



## HAFFA Briefing

14<sup>th</sup> June 2017



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IATA Hong Kong






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## CEIV Pharma in Hong Kong

**CEIV Pharma Partnership Airport : Hong Kong Airport Authority**



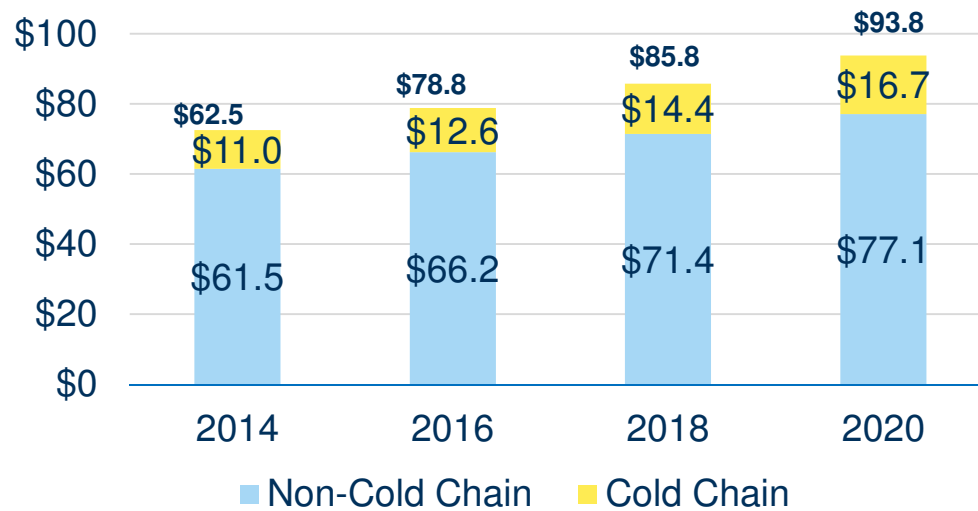
## Current status of CEIV Pharma in Hong Kong

- All companies have successfully completed the required training and certificates distributed
- 7 companies have completed the assessment stage
- 4 companies have been certified
- Target to have all companies certified by June 2017

## Background: Pharmaceutical Market Development

Spending in biopharma logistics will continue to rise to meet demand

Global Biopharma Logistics Spending  
(\$ Billions)



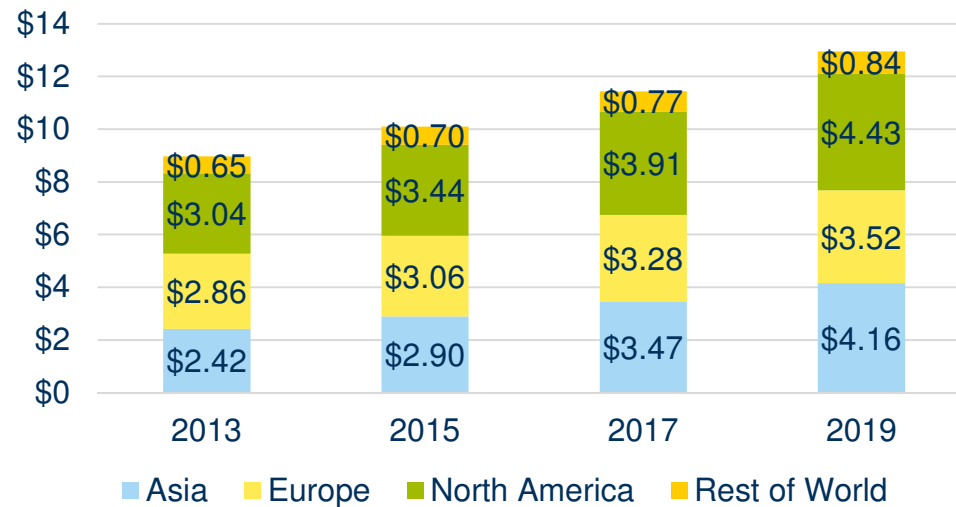
Source: Pharmaceutical Commerce

- By 2020, world sales of **cold-chain drugs and of biologics such as vaccines and insulin products will likely top \$360 billion**, in a global biopharma market exceeding \$1.4 trillion.
- It is estimated **cold-chain logistics spending in 2016 will be about \$12.6 billion worldwide** in a \$78.8 billion overall pharma logistics market.
- Clinical trial logistics, a substantial market for temperature-assured transport, is forecasted to grow at 2%/yr

## Background: Pharmaceutical Market Development

Cold chain logistics spending expected to be fastest in Asia + N. 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.

## 21 countries considered as “pharmerging”

**Pharmerging Countries (2013)**  
(\$1 Billion incremental sales in 5 years)

### PHARMERGING

#### Tier 1

China

#### Tier 2

Brazil

Russia

India

#### Tier 3

Algeria (new)

Argentina

Colombia (new)

Egypt

Indonesia

Mexico

Nigeria (new)

Pakistan

Poland

Romania

Saudi Arabia (new)

South Africa

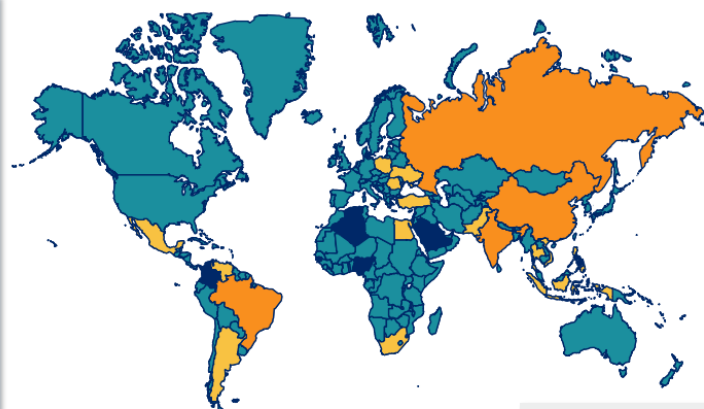
Thailand

Turkey

Ukraine

Venezuela

Vietnam



Pharmerging markets definition :  
\$1Bn incremental sales in 5 years

#### Pharmerging countries

● Tier 1 & 2 Countries

● Tier 3 Countries

● New Tier 3 Countries

### Pharmerging Markets

#### Tier 1

China 15 – 18 %

#### Tier 2

Brazil 10 – 13 %

Russia 11 – 14 %

India 9 – 12 %

India 11 – 14 %

Tier 3

Combined 7 – 10 %

**TOTAL 11 – 14 %**

### Developed Markets

US 1 – 4 %

Japan 2 – 5 %

Germany 1 – 4 %

France (-1) – 2 %

Italy 0 – 3 %

Canada 1 – 4 %

Spain (-4) – (-1) %

UK 1 – 4 %

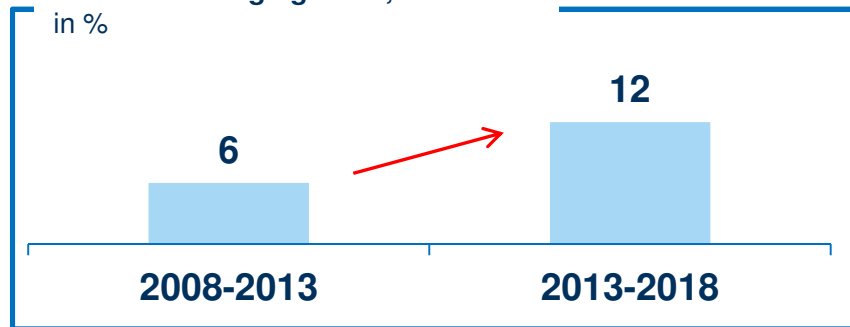
**TOTAL 1 – 4 %**

Source: IMS Health 2013

## Background: Pharmaceutical Product 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 %



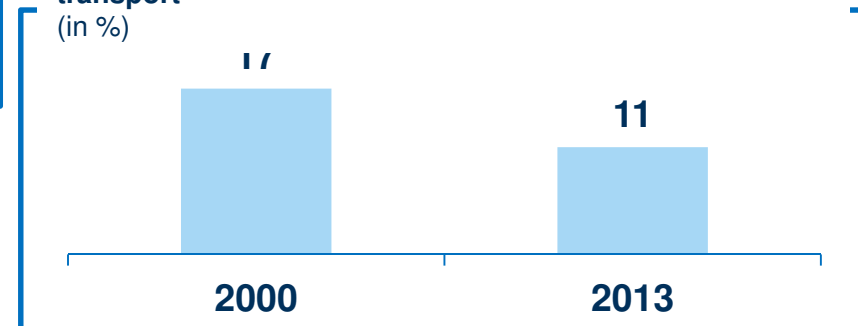
➤ Over the past 10 years, air carriers, handlers and freight forwarders have responded with branded products and services to grab a share of this lucrative and niche market.

Source: Pharmaceutical Commerce

**HOWEVER**



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





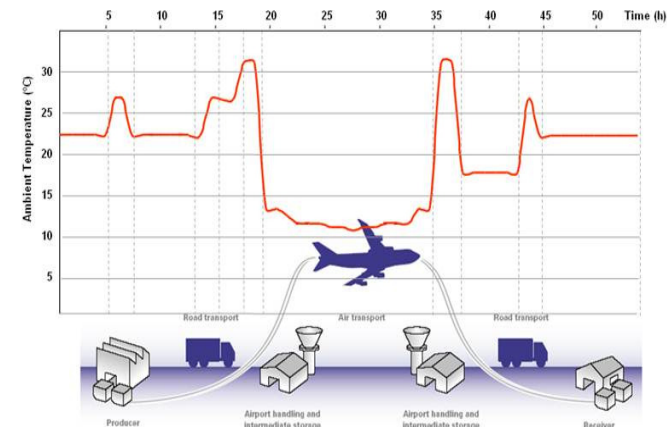
## Air Cargo Industry Concerns and Challenges

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

- 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



- 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

## 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**



## Industry's Call for Action



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

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

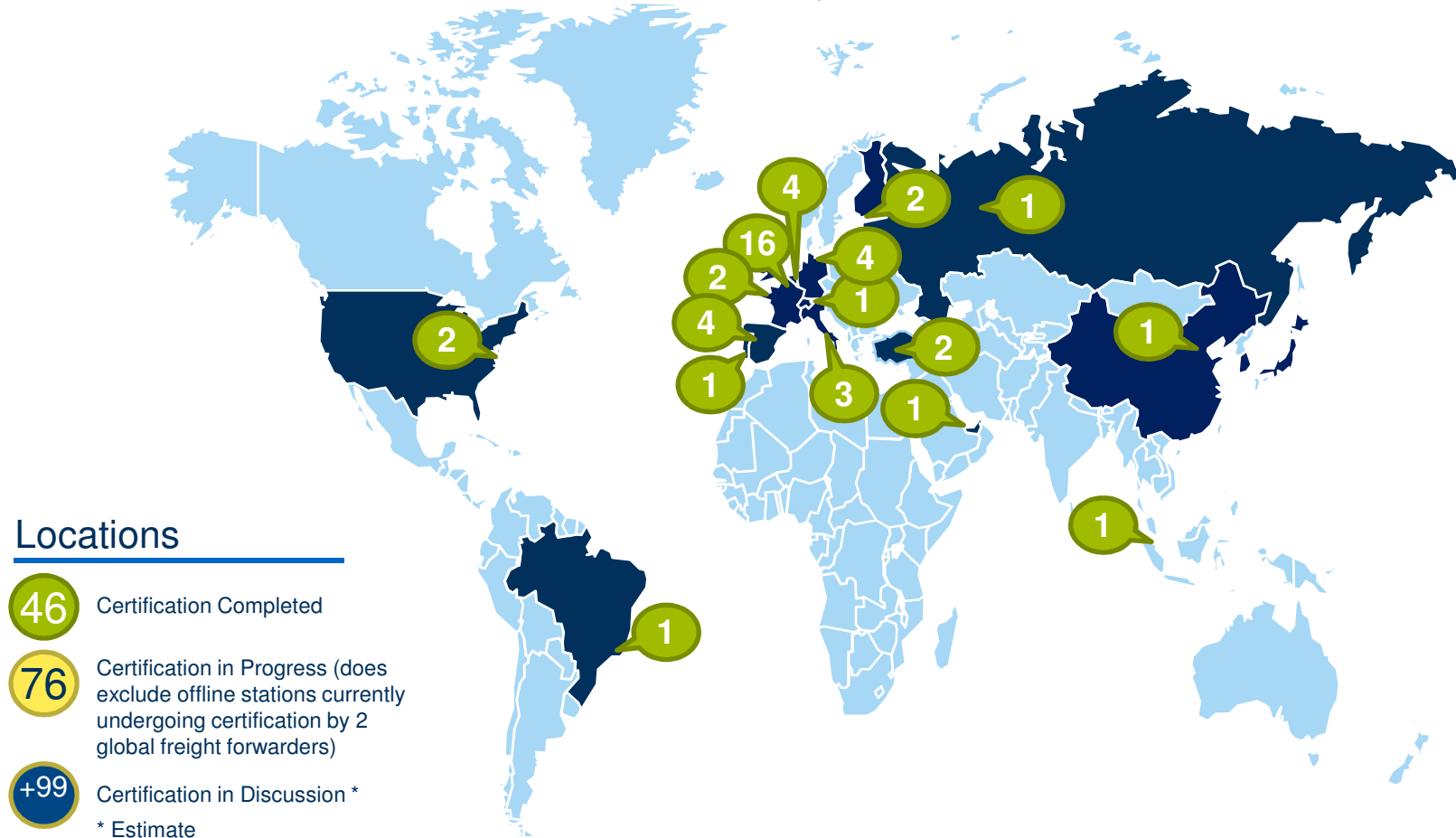
*"The **air cargo industry and IATA** need to **act urgently** to prevent further modal shift of pharmaceutical traffic to sea freight, **on the basis of quality rather than price**, according to forwarders and shippers."*

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

*"You have **various standards** and systems out there and it is a **nightmare** for those that are inside the sandwich, the **ground handler**, who is forced to enforce various systems and procedures—and it is chaos...**IATA is sleeping**"*

## CEIV Pharma (Certified Entities)

### Certified Pharmaceutical Trade Lanes Development





## Visibility for CEIV Pharma validated entities

Validated entities are visible on IATA's website

### 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).

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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			
<a href="#">Submit</a>			

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	MLP	Milan	Italy	15 Sep 2017

## List of companies CEIV Pharma certified



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	Road 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	Road Transportation	Brussels Airport (BRU)	30-Nov-15	30-Nov-17	CEIV-PH-14-0019
DHL Global Forwarding (Belgium) NV/SA	Freight Forwarder	Brussels Airport (BRU)	15-Feb-16	15-Feb-19	CEIV-PH-14-0020

## List of companies CEIV Pharma certified



Name of the company	Category	Location	Date of Certification	Validity	No. of certificate
DHL Global Forwarding (Belgium) NV/SA	Freight Forwarder	Brussels Airport (BRU)	15-Feb-16	15-Feb-19	CEIV-PH-14-0020
Shanghai Pudong Int'l Airport Cargo Terminal Co., Ltd.	Ground Handler	Pu Dong International Airport	15-Feb-16	15-Feb-19	CEIV-PH-14-0021
KLM Air Services	Airlines	Amsterdam Schiphol (AMS)	15-Feb-16	15-Feb-19	CEIV-PH-14-0022
KLM Ground Services	Ground Handler	Amsterdam Schiphol (AMS)	15-Feb-16	15-Feb-19	CEIV-PH-14-0023
Air France Air Services	Airlines	Paris Charles de Gaulle (CDG)	15-Feb-16	15-Feb-19	CEIV-PH-14-0024
Air France Ground Services	Ground Handler	Paris Charles de Gaulle (CDG)	15-Feb-16	15-Feb-19	CEIV-PH-14-0025
Geodis Wilson Belgium NV	Freight Forwarder	Brussels Airport (BRU)	15-Feb-16	15-Feb-19	CEIV-PH-14-0026
Panalpina World Transport N.V.	Freight Forwarder	Brussels Airport (BRU)	28-Feb-16	28-Feb-19	CEIV-PH-14-0027
SATS Ltd. (Changi Airport)	Ground Handler	Changi Airport (SIN)	28-Feb-16	28-Feb-19	CEIV-PH-14-0028
Bolloré Logistics Germany GmbH	Freight Forwarder	Frankfurt Airport (FRA)	30-Mar-16	30-Mar-19	CEIV-PH-14-0029
Aviapartner Belgium NV (Liege Airport)	Ground Handler	Liege Airport (LGG)	15-Mar-16	15-Mar-19	CEIV-PH-14-0031
Düsseldorf Cargo GmbH	Ground Handler	Düsseldorf Airport (DUS)	15-Mar-16	15-Mar-19	CEIV-PH-14-0032
Sharjah Aviation Services	Ground Handler	Sharjah International Airport	15-Apr-16	15-Apr-19	CEIV-PH-14-0033
Perishable Center Frankfurt (PCF)	Ground Handler	Frankfurt Airport (FRA)	31-May-16	30-May-19	CEIV-PH-14-0034
DB Schenker	Freight Forwarder	Adolfo Suárez Madrid-Barajas Airport (MAD)	31-May-16	30-May-19	CEIV-PH-14-0035
DB Schenker	Freight Forwarder	Barcelona El Prat Airport (BCN)	31-May-16	30-May-19	CEIV-PH-14-0036
Air Express Cargo SL	Freight Forwarder	Adolfo Suárez Madrid-Barajas Airport (MAD)	15-Jun-16	15-Jun-19	CEIV-PH-14-0037
OCASA	Freight Forwarder	Long Island, NY, USA	15-Jun-16	15-Jun-19	CEIV-PH-14-0038
Airpharm Logistics	Freight Forwarder	Zona Franca, Barcelona	15-Jul-16	15-Jul-19	CEIV-PH-14-0039

## List of companies CEIV Pharma certified

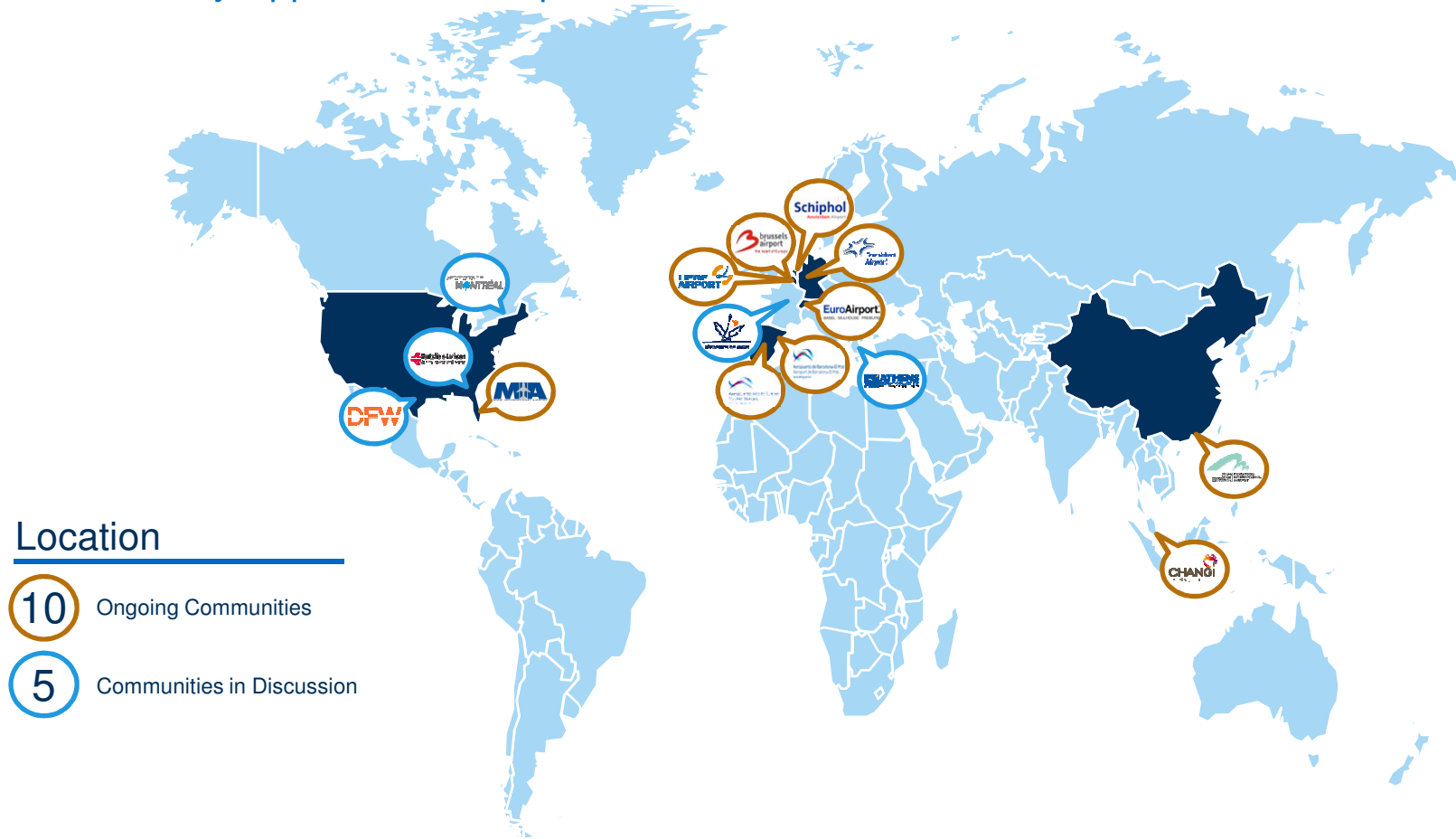


Name of the company	Category	Location	Date of Certification	Validity	No. of certificate
Turkish Airlines	Airlines	Istanbul Airport (IST)	31-Aug-16	31-Aug-19	CEIV-PH-14-0040
Turkish Airlines	Ground Handler	Istanbul Airport (IST)	31-Aug-16	31-Aug-19	CEIV-PH-14-0041
Lufthansa Cargo AG	Airlines	Frankfurt Airport (FRA)	31-Aug-16	31-Aug-19	CEIV-PH-14-0042
Lufthansa Cargo CoolCenter GmbH	Ground Handler	Frankfurt Airport (FRA)	31-Aug-16	31-Aug-19	CEIV-PH-14-0043
Bolloré Logistics Portugal	Freight Forwarder	Lisbon Airport (LIS)	30-Sep-16	30-Sep-19	CEIV-PH-14-0044
Air Express International USA, Inc. dba LiveConEx	Freight Forwarder	Plantation, FL; USA	31-Oct-16	31-Oct-19	CEIV-PH-14-0045
Aviapartner Belgium NV (Brussels Airport)	Ground Handler	Brussels Airport (BRU)	8-Dec-16	8-Dec-17	CEIV-PH-14-0046
Expeditors International NV (Brussels Airport)	Freight Forwarder	Brussels Airport (BRU)	8-Dec-16	8-Dec-17	CEIV-PH-14-0047
SDV Belgium (Brussels Airport)	Freight Forwarder	Brussels Airport (BRU)	8-Dec-16	8-Dec-17	CEIV-PH-14-0048
UTi Belgium NV - Brussels Airport	Freight Forwarder	Brussels Airport (BRU)	8-Dec-16	8-Dec-17	CEIV-PH-14-0049
Bio Pharma Logistics - Brussels Airport	Freight Forwarder	Brussels Airport (BRU)	8-Dec-16	8-Dec-17	CEIV-PH-14-0050
CONCESSIONÁRIA AEROPORTO RIO DE JANEIRO S.A.	Ground Handler	Rio Galeao (GIG)	30-Nov-16	30-Nov-19	CEIV-PH-14-0051
Yusen Logistics Amsterdam B.V.	Freight Forwarder	Amsterdam Schiphol (AMS)	30-Nov-16	30-Nov-19	CEIV-PH-14-0052
Cyber Freight Amsterdam B.V.	Freight Forwarder	Amsterdam Schiphol (AMS)	30-Nov-16	30-Nov-19	CEIV-PH-14-0053
AirBridgeCargo Airlines LLC	Airlines	Sheremetyevo International Airport (SVO)	30-Nov-16	30-Nov-19	CEIV-PH-14-0054
FB Logistics BVBA/SPRL	Road Transportation	Machelen, Belgium	30-Dec-16	30-Dec-19	CEIV-PH-14-0055



## CEIV Pharma (Community Approach)

### Community Approach Development Worldwide



## CEIV Pharma (Community Approach)

### Community Approach Development North America



#### Location

6

Stations participating in  
Community Approach in North  
America

## CEIV Pharma (Community Approach)

### Community Approach Development Europe



#### Location

51 Stations participating in Community Approach in Europe



## CEIV Pharma (Community Approach)

### Community Approach Development Europe

#### Location

51 Stations participating in Community Approach in Europe



## CEIV Pharma (Community Approach)

### Community Approach Development Asia

#### Location

**13** Stations participating in Community Approach in Asia



## CEIV Pharma (Certified) Asian Community



### Locations

- 2 Certification Completed
- 20 Certification in Progress

## CEIV Pharma Asian Community



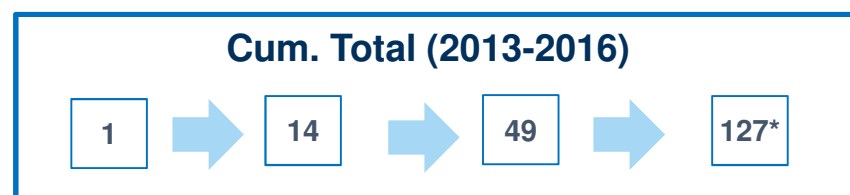
### Locations

- 2** Certification Completed
- 21** Certification in Progress (1 undisclosed)

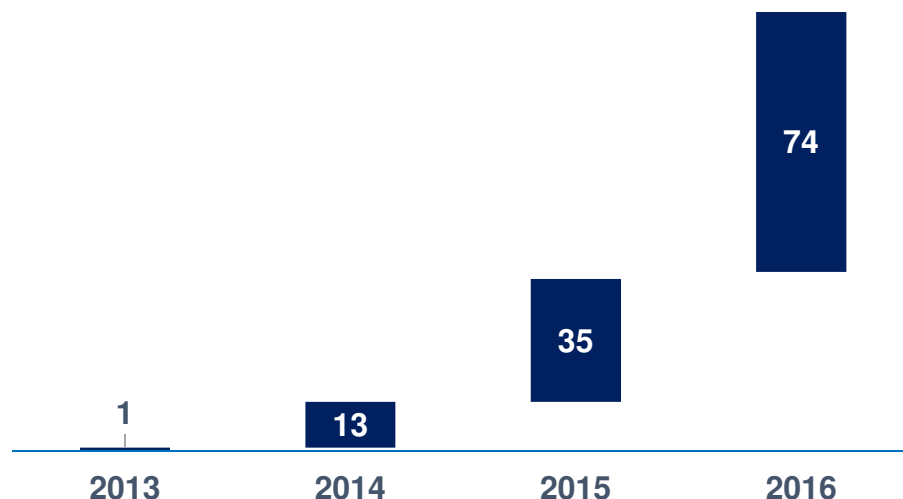
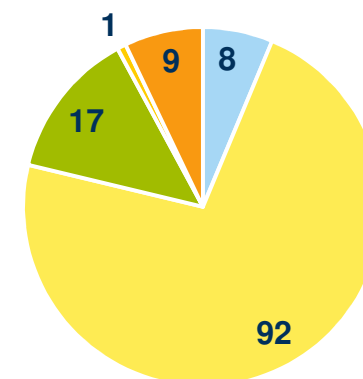
## Number of Entities Assessed

IATA expects to have assessed 127 entities by end of 2016 ...and counting

**Entities assessed 2013 - 2016;**  
in no. of entities assessed



**Entities assessed / region in 2013 -2016;**  
in no. of entities assessed



■ Area 3 ■ Area 2 ■ Area 1 ■ Area 4 ■ Area 5  
 Area 1: The Americas  
 Area 2: Europe / CIS  
 Area 3: Asia / Pacific  
 Area 4: MENA / Africa  
 Area 5: North Asia

\* exclude **off-line** stations currently undergoing certification by 2 global freight forwarders

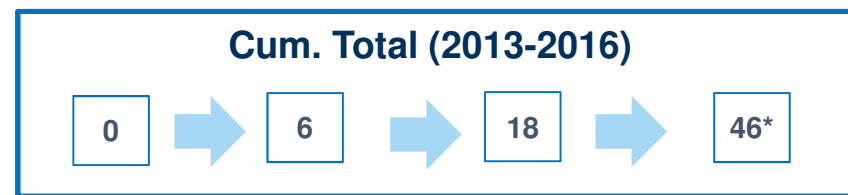
Source: IATA



## Number of Entities Assessed

IATA expects to have a minimum of 46 entities certified by the end of the year... and counting

Entities certified 2013 - 2016;  
in no. of entities certified



Minimum no. of entities that will finalize certification. Actual number will be higher.

28

12

0

6

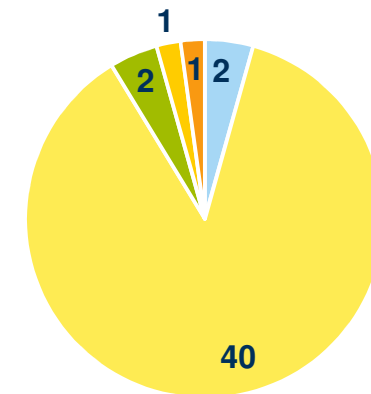
2013

2014

2015

2016

Entities certified / region in 2013 -2016;  
in no. of entities certified



Area 3 Area 2 Area 1 Area 4 Area 5

Area 1: The Americas  
Area 2: Europe / CIS  
Area 3: Asia / Pacific  
Area 4: MENA / Africa  
Area 5: North Asia

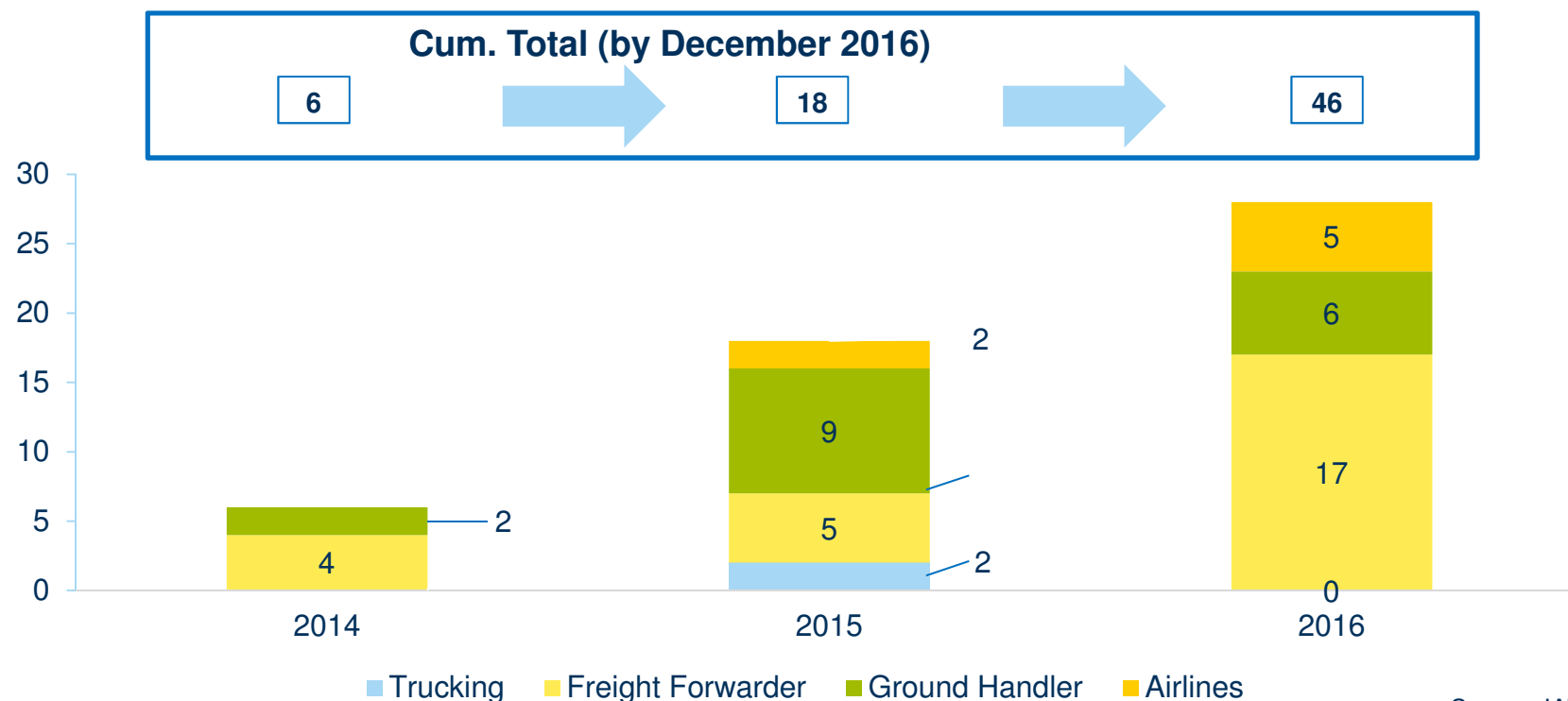
\* exclude **off-line** stations currently undergoing certification by 2 global freight forwarders

Source: IATA

## Types of Entities Certified

The majority of the entities certified are ground handlers and freight forwarders

**Entities certified by December 2016;**  
in no. of entities certified BY TYPE



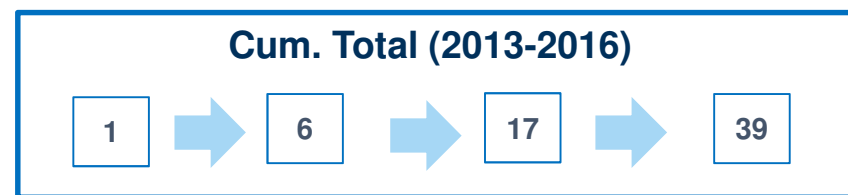
\* exclude **off-line** stations currently undergoing certification by 2 global freight forwarders

Source: IATA

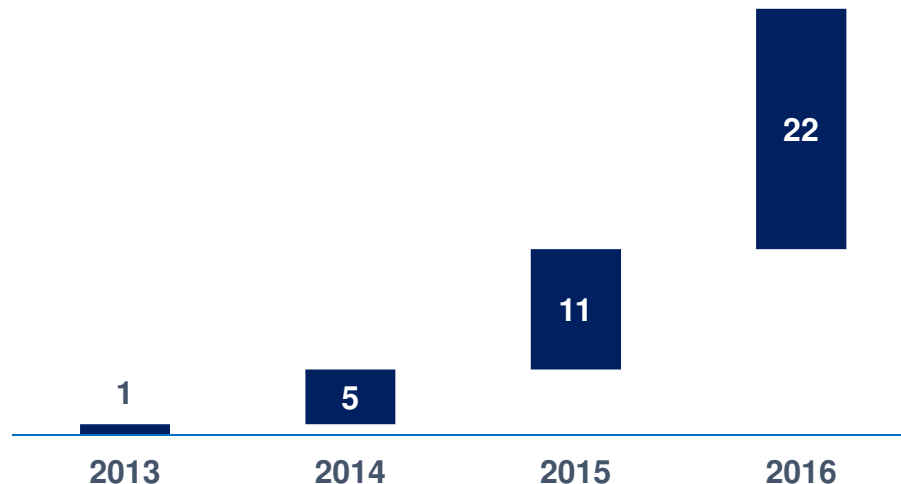
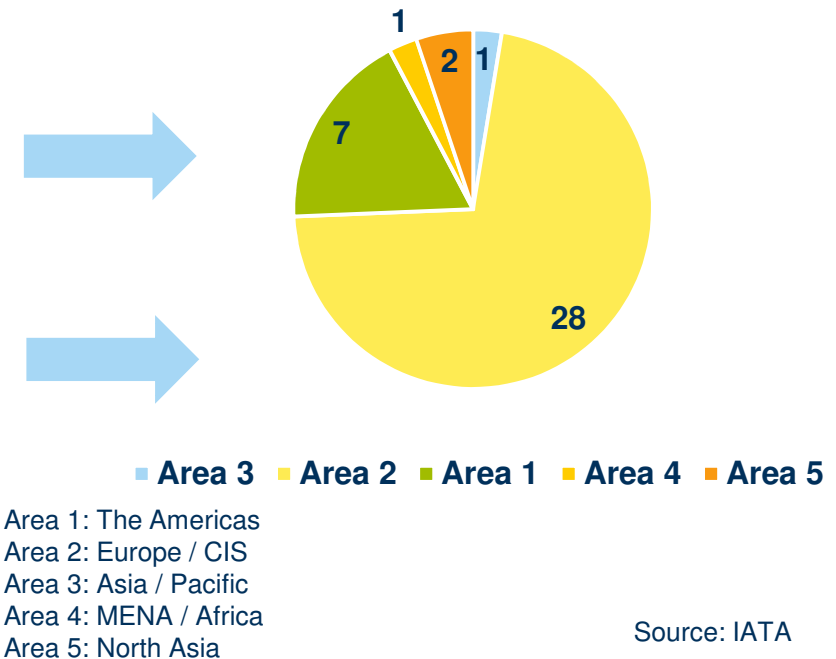
## Number of Airports / Locations

IATA will have conducted assessments at 39 airports between SEP/2014 and DEC/2016

**Locations of CEIV Pharma, 2013 - 2016;**  
in no. of airports



**Airports / region in 2013 - 2016;**  
in no. of entities assessed



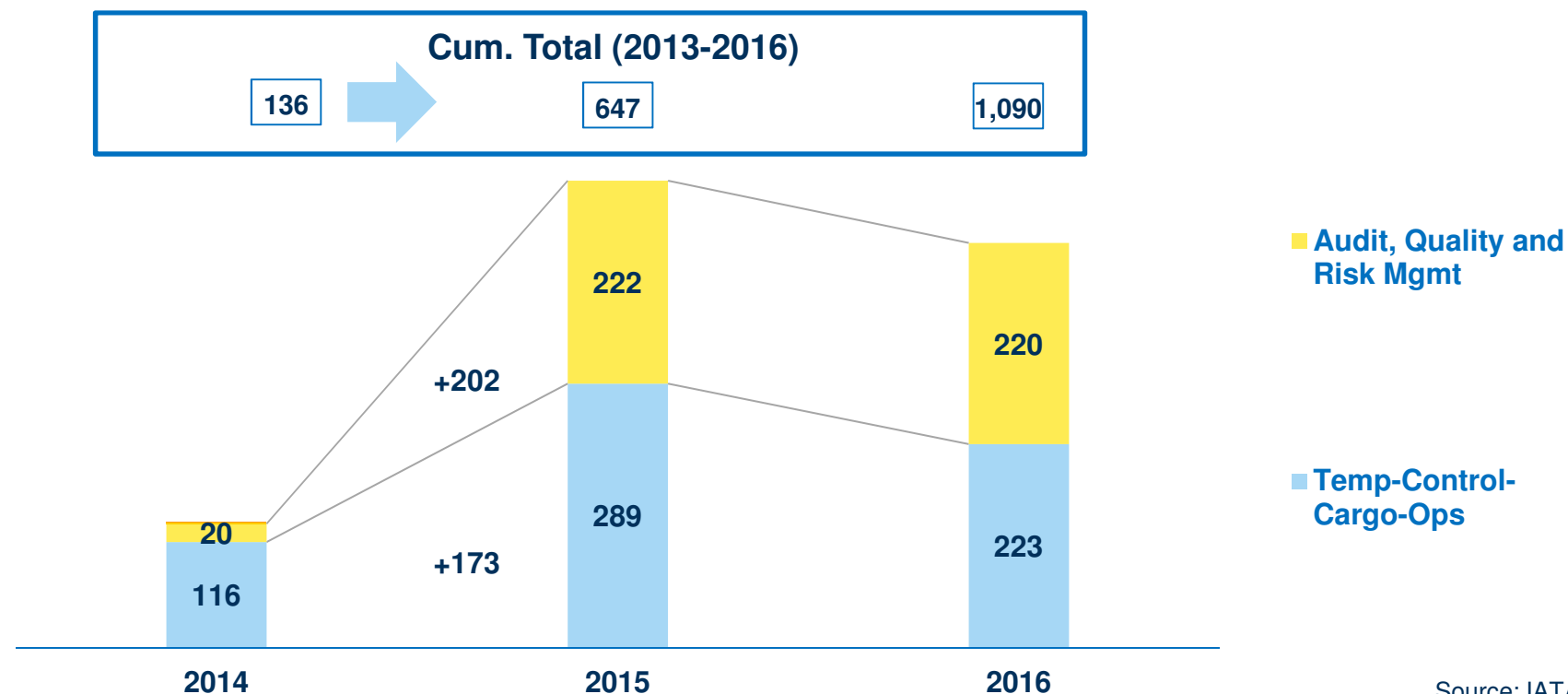
\* exclude stations currently undergoing certification by 2 global freight forwarders

Source: IATA

## Number of People Trained

Over 1,000 students trained

Students trained by end of September 2016;  
in no. of students



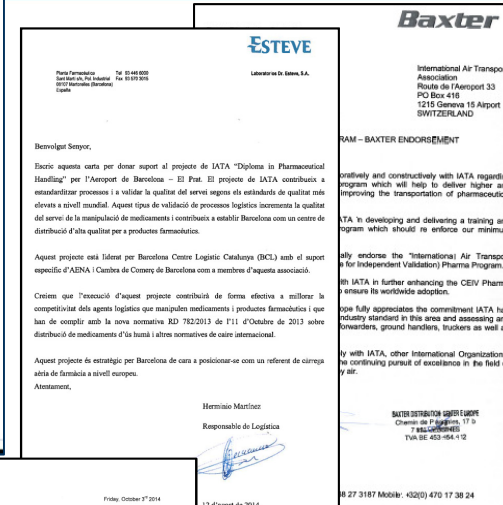


## Advocacy Governance Support from Shippers

Spain



Belgium





## Advocacy Governance Support from Shippers

### Singapore



Merck Sharp & Dohme  
Asia Pacific Services Pte Ltd  
21 Tanjong Pagar Road  
Singapore 077160  
Tel: 65 6377 2888  
Fax: 65 6377 2889  
Reg No: 201408522

Mr. Rodrigo REYES  
International Air Transport Association (IATA)  
111 Somerset Road  
#14-05 TripleOne Somerset  
Singapore 238164

15<sup>th</sup> Sep 2016

IATA CEIV PHARMA PROGRAM - Merck Sharp & Dohme (MSD) ENDORSEMENT

Dear Mr. Rodrigo REYES

Thank You for sharing the "International Air Transport Association CEIV (Center of Excellence for Independent Validation) Programme that aims at improving the handling of pharmaceutical cargo with the industry stakeholders (freight forwarders, ground handling agents, truckers, air carriers).

We are pleased to learn that the CEIV program aims to align and harmonize the International Good Distribution Practices (GDP) through establishment and implementation of global standardized work procedures, provide training support and to having an independent audit programme in place.

In this context, I am pleased to endorse IATA's efforts and commitment in setting an industry standard and driving this programme at a global scale which will benefit the industry stakeholders with improved product handling efficacy and best practices when transporting pharmaceutical cargoes via Airfreight.

I look forward in working constructively with IATA and other related International Organizations or Regulators. Please let me know if I can be of any further assistance in the pursuit of Operational Excellence in the Air Cargo transportation of Pharmaceutical products.

Kind regards and best wishes for coming successes

Yours faithfully,  
  
Wong Jie  
Associate Director, Product Handling & Cold Chain, Asia-Pacific  
Supply Chain, Global Centre of Excellence (CoE)  
Merck Sharp & Dohme Asia Pacific Services  
Email: [wongjie@merck.com](mailto:wongjie@merck.com)  
Mobile: +65 9247 2701





## Endorsement from European Shipping Council



ESC



EUROPEAN SHIPPERS' COUNCIL

15 July 2015

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

### IATA CEIV PHARMA PROGRAM – European Shippers' Council ENDORSEMENT

Dear Mr. Windmüller,

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 Delewaere  
Secretary General – European Shippers' Council

European Shippers' Council  
Rue de l'Europe 1  
1049 Brussels  
Belgium  
Phone: +32 2 2343181  
info@european-shippers.eu  
www.european-shippers.eu





## Endorsement from Belgian Regulator

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

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

*Josiane Van der Elst, Director General DG Inspection FAGG says*

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

**fagg – afmps, November 25, 2014**



## Testimonials

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

*Frank van Gelder, Adelanter, 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*