



Airfreight and Pharmaceuticals
Go Hand in Hand

Regulations, Regulations and Regulations

Analyzing key regulations in two major industries

Shared Regulatory Themes and Industry Comparison





Air Freight Regulatory Focus

Air freight regulations prioritize safety, security, customs compliance, and environmental standards to ensure safe transport of goods.



Pharmaceutical Industry Regulations

Pharma regulations focus on patient safety, product integrity, cold chain management, serialization, and adherence to GMP, GDP, and GCP.



Shared Regulatory Themes

Both industries emphasize traceability, documentation, temperature control, risk management, and strong compliance culture.



Pharmaceutical Industry Regulations



Quality and Production Standards

GMP ensures the production and quality control of drugs meet strict safety and efficacy requirements.



Clinical Trials Oversight

GCP governs clinical trials to ensure ethical standards and reliable data for new medicines.



Regulatory Authorities

Bodies like FDA and EMA enforce regulations ensuring drug safety and market authorization



Emerging Digital and Safety Regulations

All health regulations and pharmacovigilance support safe innovation and ongoing drug safety monitoring.





Air Freight and Airline Industry Regulations



Standardized Cargo Procedures

IATA Cargo Rules standardize international air cargo operations for safety and efficiency.



Security and Safety Regulations

TSA and ICAO regulations ensure advanced security protocols and global aviation safety benchmarks.



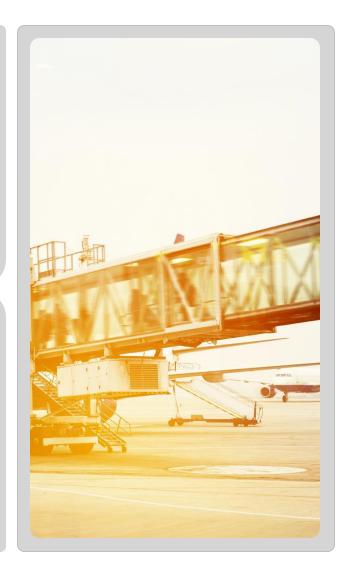
Cargo Information and Compliance

PLACI and Customs Compliance require early data submission and accurate declarations for cross-border trade.



Personnel Training and Documentation

Continuous staff training and e-documentation standards improve handling of complex cargo scenarios.





Shared Characteristics of Air Freight and Pharmaceutical Industries



Precision and Timing

Both industries depend on precise timing to ensure efficient delivery and patient safety in their operations.



Regulatory Compliance

Strict adherence to aviation and health regulations ensures safety and quality in air freight and pharmaceuticals.



Logistics and Supply Chain

Meticulous planning and coordination manage global transport of goods and sensitive pharmaceutical products.



Technological Innovation

Advanced tracking, automated equipment, and digital technologies drive operational efficiency in both industries.







Updated AWB IATA Service Levels



IATA Service Levels

Service Level	Temperature Range	Typical Use
Controlled Room Temperature (CRT)	+15°C to +25°C	Most vaccines, biologics, and oral drugs
Refrigerated (Cold Chain)	+2°C to +8°C	Sensitive biologics, insulin, and some vaccines
Frozen	-20°C or below	Certain biologics, APIs, and long- term storage items
Deep Frozen	-70°C or below	mRNA vaccines, cell therapies, and clinical trial samples
Ambient	+2°C to +30°C	General healthcare products with wider tolerance



IATA Service Levels and their Requirements



Time & Temperature Sensitive Label

Required for all TTSPP shipments, this label must clearly display the external temperature range.



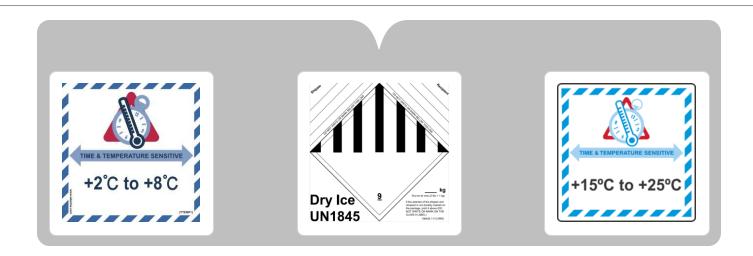
Acceptance Checklist

Before accepting cargo, airlines and ground handlers are responsible for confirming packaging integrity, proper documentation, and adherence to temperature requirements.



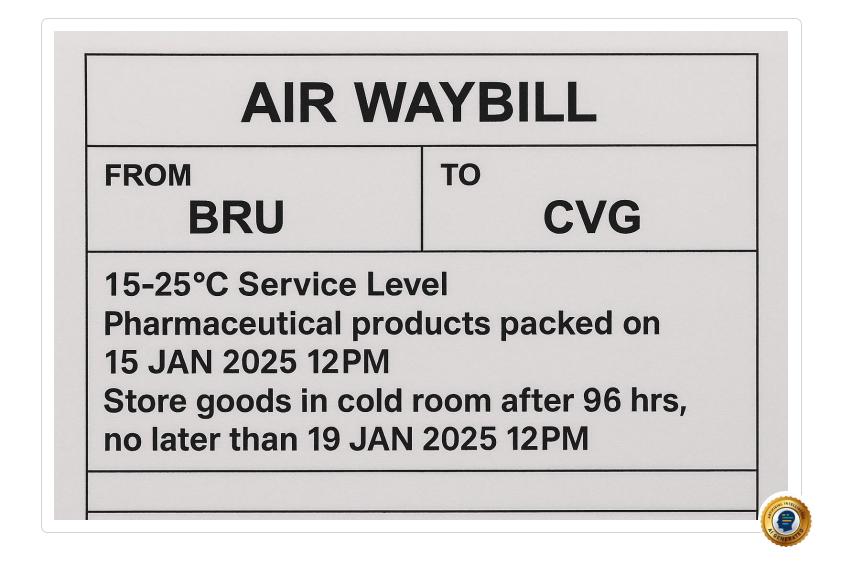
CEIV Pharma
Certification

Airlines, freight forwarders, and ground handling agents are recommended to obtain CEIV Pharma certification to guarantee compliance with GDP standards.





We all know this!





Service level 15-25°C, BUT...



MAX: 96hrs – 120 hrs

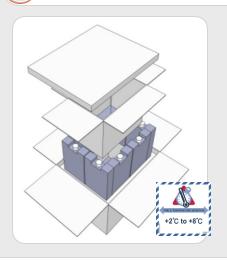
If lead time is greater than Qualified Time:

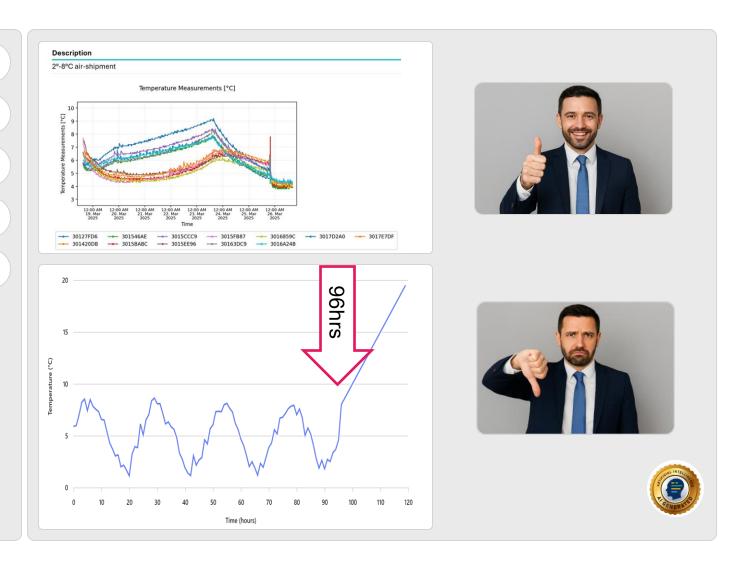
ACTION Transfer to 2-8°C area



What can go wrong?

- Failure to comply with regulations.
- Deviations in temperature control
- Compromise of product quality
- Breakdowns in operational communication
- Incomplete or missing documentation

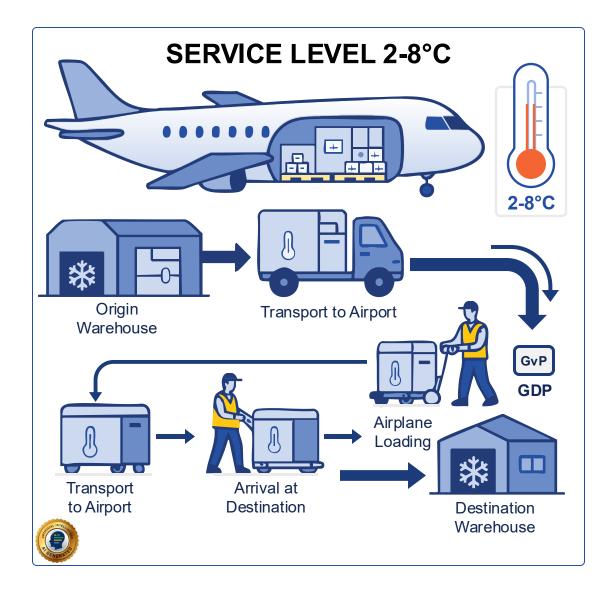




Dummy data used



To Be "Service level 2-8°C"



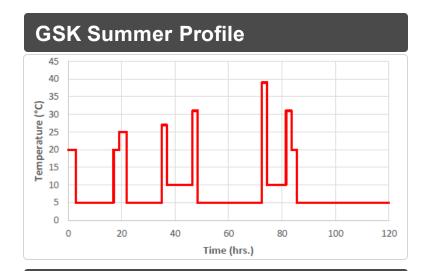
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If lead time is greater than Qualified Time:

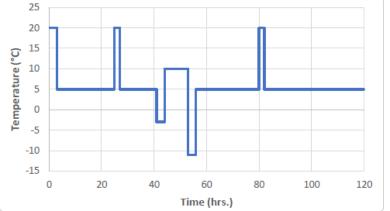
NO further action (Product is at 2-8°C)



Temperature Profile 2-8°C / 120 Hrs and results (Single pallet shipper)



GSK Winter Profile 25







Alignment with IATA Service Level's







Advanced Cold Chain Logistics for 2-8°C Shipments



Some history on cold chain (with a smile)

- Approximately 25 years ago, a major perishable goods center was set up in BRUCARGO.
- Defore this, there was little anticipation regarding the handling of cargo requiring temperatures between 2-8°C.
- As a result, very stringent OQ temperature profiles were created, assuming a service level of 15-25°C.
 - European Cold Chain Committee was born (a family of Guru's ©)
 - The system was certified for a duration of 96 hours.
 - It was widely assumed that 96 hours would be adequate for Door-to-Door transportation.
- Matter 20 years, all forwarders and ground handling agents have established cold rooms as well as areas maintained at 15-25°C.
- Expectations significantly increased.
- As a result, OQ temperature profiles became less stringent.
- Certification covers 96 to 120 hours with a service level of 2-8°C.



Pallet Shipper Solutions (examples)

















Phase Change Material (PCM)

Water Based

Active

Vacuum panels

EPS

PU

Passive

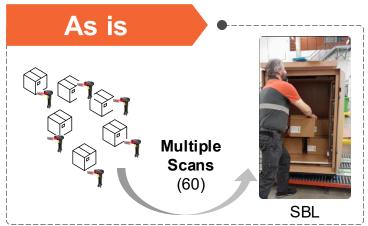
Reusable

Qualified duration

Reverse Logistics



Opportunities and Improvements



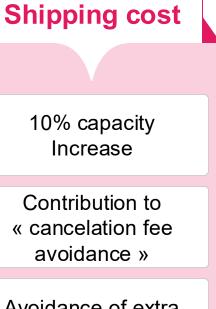






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Avoidance of extra lease days



Sustainability

Reversed Logistics

Recycling at destination



Recent Technological and Operational Advancements



Temperature Control Technology

IoT-enabled containers provide real-time temperature and humidity monitoring, reducing risks in pharmaceutical shipments.



Traceability and Compliance

Blockchain platforms and automated software enhance transparency, security, and regulatory adherence in airfreight.



Al-Driven Routing and Scheduling

Al tools optimize shipment routes and scheduling, improving efficiency and reducing operational delays.



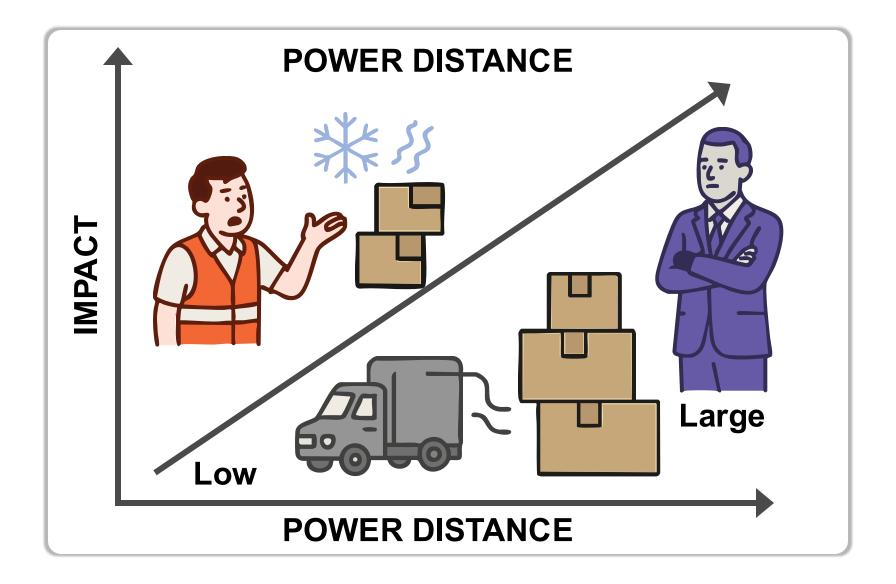
Certified Handling Infrastructure

Upgraded facilities feature zoned cold corridors and robotics, ensuring product integrity and lowering emissions.





The key to success, limit the « Powerdistance in Logistics »





Cold Corridor

Definition:



"A fully controlled logistics lane for pharma shipments maintaining strict +2°C to +8°C conditions using lightweight insulation (blankets) and fine-tuned operations."





Features

Active Cold Corridor

Nonstop flights without any layovers

Dedicated staff exclusively assigned

Aircraft cargo hold maintained at +5°C

Managed by forwarder using proprietary fleet

CEIV/GDP certified handling at both departure and arrival locations

Loading and unloading given priority status

Use of lightweight blankets and PCM packs

Continuous temperature monitoring from start to finish

Standard operating procedures with backup plans in place



Passive Cold Corridor

Focus on Direct flights (less transit points)

Strategic partners

Standard 2-8°C service (setpoint aircraft hold?)

CEIV/GDP certified handling at origin & destination

Prioritized loading/unloading (power distance?)

Blankets/ all sided PCM

End-to-end temperature monitoring

Routes with buffer time and anticipated weather events. Contingencies within network.



Features

Active Cold Corridor

- Nonstop flights without any layovers
- Dedicated staff exclusively assigned
- Aircraft cargo hold maintained at +5°C
- Managed by forwarder using proprietary fleet
- CEIV/GDP certified handling at both departure and arrival locations
- Loading and unloading given priority status
- Use of lightweight blankets and PCM packs
- Continuous temperature monitoring from start to finish
- Standard operating procedures with backup plans in place

Passive Cold Corridor

- Focus on Direct flights (less transit points)
- Strategic partners
- Standard 2-8°C service (setpoint aircraft hold?)
- CEIV/GDP certified handling at origin & destination
- Prioritized loading/unloading (power distance?)
- Blankets/ all sided PCM
- End-to-end temperature monitoring
- Routes with buffer time and anticipated weather events.
 Contingencies within network.



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