



CEIV
Center of Excellence
for Independent Validators

Pharmaceutical Handling



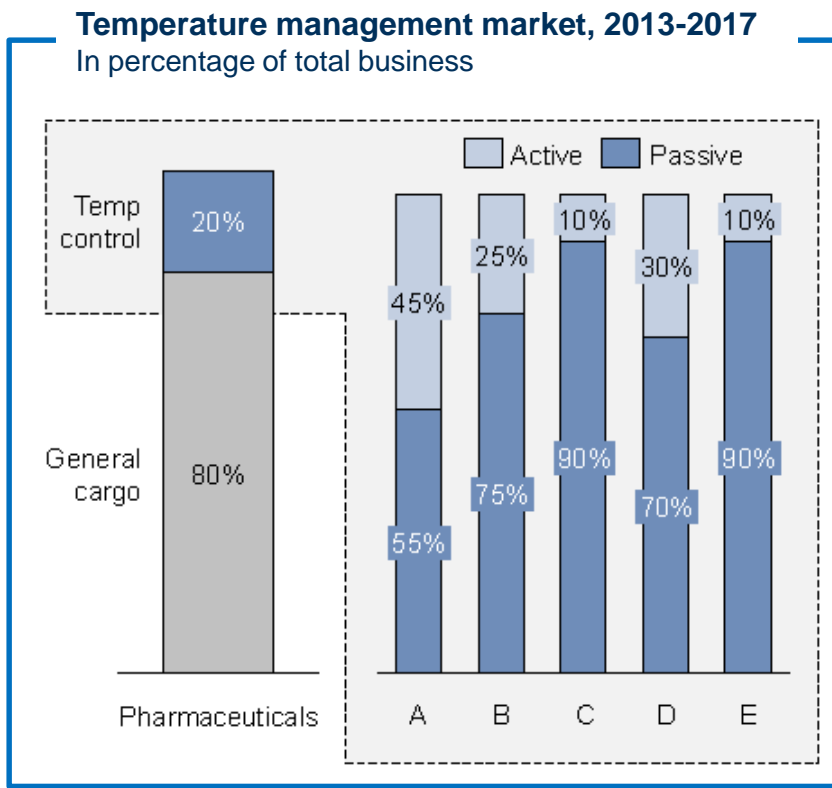
FRA 
AIR CARGO COMMUNITY

**„FRA meets Pharma“
November 28, 2017**

- 1.0 **Introduction:** Pharma logistical market growing – Concerns and Challenges
- 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 CEIV Pharma: Update of activities

Background: Pharmaceutical Product Logistics

Temperature control share of pharma



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**.

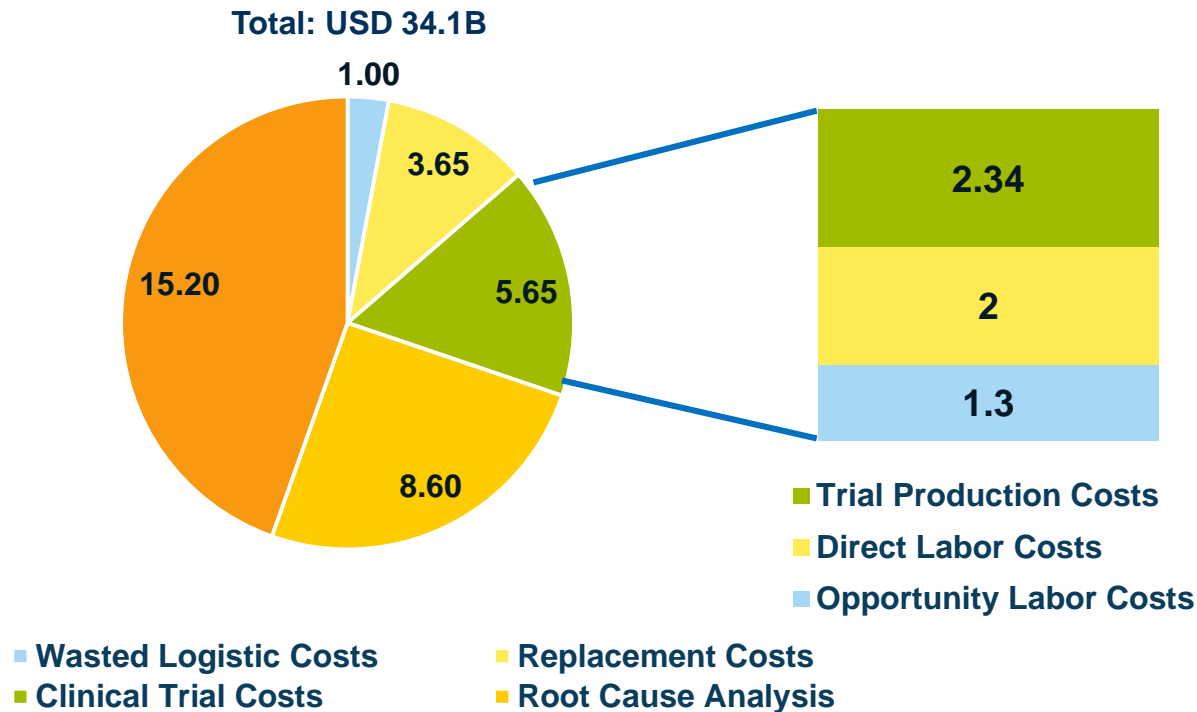
➤ Active temperature control solutions demand a yield premium due to complex requirements.

➤ Passive solutions drive volume and are less costly to implement.

Background: Critical Issues Raised by the Shippers

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

Losses associated with temperature excursions
In USD Billion

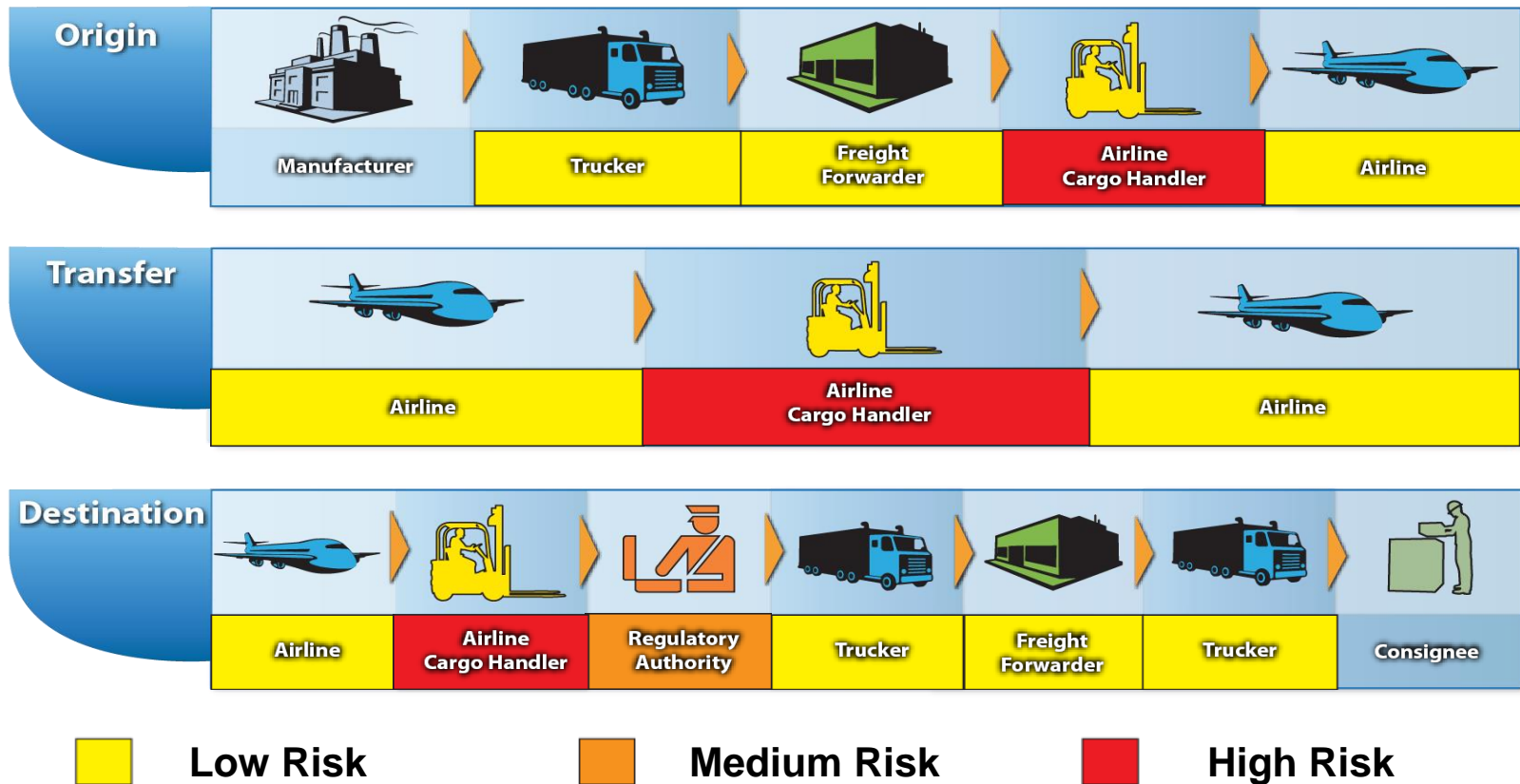


↗ The average costs of root cause analysis for each excursion can range from \$3K to up to \$10K (avg. USD 6.5K per year)

Source: World Health Organization, Parenteral Drug Association, worldpharmaceuticals.net, cargosense.com, other industrial analysis

Background: Air Cargo Industry Concerns and Challenges

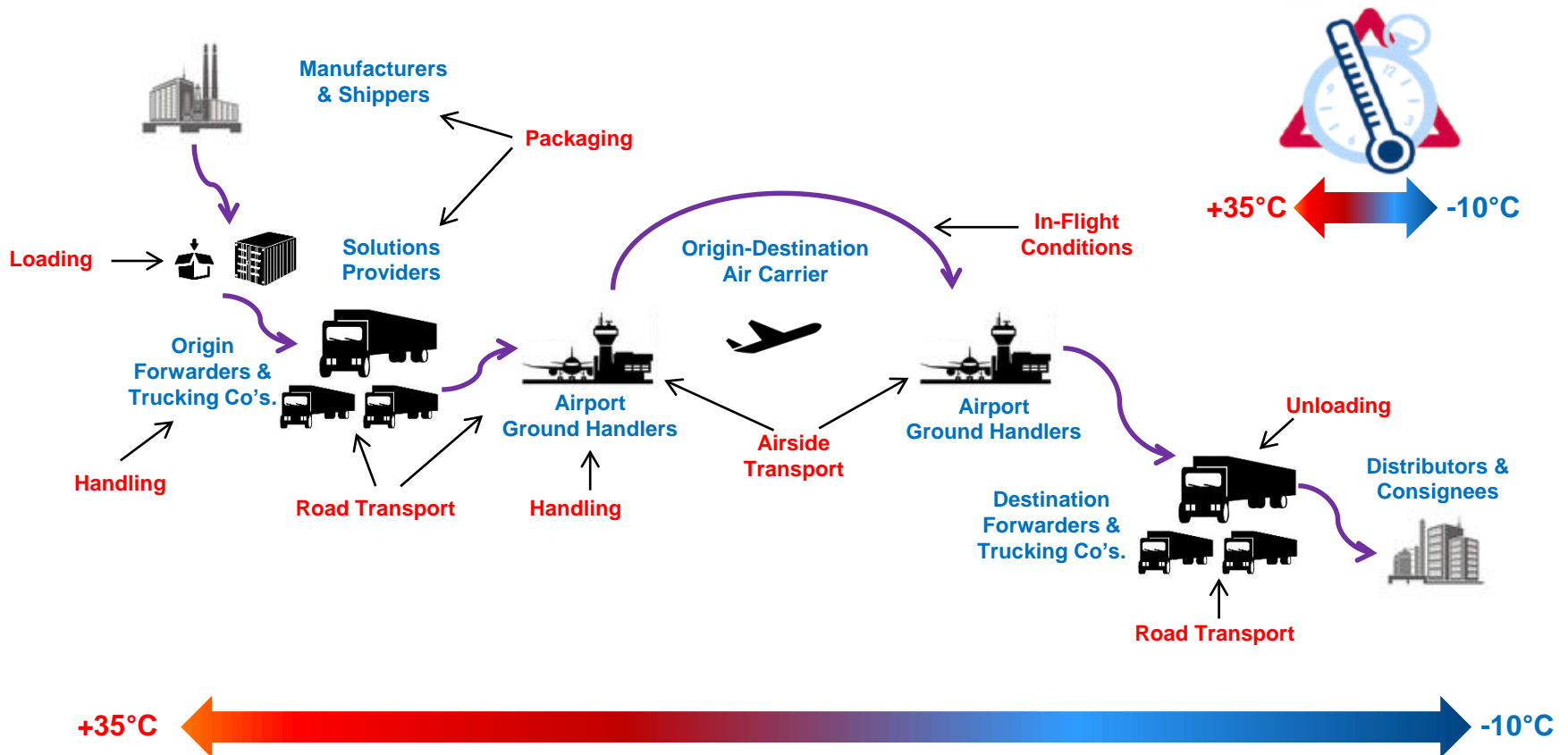
Temperature Excursions – Where do they occur?



Source: Expeditors

Background: Air Cargo Supply Chain Challenges

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



- 1.0 Introduction: Pharma logistical market growing – Concerns and Challenges
- 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 CEIV Pharma: Update of activities

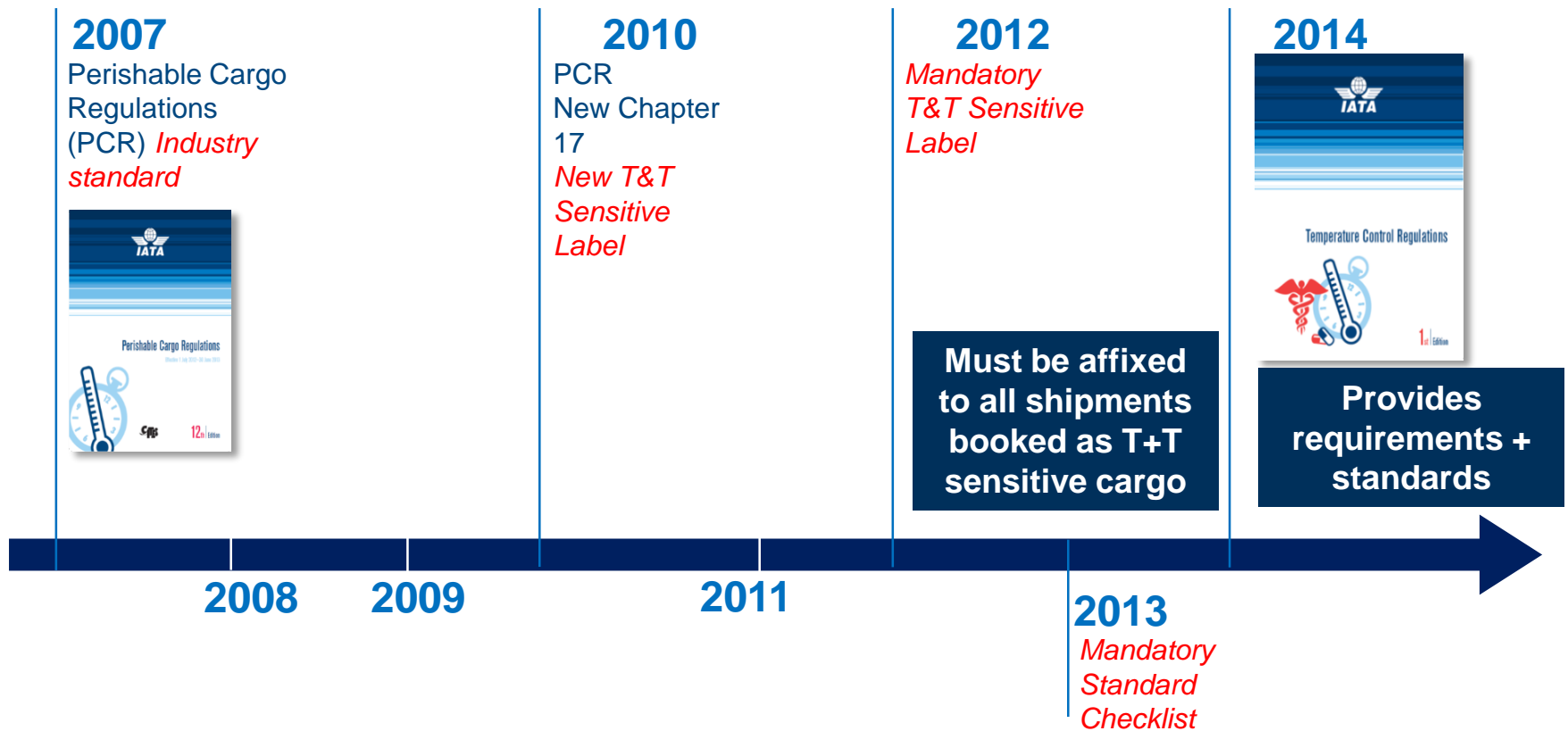
Industry Cooperation in Air Cargo

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



IATA a Standard Setting Organization

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



Content

- 1.0 Introduction: Pharma logistical market growing – Concerns and Challenges
- 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

CEIV Pharma

To ensure the integrity of the product throughout the supply chain

»» OBJECTIVES



Prevent sanitary issues caused by temperature excursions during transportation.

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

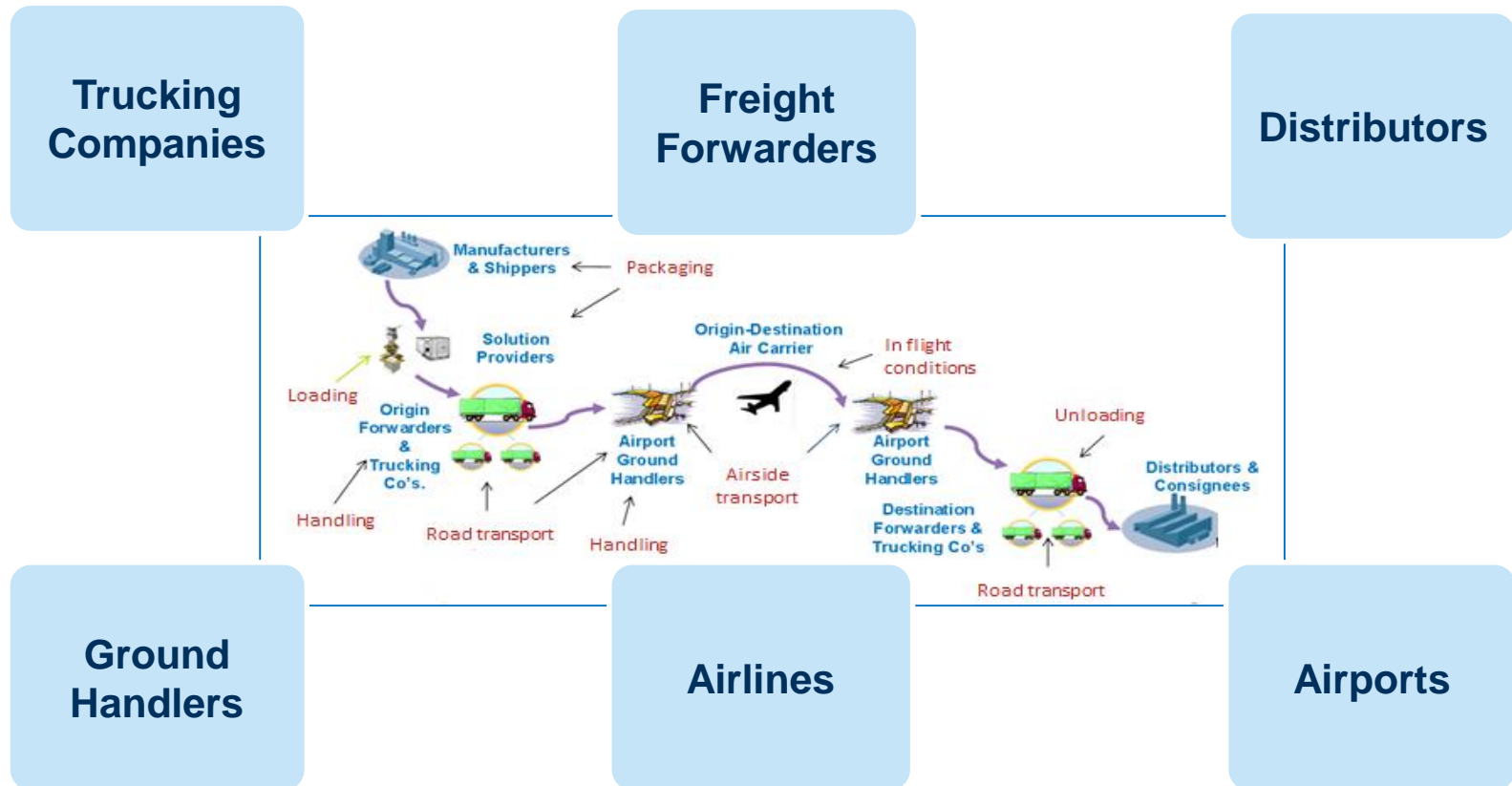
Ensure product integrity

Elevate level staff competency through efficient and robust training program.

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

CEIV Pharma targets

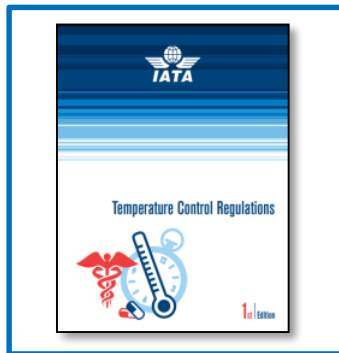
Who does CEIV Pharma target? The supply chain



CEIV Pharma Standard

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

IATA GUIDELINES



GOOD DISTRIBUTION PRACTICES



LOCAL + REGIONAL GUIDELINES



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.

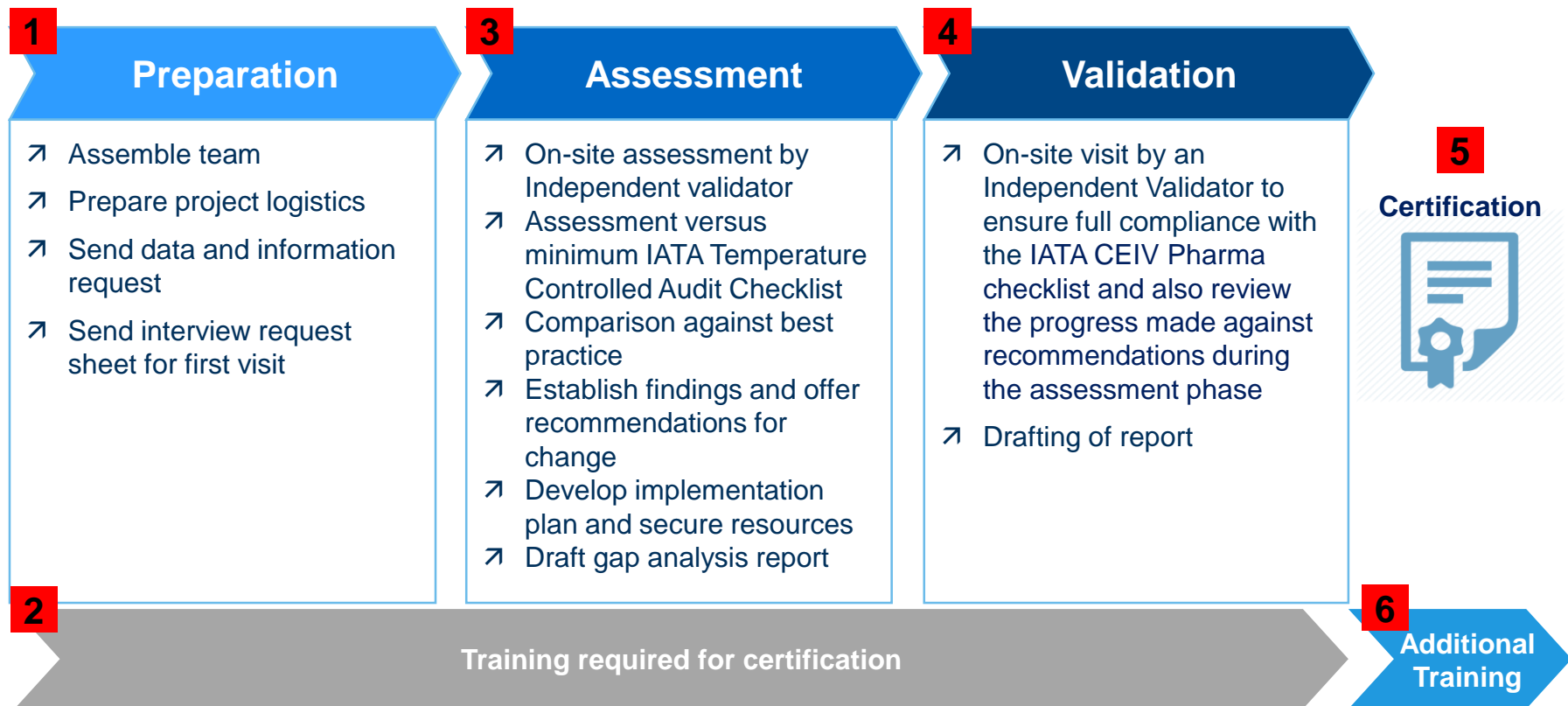


Content

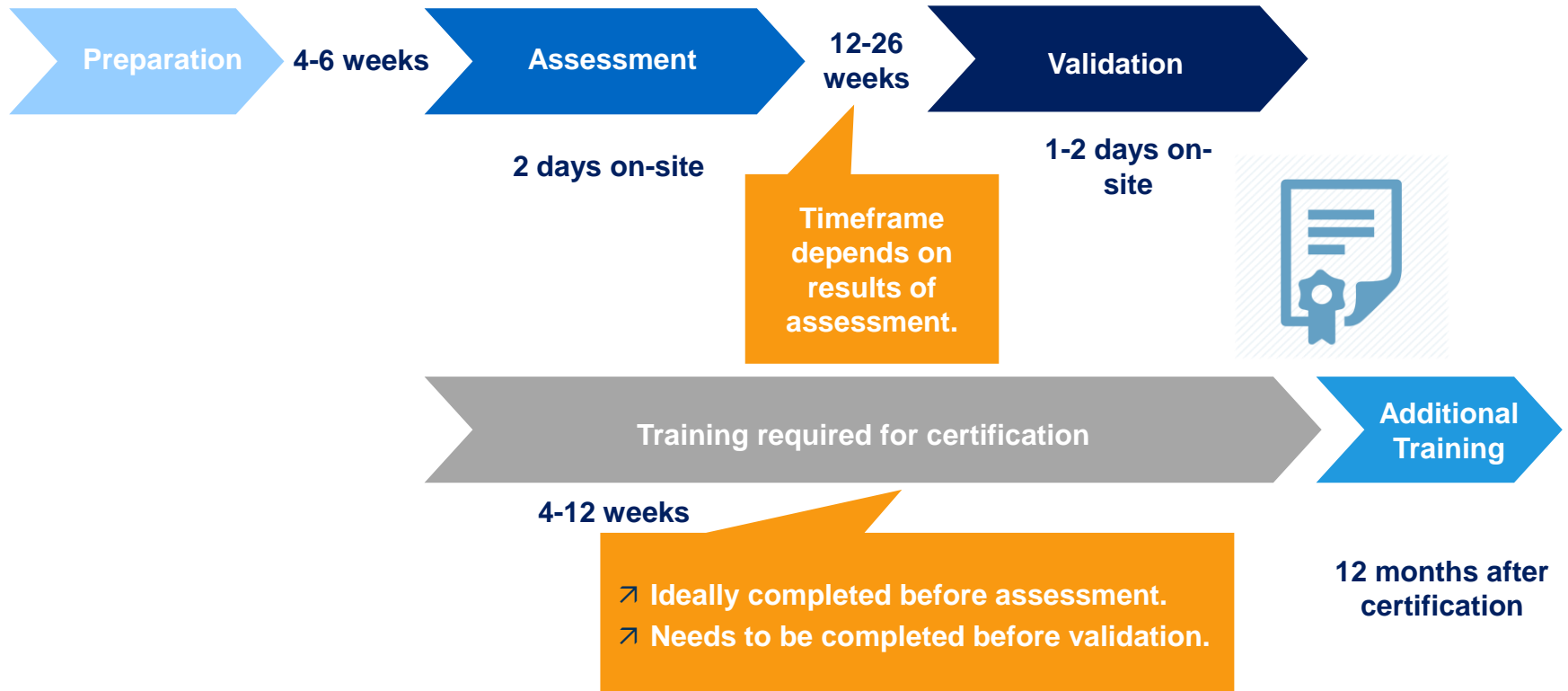
- 1.0 Introduction: Pharma logistical market growing – Concerns and Challenges
- 2.0 Standards + Regulations: The nature of the industry requires strong cooperation and IATA as a standard setting organization
- 3.0 Objective: CEIV Pharma is a concerted effort to improve the level of competency, operational 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 CEIV Pharma: Update of activities

Certification Approach and Methodology

IATA will certify companies in several steps



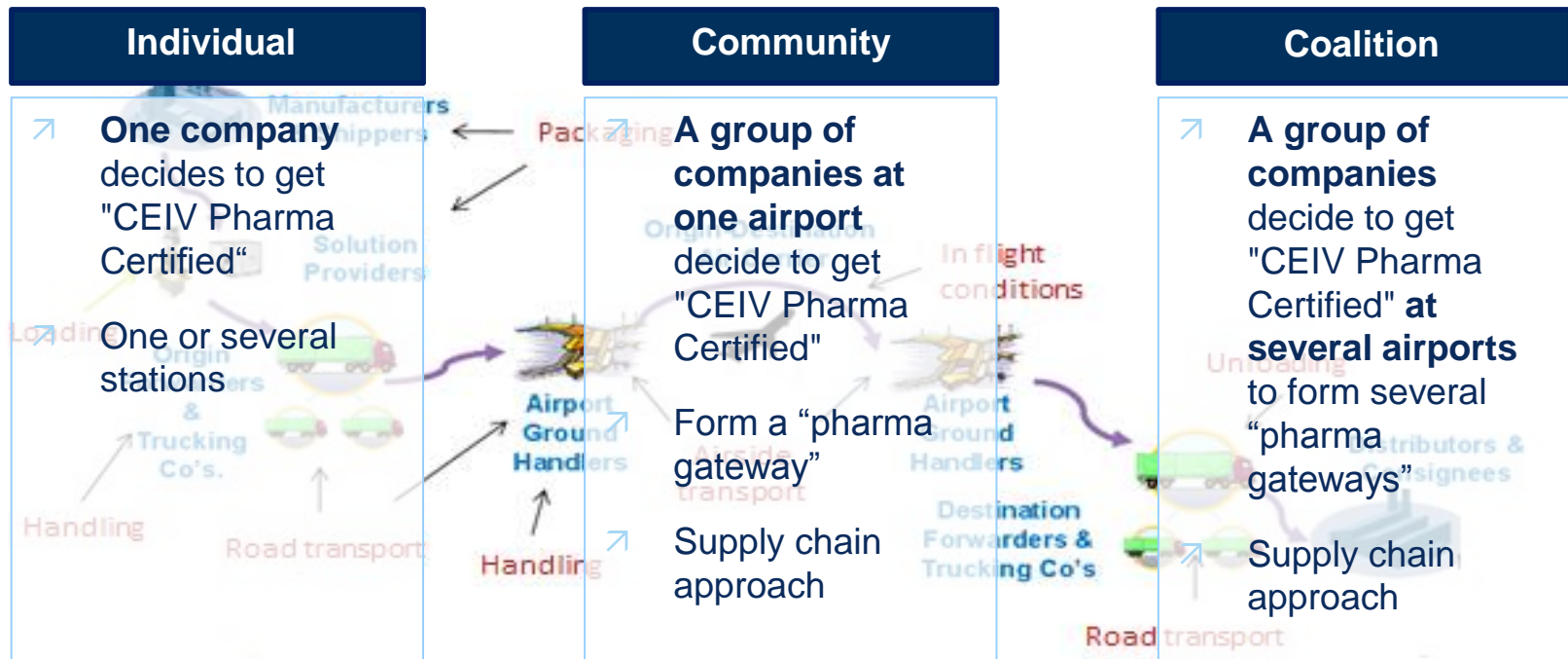
Certification Timeline (general approach)



- 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 with qualified experts**
- 6.0 CEIV Pharma: Update of activities

CEIV Pharma Certification Approach

There are different approaches to obtain certification



Project structure – Who is involved and who can participate?

Everyone in the value chain can participate in the certification process

Example (BRUCargo)

Pharma shippers



Forwarders with pharma focus



Handlers



Truckers



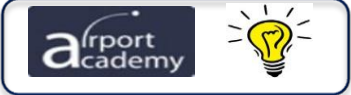
Airlines



Regulators



Facilitators



- 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 **CEIV Pharma: Update of activities**

CEIV Pharma (Certified Entities)

Certified Pharmaceutical Trade Lanes Development

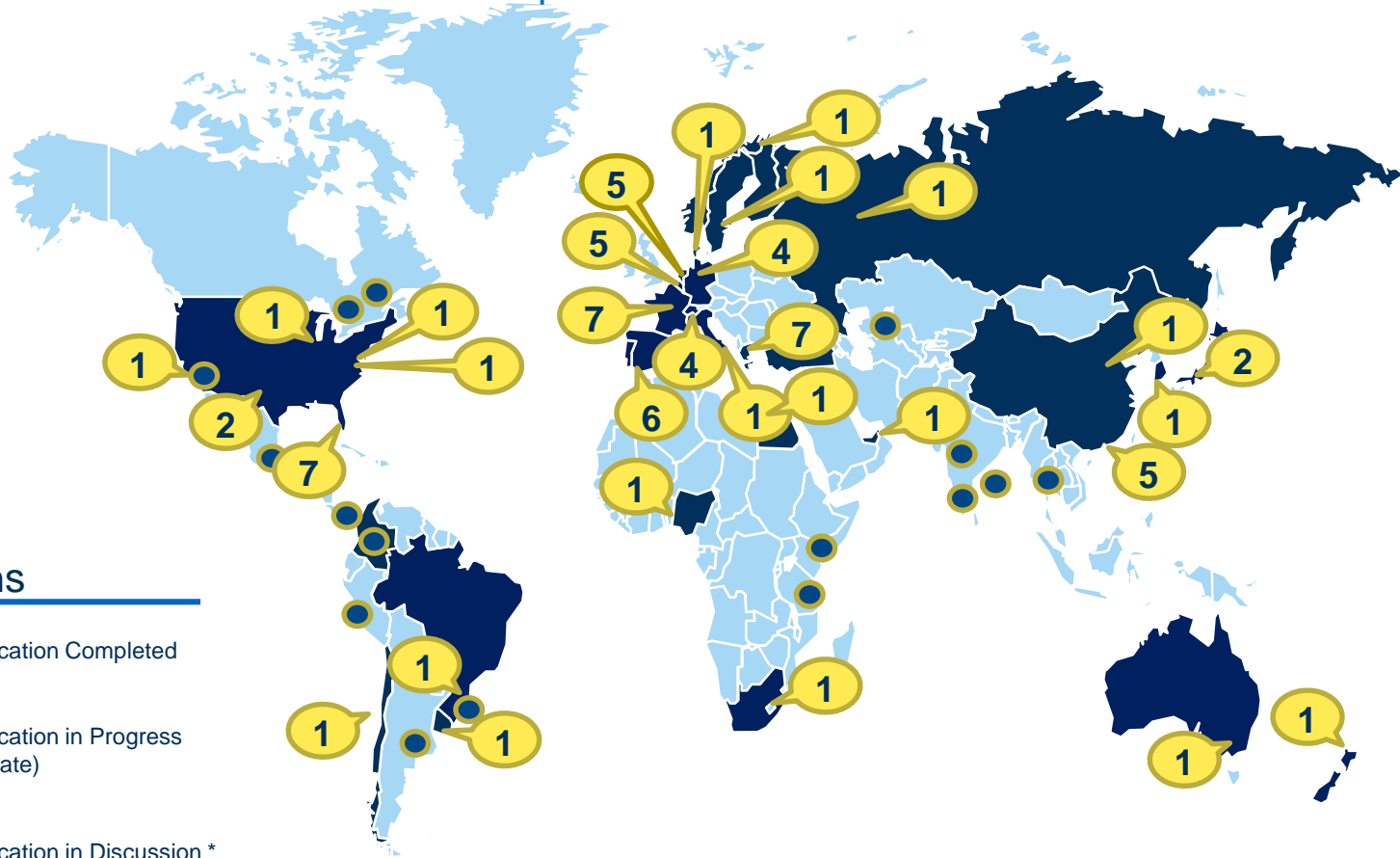


Locations

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

CEIV Pharma (Certification in Progress)

Pharmaceutical Trade Lanes Development

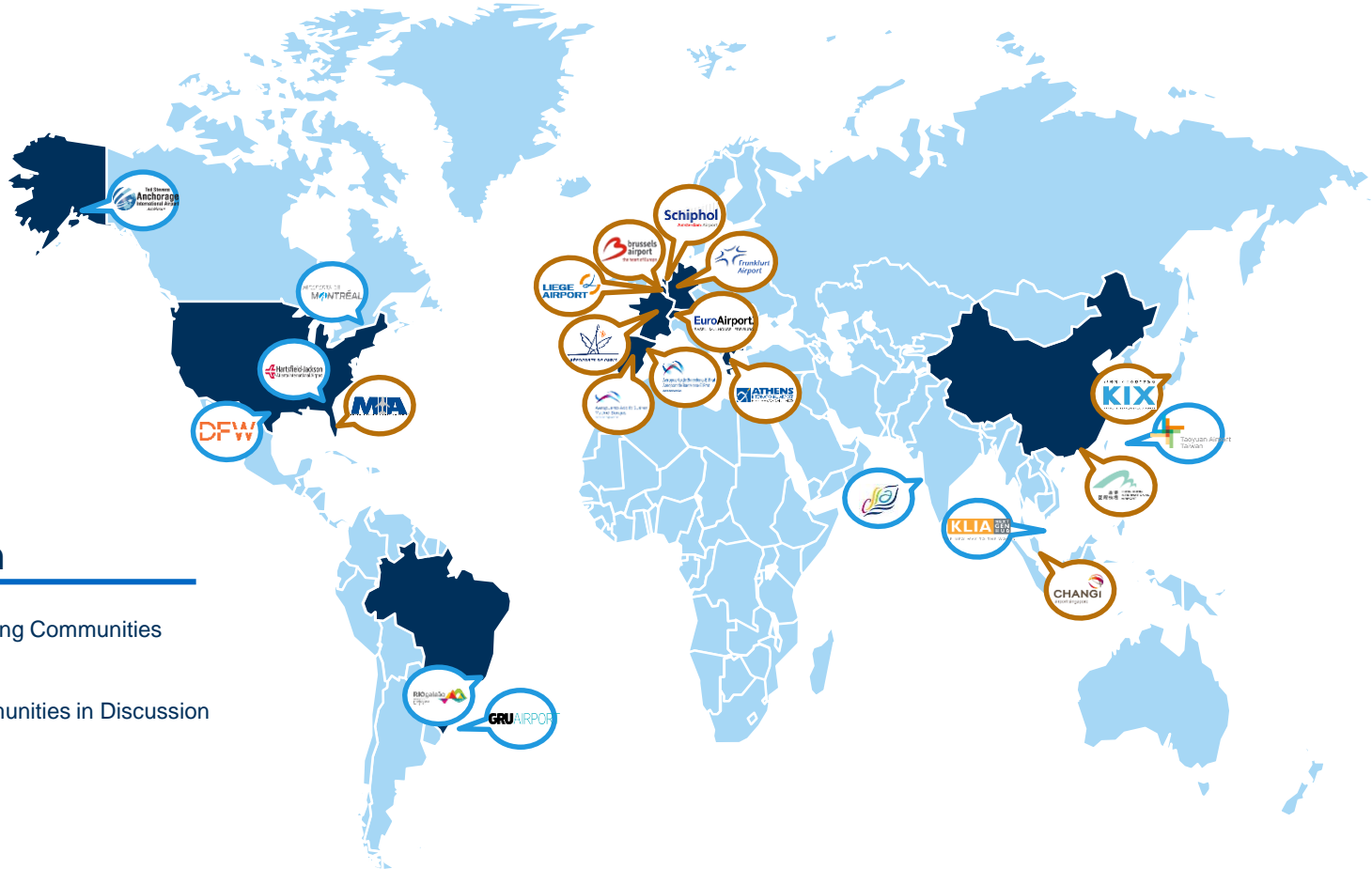


Locations

- 182 Certification Completed
 - +75 Certification in Progress (estimate)
 - +99 Certification in Discussion *
- * Estimate

CEIV Pharma (Community Approach)

Community Approach Development Worldwide



Location

- 12** Ongoing Communities
- 9** Communities in Discussion

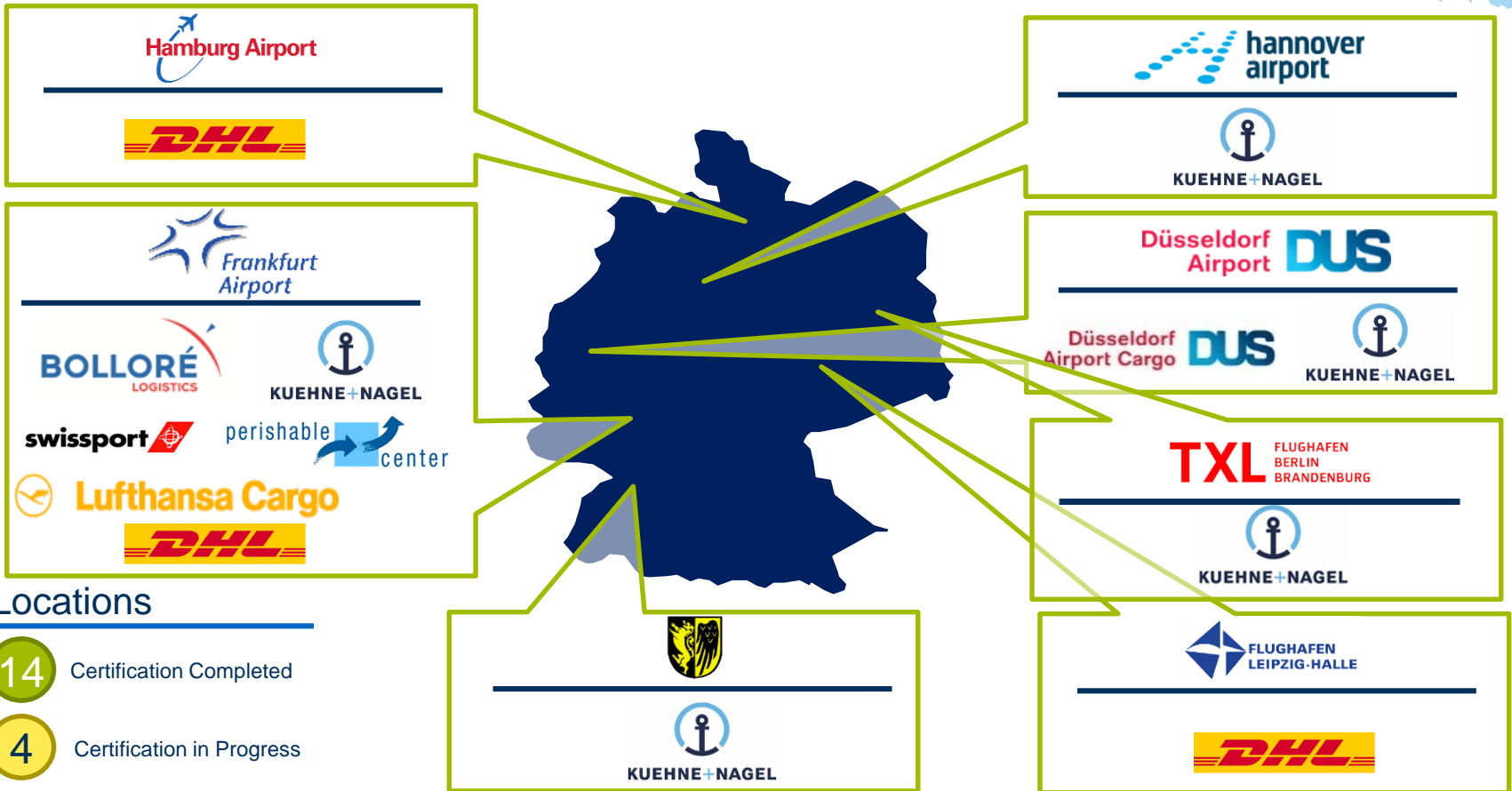
CEIV Pharma (Community Approach)

Community Approach Development Europe

Location

64 Stations participating in Community Approach in Europe

CEIV Pharma (Certified) Germany



Locations

14 Certification Completed

4 Certification in Progress

CEIV Pharma (in progress)

Germany



Frankfurt Airport

CELEBI CARGO

FCS
Frankfurt Cargo Services

FRAPORT

LUG
aircargo handling

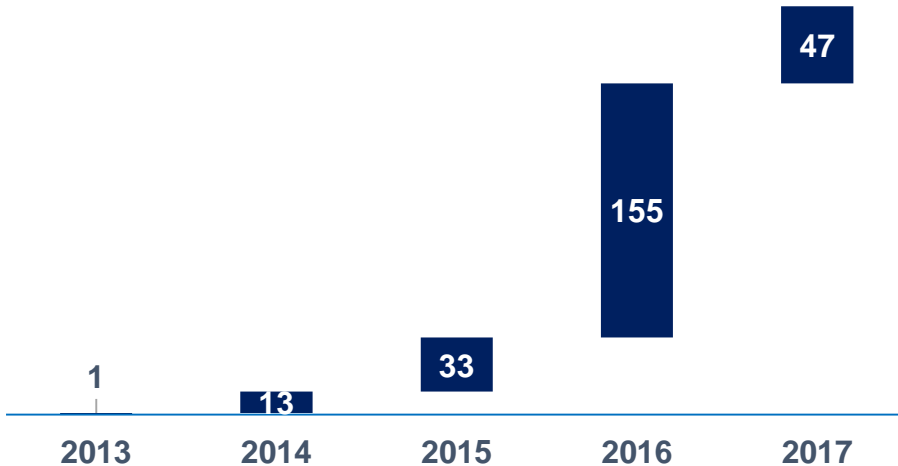
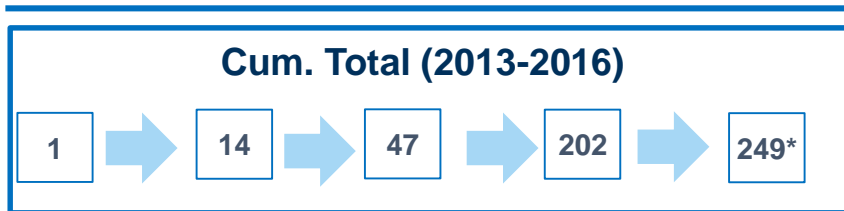
Locations

- 14 Certification Completed
- 4 Certification in Progress

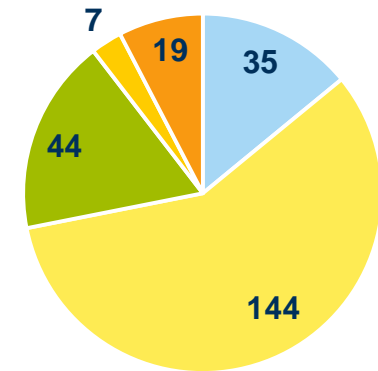
Number of Entities Assessed

IATA expects to have assessed 249 entities by end of 2017 ...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

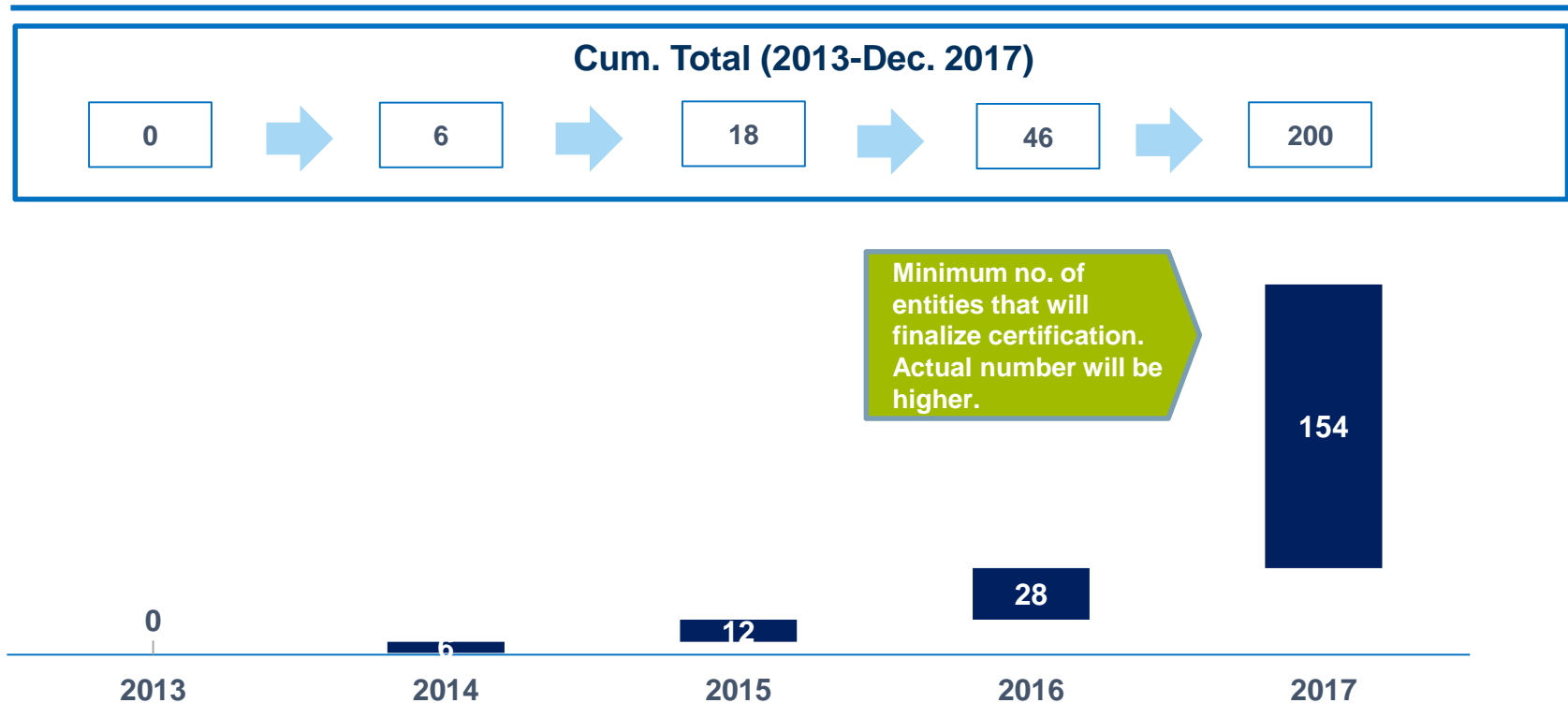
Area 1: The Americas
Area 2: Europe / CIS
Area 3: Asia / Pacific
Area 4: MENA / Africa
Area 5: North Asia

Source: IATA

Number of Entities Certified

IATA expects to have a minimum of +190 entities certified by the end of the year... and counting

Entities certified 2013 - 2017;
in no. of entities certified



Source: IATA



Thank you!