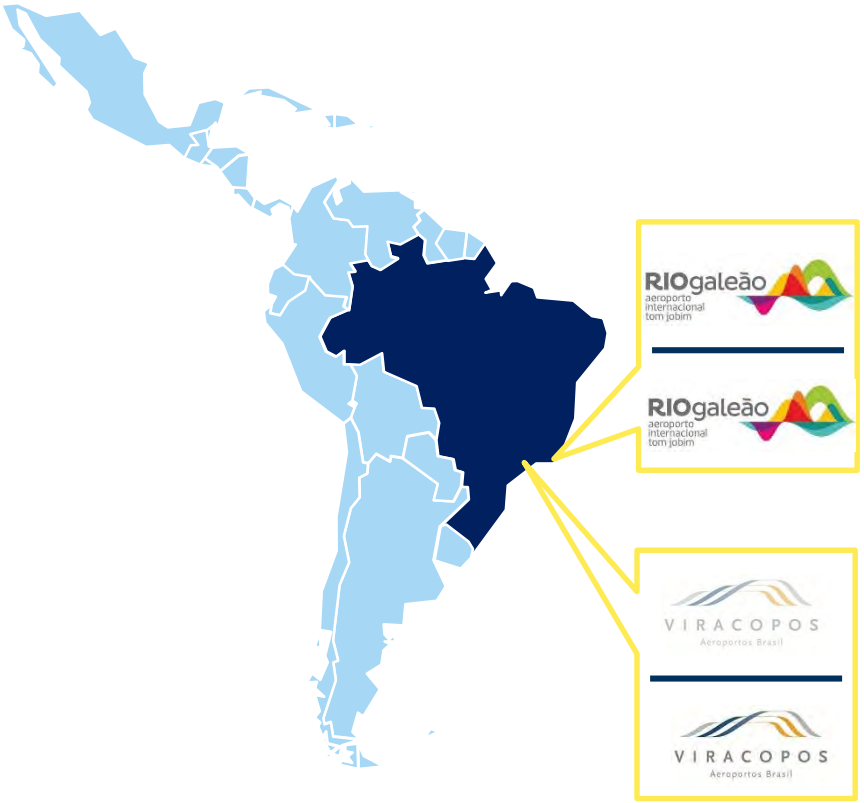
Locations

0 Certification Completed

1 Certification in Progress

CEIV Pharma

Latin American Community



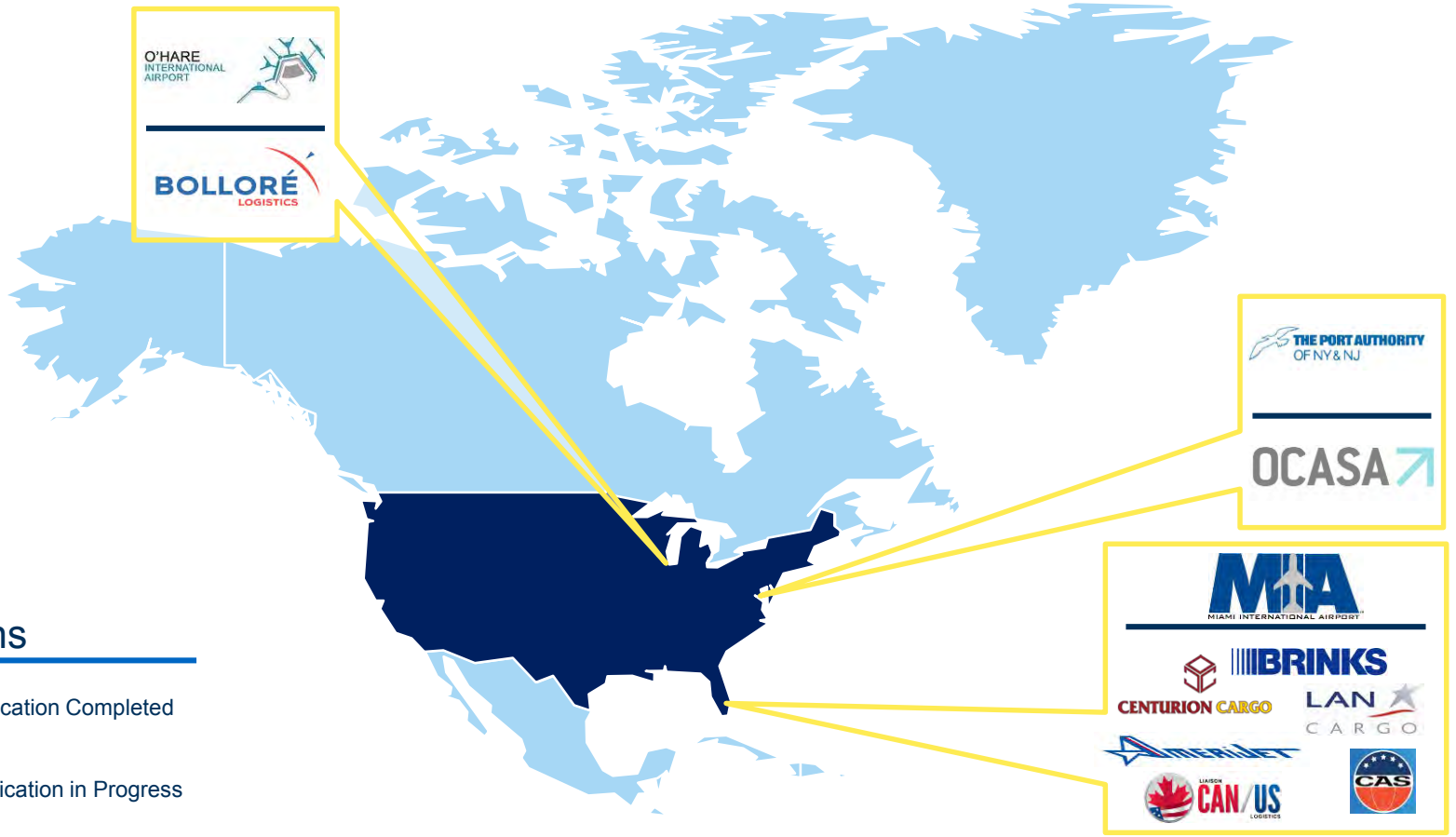
Locations

0 Certification Completed

2 Certification in Progress

CEIV Pharma

North American Community

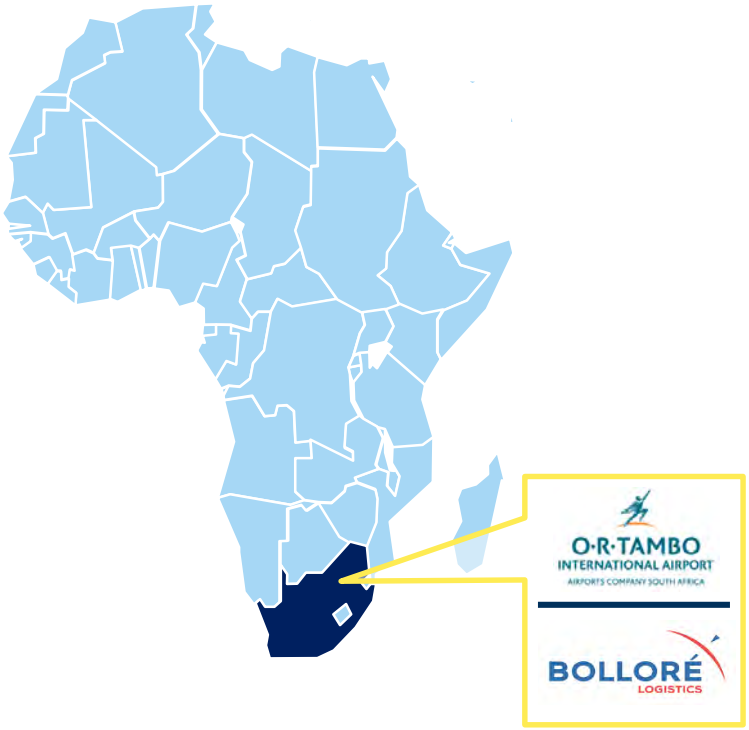


Locations

0 Certification Completed

8 Certification in Progress

CEIV Pharma
African Community



Locations

0 Certification Completed

1 Certification in Progress

Advocacy Governance

Support from Shippers

Spain

ESTEVE más cerca

PLANET AIR CARGO S.L.

ferrer

Belgium

zoetis

MSD

Baxter

Johnson & Johnson

TERUMO

Endorsement from European Shipping Council

ESC EUROPEAN SHIPPERS' COUNCIL

15 July 2015

International Air Transport Association
Route de l'Aeroport 33
PO Box 416
1215 Geneva 15 Airport
SWITZERLAND

IATA CEIV PHARMA PROGRAM – European Shippers' Council ENDORSEMENT

Dear Mr. Windmuller,

We are pleased to be working collaboratively and constructively with IATA 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 context, we are recognizing IATA in developing and delivering a training and assessment as well as validation program that meets the needs of pharmaceutical companies and industry alike.

We are therefore pleased to formally endorse the International Air Transport Association Center of Excellence for Independent Validation Pharmaceutical (CEIV Pharma) Program.

We look forward to working closely with IATA in further enhancing the CEIV Pharma program and promoting the program to ensure its worldwide adoption.

In this respect, The European Shippers' Council fully appreciates the commitment IATA has demonstrated in looking to setting an industry standard in this area and assessing and training industry stakeholders (freight forwarders, ground handlers, truckers as well as air carriers) while implementing them.

We will continue to work constructively with IATA, other International Organizations, Regulators as well as the industry in the continuing pursuit of excellence in the field of transporting pharmaceutical products by air.

Yours sincerely,

Nik Delmeire
Secretary General – European Shippers' Council

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

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

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

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

THANK YOU

For further information, contact:

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Miami, FL

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Tel: + 1 305 779 9873
Mob: + 1 305 586 4666