

Ensuring Safe and Compliant Air Freight for Clinical Trial Shipments

Navigating Temperature-Controlled Logistics
and Regulatory Challenges

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Who we are



-  **330** airline members
-  **80%** of global air traffic
-  **120** country representative

- ❖ 56 offices in 53 countries
- ❖ 1,400 employees
- ❖ Founded in Havana, Cuba in April 1945
- ❖ Head Office: Montreal, Canada
- ❖ Executive Office: Geneva, Switzerland
- ❖ Regional Offices: Madrid, Singapore, Beijing, Amman, Miami

Agenda

Market Outlook

- Air Cargo Market Outlook
- Pharmaceutical Air Cargo Demand

IATA Standard Development

- IATA Standard-Setting Organization
- Board and Working Groups Activities

IATA Temperature Control Regulations (TCR)

- Key Regulatory Changes for 2025
- Standards Impacting Clinical Trial Shipments

IATA Pharma Solutions

- IATA CEIV Pharma Certification
- IATA Business Intelligence
- IATA Training & Events

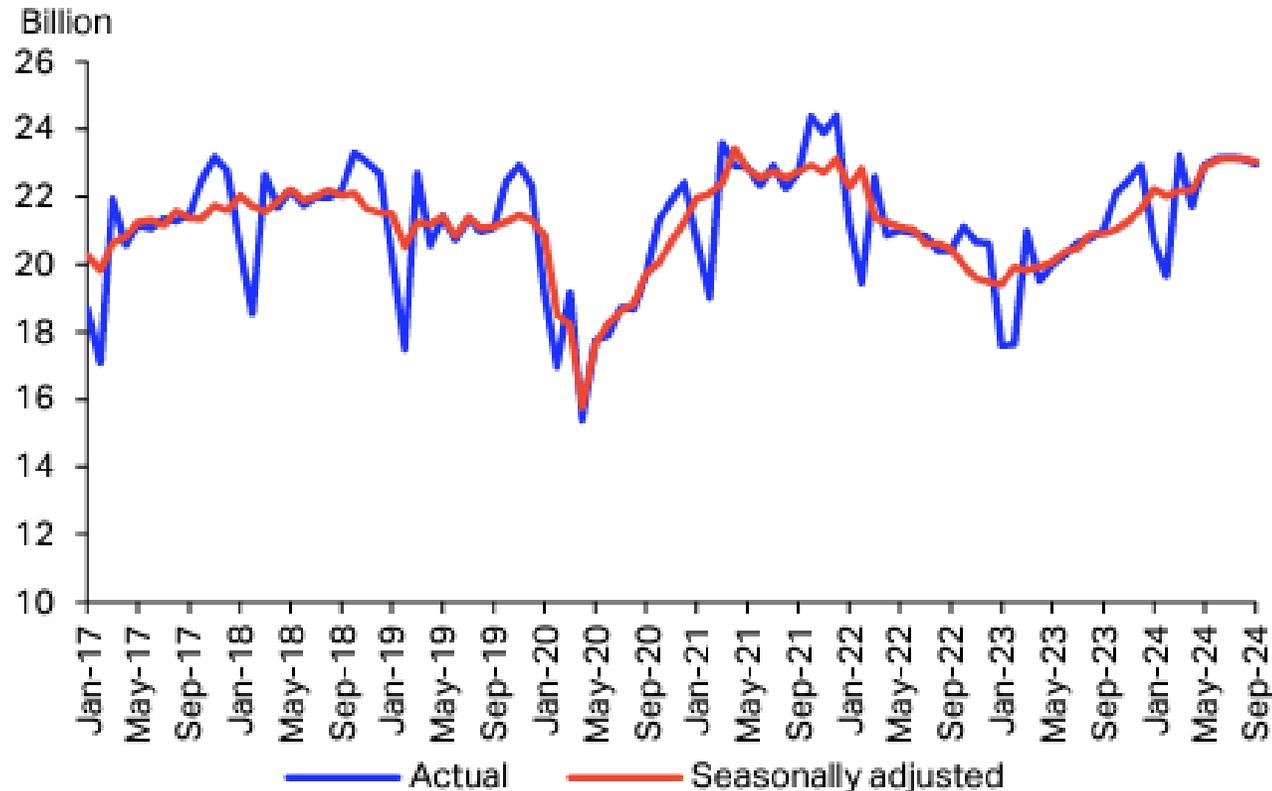


Market Outlook



Air Cargo Demand Sustains Growth

Chart 1 – Industry CTK, billion

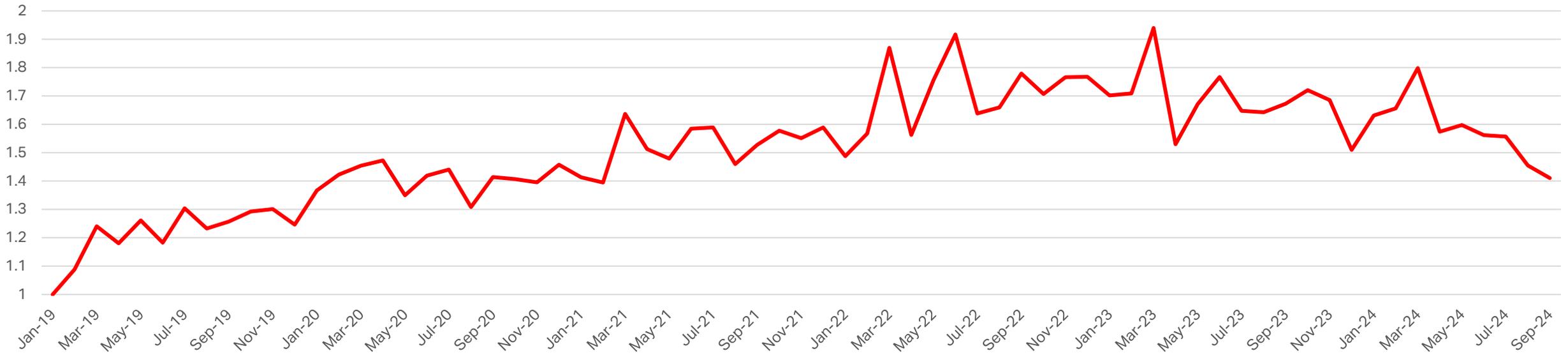


Source: IATA Sustainability and Economics using data from IATA Information and Data - Monthly Statistics



Pharmaceuticals Airfreight Demand

Pharmaceuticals Chargeable Weight Index from 2019 to 2024

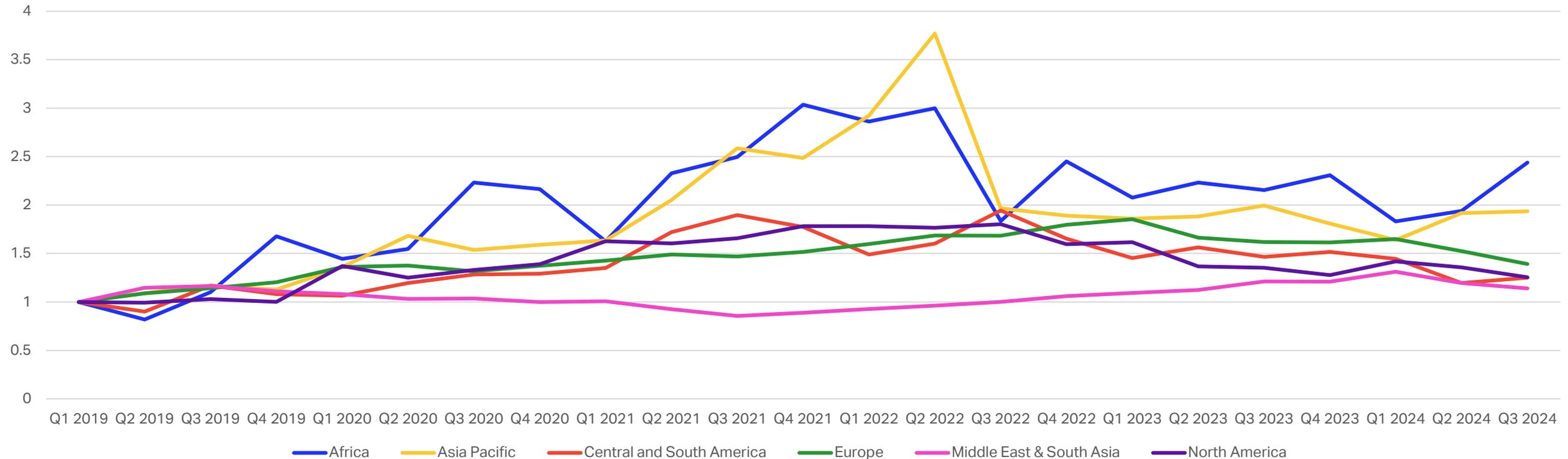


Based on [IATA CargoIS](#) (Intelligence Services)



Pharmaceuticals Demand by Origin Region

Pharmaceuticals by origin region - Chargeable weight index – Index Q1 2019



Based on [IATA CargoIS](#) (Intelligence Services)





Top 10 Country-to-Country Pharma Flows in 2024 YTD (September)

- 1 India to United States
- 2 Switzerland to China
- 3 Germany to United States
- 4 Germany to China
- 5 India to Germany
- 6 United States to Japan
- 7 India to Canada
- 8 India to Netherlands
- 9 India to United Kingdom
- 10 France to China

Standard Development



IATA is a Standard Setting Organization



Setting Standards for Industry by Industry

IATA Airlines

Live Animals & Perishables Board (LAPB)
10 Airline members

Industry Experts

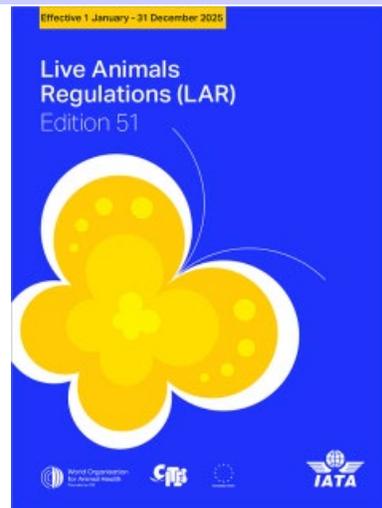
LAPB Advisory Group + Animal Care Team
9 members

Perishable Cargo Working Group (PCWG)
16 members

Healthcare Cargo Working Group (HCWG)
17 members

Join us to take part in standard setting activities.

Contact us at larper@iata.org



Key Regulatory Changes



Temperature Control Regulations (TCR)

Contains all the information and requirements you need to ship compliant temperature-sensitive products.

2025 Significant Changes

▪ Chapter 7 Documentation

1. Section 7.1 Air Waybill restructured and rewritten for clarity. Example of Air Waybill updated
2. Content from former Chapter 17 moved and restructured to section 7.2 IATA Acceptance Checklist for Time and Temperature Sensitive Healthcare Shipments.

▪ Chapter 9 Marking and Labelling

1. Creation of separate Chapter on Marking and Labelling. Content from Chapter 17 moved and restructured to section 9.3 Labelling.
2. Addition of examples of Time and Temperature Sensitive labels.
3. Addition of section 9.1 on shipper's general responsibility.
4. Section 9.2 Marking renumbered, and content revised.

▪ Chapter 10 Handling Procedures

1. Content from former Chapter 8 Acceptance and Control and Chapter 17 restructured and revised.
2. Content from former Chapter 17 moved to sections 10.6.1 Critical Control Points, 10.11.1 Types of Refrigeration System, and 10.11.2 Freezers.
3. Deletion of content on Hazard Analysis Critical Point



Temperature Control Regulations (TCR)

2025 Significant Changes cont.

- **Across these Regulations**

1. Deletion of irrelevant content on perishable cargo:
2. Deletion of former Chapter 10 Perishable Handling Procedures.
3. Deletion of former Chapter 12 Airport Ground Operations.
4. Deletion of former Chapter 13 Perishable Handling Facilities. Content on Cold Room and Freezers moved to section 10.11 Storage.
5. Deletion of former Chapter 17—Air Transport Logistics for Time and Temperature Sensitive Healthcare Products. Content from Chapter 17 moved, reorganized and revised in other sections of these Regulations.

- **Glossary**

1. Addition of definition VARIATION.

- **Nomenclature**

1. Creation of sections 2.1 Technical Abbreviations and 2.2 Cargo Handling Codes.

- **Updates and addition of new State & Operator Variations**

Accessing up-to-date state and operator regulations, packing requirements and documentation before you ship helps prevent losses and improves patient health.



The table below summarizes the changes between the 2024 and 2025 editions of these Regulations:

TCR 12 th edition (2024)	TCR 13 th edition (2025)
PREFACE	PREFACE
INTRODUCTION	INTRODUCTION
ACKNOWLEDGEMENTS	ACKNOWLEDGEMENTS
Chapter 1—Application of these Regulations	Chapter 1—Application of these Regulations
1.1 General	1.1 General
1.2 Shipper Responsibilities	1.2 Shipper Responsibilities
1.3 Operator Responsibilities	1.3 Operator Responsibilities
1.4 Special Conditions	1.4 Special Conditions
1.5 Training	1.5 Training
1.6 Cargo Services Conference Resolutions	1.6 Cargo Services Conference Resolutions
1.7 Relationship of the Language Editions	1.7 Relationship of the Language Editions
Chapter 2—State Variations	Chapter 2—State Variations
2.1 Government Regulatory Agencies	Appendix A—Competent Authorities
2.2 Specific Variations by Countries	2.1 Specific Variations by Countries
Chapter 3—Operator Variations	Chapter 3—Operator Variations
3.1 General Operator Information	Appendix B—General Operator Information
3.2 Specific Operator Variations	3.1 Specific Operator Variations
Chapter 4—Healthcare Shipments	Chapter 5—Healthcare Shipments
4.1 General	5.1 General
4.2 Shipment Temperature Ranges	5.2 Shipment Temperature Ranges
4.3 Temperature Mapping Recommendations	5.3 Temperature Mapping Recommendations
Chapter 5—Packing	Chapter 8—Packing
5.1 General	8.1 General
5.2 Types of Thermal Packagings and Temperature-Controlled Containers	8.2 Types of Thermal Packagings and Temperature-Controlled Containers
5.3 Selection and Handling Considerations	8.3 Selection and Handling Considerations
Chapter 7—Documentation and Labelling	Chapter 7—Documentation
7.1 Air Waybill	7.1 Air Waybill
7.2 Cargo Handling Codes	Nomenclature—2.2 Cargo Handling Codes
7.3 Aircraft Operation Related Documents	7.4 Aircraft Operation Related Documents
7.4 Special Load Notification to Captain	7.3 Special Load Notification to Captain
7.5 State Documents	Deleted
7.6 Labelling	9.3 Labelling
7.7 Marking	9.2 Marking
7.8 WHO Documentation and Labelling for Vaccines	Deleted

TCR 12 th edition (2024)	TCR 13 th edition (2025)
Chapter 8—Acceptance and Control	Chapter 10—Handling Procedures
8.1 General Knowledge	10.1 General
8.2 Hazard Analysis Critical Control Point	Deleted
8.3 Cold Chain Management	10.6 Quality Management
8.4 Load Acceptance	10.3 Loading, Departure and Flight
8.5 Signs of Abnormal Loads	Deleted
8.6 Tips and Check List	Deleted
Chapter 9—Shipment Tracking and Monitoring	Chapter 6—Shipment Tracking and Monitoring
9.1 General	6.1 General
9.2 Types of Tracking/Monitoring Devices	6.2 Types of Tracking/Monitoring Devices
9.3 Considerations when Using Tracking Devices	6.3 Considerations when Using Tracking Devices
Chapter 10—Perishable Handling Procedures	Chapter 10—Handling Procedures
10.1 Effects of Handling Operations on Perishables Quality	5.1 General 10.1 General
10.2 Incompatible Loads and Segregation	10.1 General
Chapter 12—Airport Ground Operations: Terminal and Ramp Side	Deleted
12.1 General Knowledge	10.3 Loading, Departure and Flight 10.4 Unloading
12.2 Weather and Geographical Locations	Deleted
Chapter 13—Perishable Handling Facilities	Deleted
13.1 General Knowledge	10.11 Storage
13.2 Cold Room and Freezers	10.11 Storage
Chapter 17—Air Transport Logistics for Time and Temperature Sensitive Healthcare Products	Deleted
17.7 Key Risk Factors	8.3 Selection and Handling Considerations 10.1 General
17.8 Critical Control Points	7.2 IATA Acceptance Checklist for Time and Temperature Sensitive Healthcare Shipments Chapter 10—Handling Procedures
17.10 Package Labeling for Healthcare Products	9.3 Labelling
17.12 Quality Management Systems	10.6 Quality Management
17.13 Additional Environmental Considerations	5.4 Additional Environmental Considerations
17.14 Further Reading	Bibliography
Appendix B—General Design Requirements for Thermal, Insulated and Refrigerated Containers	Deleted
Appendix C—Example of a Process Flow of Time and Temperature Healthcare and Pharmaceutical Shipments with their Possible Applicable IATA Special Handling Codes	Appendix E—Example of a Process Flow of Time and Temperature Healthcare and Pharmaceutical Shipments with their Possible Applicable IATA Special Handling Codes
Appendix D—Guidelines for Center of Excellence for Independent Validators (CEIV) for Pharmaceutical Logistics Audit Checklist	Appendix D—Guidelines for Center of Excellence for Independent Validators (CEIV) for Pharmaceutical Logistics Audit Checklist



IATA TCR & Clinical Trial Shipments

Standardized Packaging Solutions

- Ensures uniformity and compliance across the industry
- Minimizes risk of damage or contamination during transit

New Technologies

- Encourages adoption of innovative solutions for better monitoring and control
- Improves efficiency and reliability in handling pharmaceutical shipments

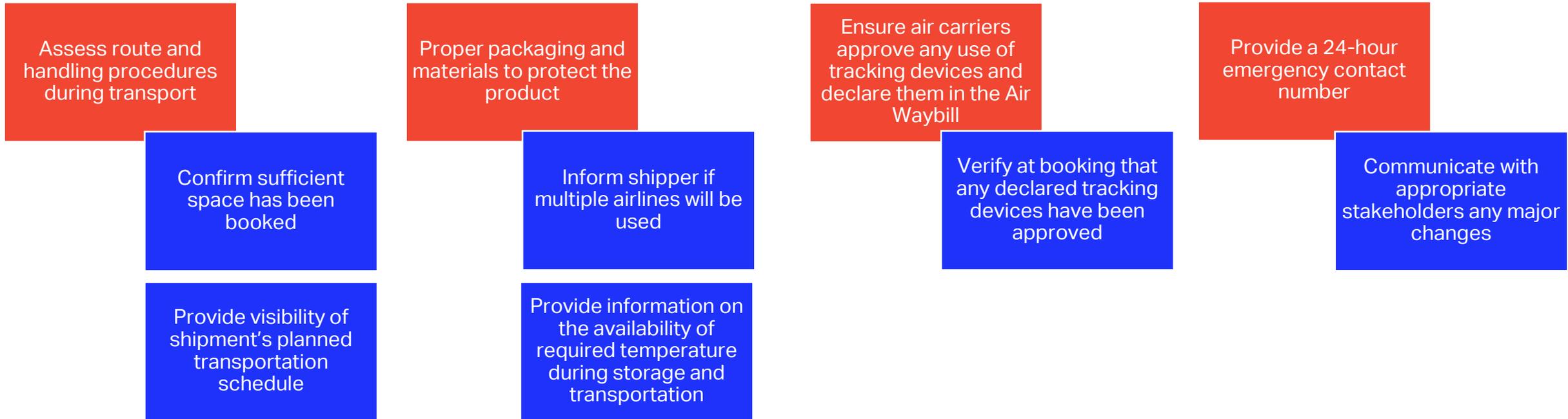
Shipment Requirements

- Detailed requirements for shipments' unique needs, including temperature control, packaging, and delivery timelines.

Safe and efficient transportation of clinical trial shipments



Shipper and Operator Responsibilities



Shipper Responsibilities
Operator Responsibilities



Fostering Collaboration Across the Supply Chain

Partnerships between stakeholders

- Work with collaborators and discuss specific shipment needs up front to ensure better planning and execution.
- Implement solutions together for smoother handling, timely delivery and overall improved handling procedures.

Communication and transparency for smoother operations

- Effective communication between shippers and carriers is essential for successful clinical trial shipments to minimize risks.
- Proactive communication helps anticipate potential issues (e.g., temperature excursions, delays).



Shippers Expectations in Cold Chain

In the US and European markets, companies have become increasingly cautious about regulatory compliance

Pharma Shipper Situation

Impact on Air Cargo industry

Leading pharma companies in these markets have reportedly implemented effective compliance management systems internally.

Pharma companies are realigning their quality and compliance structure to conform to the constantly evolving regulatory guidelines.

With the FDA and other regulators broadening the scope of compliance requirements, it helps if companies have a holistic approach and make regulatory compliance part of their corporate strategy.

Compliance is a priority for the air cargo sector. Air cargo sector performance not encouraging and increased regulation will continue to contribute to the compliance challenges facing the industry.

They will demand the same from their business partners.

Companies ought to be proactive in setting up stringent internal controls as part of their commitment towards quality and compliance. Include effective training, proper timely communication, periodic reviews / follow-up, and support from the top management.



IATA Pharma Solutions

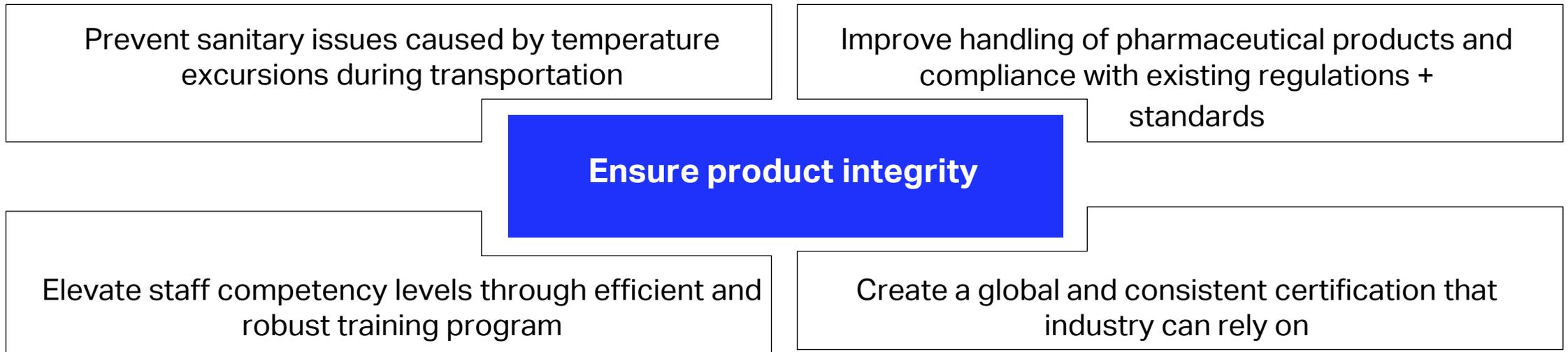


CEIV: Excellence beyond Compliance

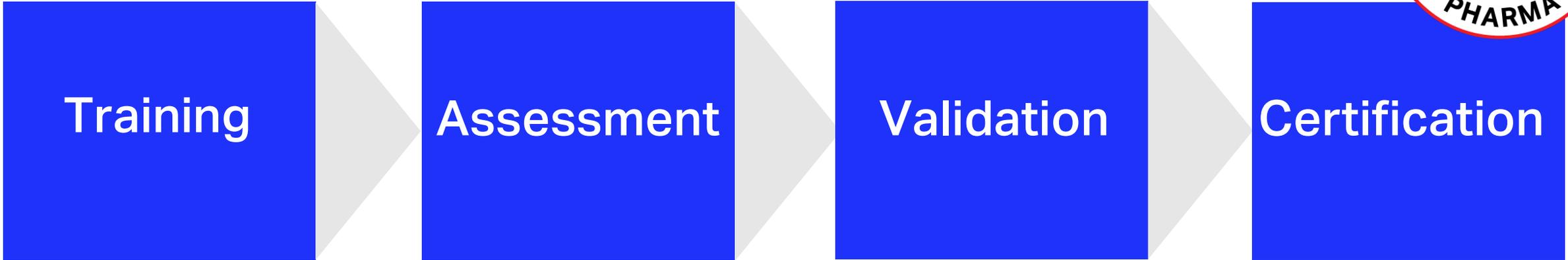
- Compliance, standardization, accountability and transparency across the supply chain
- Properly trained stakeholders on regulations and standards
- Adequately equipped facilities throughout the supply chain
- Global certification for handling of pharmaceutical cargo
- Common audit format to minimize the disruptions and increase effectiveness
- Ability to easily search and identify stakeholders that meet requirements



Ensuring shipment integrity throughout the supply chain



IATA CEIV Pharma Certification



- ✓ Qualification of responsible person
- ✓ Training for other personnel involve in processing of air freight shipments

- ✓ Assessment by independent validator
- ✓ Assessment versus international standards and best practices
- ✓ Establish findings

- ✓ Validation by Independent Validator
- ✓ Review the progress made on the recommendations established during the assessment

- ✓ Certification issued, once all major gaps have been closed
- ✓ Spot-check, quality assurance and continues improvements
- ✓ Re-certification



IATA ONE Source

Providing Industry Transparency

- Free industry platform
- Up-to-date certification and infrastructure information
- Reliable information
- Easy to use
- Unparalleled transparency and visibility
- Enables you to find the right business partner for your needs

https://onesource.iata.org

IATA

FastHandling

IATA Validation Programs

Cargo Commodities

- ✓ General Cargo
- ✓ Dangerous Goods
- Perishables
- ✓ Live Animals
- Airmail
- ✓ Pharmaceuticals

Station Overview

- 1,500 Employees
- Total facility space 1,500 m²
- ✓ On-Airport
- ✓ Direct Ramp Access

Equipment & Infrastructure

Facility Equipment & Infrastructure

Temperature Control

Live Animals Capacities

Electronic System Capacities



Cargols

- The most comprehensive and accurate air cargo market intelligence for over 20 years recognized by 300+ corporate clients worldwide.
- Supports data-driven decision-making, market trends research for different verticals (e.g. Pharmaceuticals, cool goods) and supplier behavior analysis.
- Unrivaled market data derived from **\$65B** in actual transaction annually by **30,000+** freight forwarders and **200+** airlines across **80,000+** city-to-city and **140,000+** airport to airport trade lanes.





Get Trained on Temperature Controlled Standards

Temperature Control Regulations



- [Temperature Controlled Cargo Operations](#)
- [Temperature-Controlled Container Operations](#)
- [Audit, Quality and Risk Management for Temperature Controlled Cargo](#)
- [CEIV Pharma Refresher](#)

**IATA
WORLD
CARGO**

SYMPOSIUM

Dubai, UAE
15-17 April 2025

JOIN US AT
THE WCS 2025!

Partner Best Airline

Host Partner



SkyCargo

#IATAWCS



Thank you!

Find out more at:

[iata.org/tcr](https://www.iata.org/tcr)

[iata.org/pharma](https://www.iata.org/pharma)

[iata.org/ceiv-pharma](https://www.iata.org/ceiv-pharma)

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