

IATA CEIV Pharma Certification Program 2.0



Leading industry GDP standard for time and temperature sensitive pharmaceutical products

The global trade association of the world's airlines

IATA was founded in Havana, Cuba in April 1945

IATA in brief

Some **290** passenger and cargo member airlines, representing **83%** of global air traffic

65 member airlines operate different business models from full-service carriers

Head Office: **Montreal, Canada**

Executive Office: **Geneva, Switzerland**

Regional Offices: **Amman, Beijing, Madrid, Miami, Singapore**



To represent,
lead and serve
the airline
industry

3
Mission



Working together to shape the future
growth of a safe, secure and sustainable
air transport industry that connects and
enriches our world

4
Vision



We build **standards through expertise**

We champion the **global big picture**

We partner for **mutual benefit**

We act with a **simple human touch**

Our Brand Values define what we value and how we behave to help us deliver the IATA mission and vision. We all have different personalities, styles and

areas of expertise, are at different levels of the organization, and play different roles. But you will recognize us by the consistent way in which

we act and behave. We live our values and embody the supporting behaviors to make IATA a great place to work.

Values



About air cargo

- Scheduled air cargo started 90 years ago with mail
- Consists of general & special cargo e.g. perishables
- Speed and on time delivery are the competitive advantages
- Air cargo transports over US \$8 trillion worth of goods annually, accounting for approximately 33% of world trade by value while transporting only 0.5% of trade by volume.
- About 48 million tons of freight is transported annually with a value of well over \$5 trillion



Center of Excellence for Independent Validators (CEIV Pharma 2.0)

Pharmaceutical manufacturing industry demand for quality and compliance in transport of time and temperature sensitive Pharma products is a continuous motivation for a CEIV Pharma Certification program.

Since 2015, The CEIV Pharma Certification program is a highest-level standard for the industry. Today, CEIV Pharma 2.0 sets a new level of excellence in quality services designed to meet global Good Distribution Practices (GDP) regulations.

IATA CEIV Pharma certification program represents a compilation of global GDP regulations, mainly from EU Commission (EU GDP Guidelines), WHO Annex 5 and 9, United States Pharmacopeia (USP), Health Canada (GUI), Singapore regulations and other global regulatory documents.



Over 600

CEIV Pharma
Certifications and
recertifications



Center of Excellence for Independent Validators (CEIV Pharma 2.0)

CEIV Pharma represents a unique compliance proposition, designed to facilitate GDP (GxP) global requirements. The CEIV Pharma program enables organizations to deliver GDP (GxP) compliant services to all Pharma customers regardless of the product characteristics or requirements.

What does it mean for an organization to be GDP certified?

Only national regulatory authorities can issue (inspect) a valid GDP certificate.

This is in most of the cases a GDP certificate for in-transit storage if such is required by the national authorities of the market the logistics vendor is operating at.



The CEIV Pharma Certified organizations are focusing on processes designed to meet global GxP requirements.

Is the logistic vendor (Forwarder, GHA, road carrier, etc.) required to get inspected by the authorities and to gain a Wholesaler Distribution (WD) license for GDP (in transit storage)?

Only in very rare cases like UK. For most of the world the logistics vendors are not required to obtain national authority WD license.

How to comply to GDP regulations than and prove to your pharma customer your systems are compliant?



Airfreight service that is beyond speed and efficiency.

CEIV Pharma envelope features **compliance beyond standard GDP requirements and regulations**. A comprehensive, GDP compliant approach in designed of Quality and Risk Management Systems for handling and transport of time and temperature sensitive Pharma products (TTSP).

Being continuously **up-to-date with global GDP regulations and requirements**, IATA has ensured that continuous line of contemporary, GDP based trainings, and educational programs are available

Training modules for **Pharma Responsible Persons** offer profound GDP knowledge on Pharma products and requirements and are tailored for airfreight professionals ensuring their expertise and skills are developed to respond to global GDP regulatory requirements.



Center of Excellence for Independent Validators (CEIV Pharma 2.0)

Global GDP regulations and requirements are offering pharmaceutical manufacturers, logistics vendors and distributors an insight on **WHAT is expected** to be compliant to GDP provisions.

The CEIV Pharma Certification program takes those requirements and pharma customers to a next level, **delivering straight forward KNOW-HOW on how to become a GDP compliant** organization and thus attract the confidence of your pharma clients.

This know-how transferred in contemporary GDP processes and service ensure continuous quality oversight of pharma shipments and products thus ensuring safe delivery to patient.



CEIV Pharma certification envelope offers a unique GDP compliance proposition, [transferring Shippers and Regulators requirements](#) into compelling arguments.

VALIDATION (Qualification)

Ensures compliance requirements are embedded in a risk-based processes and services design.

VISIBILITY

Achieved by documented process mapping on all CCP, definition of roles and responsibilities of all internal and external stakeholder interfaced in the process.

TRACEABILITY

Processes designed to ensure quality, reliability and control of risks by following defined time-stamps on all process CCP.



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ACCOUNTABILITY

Continuous education program on GDP (GXP) for airfreight Pharma RPs and professionals ensures:

- Product safety and quality
- Deviations (temperature excursion) reduction
- GDP storage conditions and temperature-controlled supply chain
- GDP compliant services and products design
- Supply chain efficiency (GDP service and speed of delivery)
- Technologies integration (from real-time monitoring to RFID and IoT).



The **GDP compliance requirements** existing today in global Pharma supply chain are **delivered as a standard** in a CEIV Pharma certification program.

Temperature controlled storage: Profound know-how on how to ensure Good Storage Practices (GSP) in accordance with the global regulations. This includes a specifically designed IATA courses on Temperature Mapping as a methodology to qualify temperature-controlled storage premises.

Temperature mapping: Using regulatory standards (WHO Annex 9), CEIV Pharma program provides know-how on temperature mapping as a qualification methodology for all temperature-controlled systems (storage premises, vehicles, containers, equipment, etc.).

Compliant QRMS: Certified by IATA, the QRMS is verified for its content and efficiency in accordance with mainstream global regulatory documents and requirements.

Change control: Controlled process designed to meet expectations of Regulators and Shippers ensuring consistency and controls when changes are required.

Validated/qualified systems: Processed defined to ensure documented risk assessments on intended use of premises, equipment, vehicles, containers and in general – processes, ensures risk identification and mitigation thus reducing number of deviations, supply chain disruptions and costs of non-quality.



The **GDP compliance requirements** existing today in global Pharma supply chain are **delivered as a standard** in a CEIV Pharma certification program.

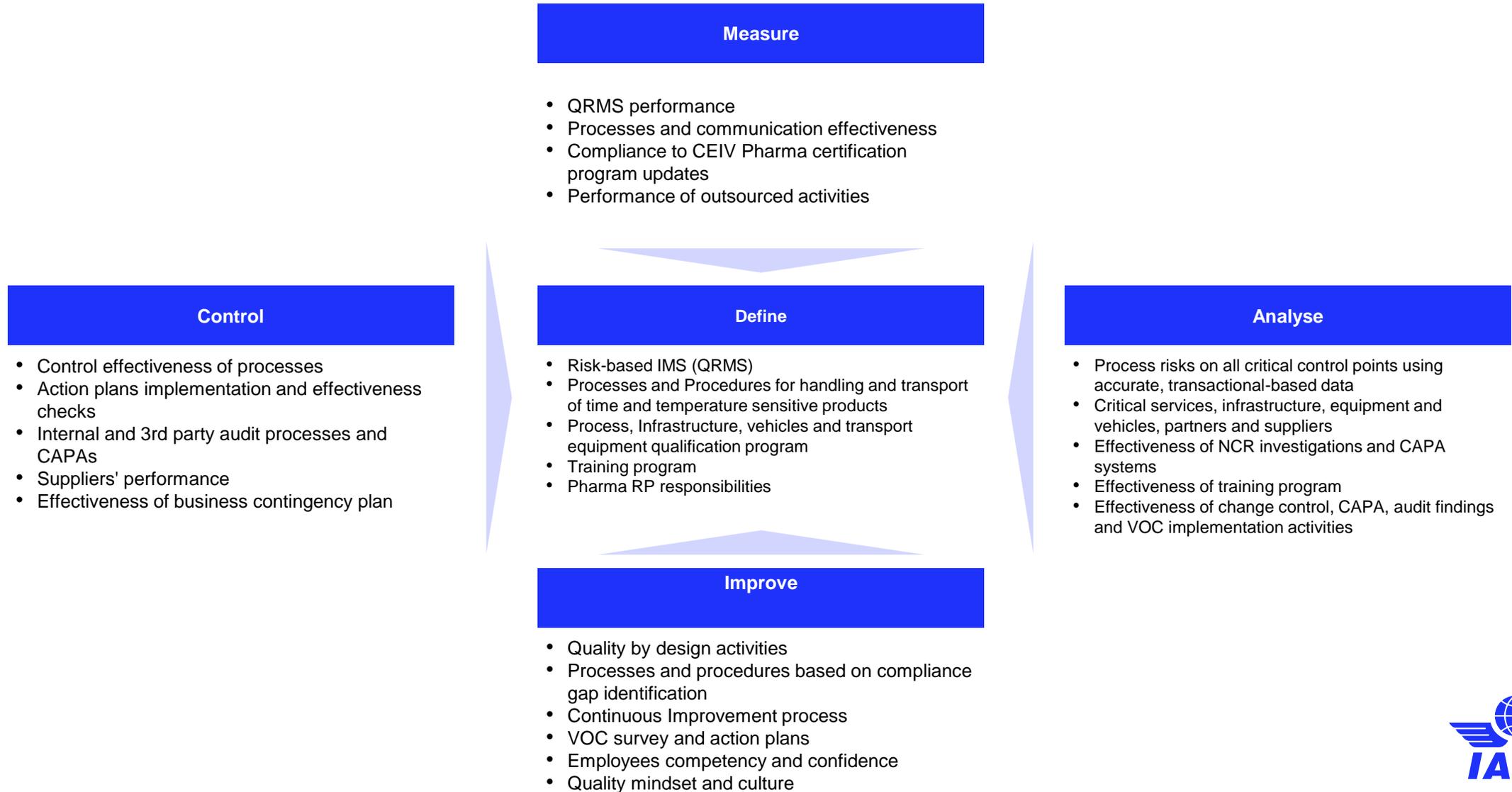
Risk management: Going beyond risk identification and mitigation, the CEIV Pharma program enables establishment of a Risk Based Thinking program ensuring unidentified risks are becoming root cause for a deviations.

Computerized systems: Understanding that any GxP critical data exchanged, transmitted or distributed through a computerized system requires validation or a documented risk assessment on its criticality ensures compliance to global data integrity regulations.

Quality Continuous Improvement program: The PDCA program designed to use all aspects of the QRMS as a source of continuous quality improvement activities to enhance all aspects of service levels.



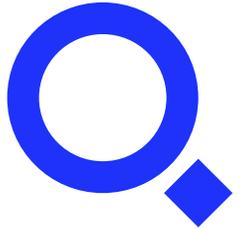
CEIV Pharma 2.0 ensures a GDP Process-centric service navigating through global GDP regulations and industry best practices



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Define

- Risk-based IMS (QRMS)
- Processes and Procedures for handling and transport of time and temperature sensitive products
- Process, Infrastructure, vehicles and transport equipment qualification program
- Training program
- Pharma RP responsibilities

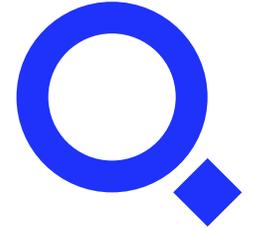


- CEIV Pharma 2.0 covers 11 distinct areas: Quality and Risk Management System (including GDocP), Personnel including provisions for Pharma RP, Training, Qualification/Validation Master Plan, Infrastructure and equipment, Quarantine, Supplier management, Internal audit and self-inspections, Transportation (by road and air) and Airfreight operations.
- GDP vs. CEIV Pharma Certification program gap analysis shows exactly those attributes are listed as requirements in global mainstream GDP regulations.

CEIV Pharma 2.0 ensures a GDP Process-centric service navigating through global GDP regulations and industry best practices

Measure

- QRMS performance
- Processes and communication effectiveness
- Compliance to CEIV Pharma certification program updates
- Performance of outsourced activities

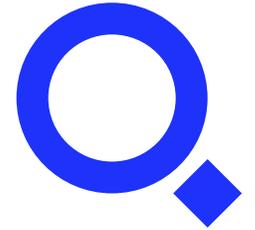


- CEIV Pharma Certificate is valid for 3 years. Program updates are regularly provided by IATA in a form of updated CEIV Pharma Certification Checklist and Guidelines.
- Organizations are recertified within 36 months in accordance with the latest updates and versions of a CEIV Pharma Certification criteria.
- Pharma Responsible Persons of the organization are provided a contemporary Refresher training module as a prerequisite for an organization to be recertified.

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Analyze

- Process risks on all critical control points using accurate, transactional-based data
- Critical services, infrastructure, equipment and vehicles, partners and suppliers
- Effectiveness of NCR investigations and CAPA systems
- Effectiveness of training program
- Effectiveness of change control, CAPA, audit findings and VOC implementation activities

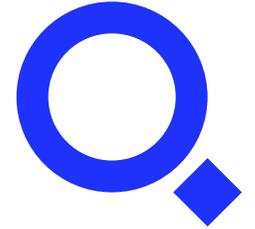


- Documented risk assessments on all handling and transport (route) processes is a CEIV Pharma standard for a certified organizations. A comprehensive training program provides organizations with How-to establish a compliance to these GDP provisions.
- Ontime and efficient deviations handling systems with CAPA implementation and effectiveness check are directly connected with Pharma customer level of confidence and satisfaction.
- Defined and efficient Change control process ensures confidence and controls over the changes thus maintaining the service level and customer trust.

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Improve

- Quality by design activities
- Processes and procedures based on compliance gap identification
- Continuous Improvement process
- VOC survey and action plans
- Employees competency and confidence
- Quality mindset and culture

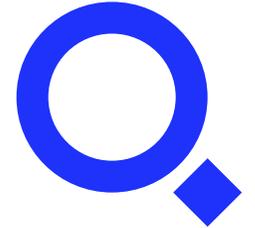


- Continuous education and quality improvement program are foundation of a CEIV Pharma Certification program ensuring certified organizations are always up-to-date with the global GDP regulations and requirements.
- Voice of Customer (VOC) plays an important role in understanding specific product / market requirements. CEIV Pharma program provides a supporting role through number of organizations and interest groups.
- Besides airfreight CEIV Pharma, no other transport industry requires a dedicated Pharma RP with extensive, continuous education on GDP. This is a crucial confidence building block for logistics vendors.

CEIV Pharma 2.0 ensures a GDP Process-centric service navigating through global GDP regulations and industry best practices

Control

- Control effectiveness of processes
- Action plans implementation and effectiveness checks
- Internal and 3rd party audit processes and CAPAs
- Suppliers' performance
- Effectiveness of business contingency plan



- Quality control, performance measurement and contractually defined KPIs, are extended to outsourced activities and subcontractors making sure same level of service is maintained.
- Annual Internal audits and regular self-inspections are ensuring organization readiness for customer audits and are an important milestone in PDCA – continuous quality improvement cycle.
- Developing a documented Business Continuity Plan, tested annually, enforces a culture of readiness for all circumstances (geopolitical crises, environmental challenges and supply chain disruptions).

Center of Excellence for Independent Validators (CEIV Pharma 2.0)

Our core teams of GDP experts from airfreight and Pharma manufacturing industry continuously work on [transforming GDP requirements into global CEIV Pharma standards and setting up new service levels.](#)

IATA's commitment to ensure transfer of GDP knowledge and expertise into a comprehensive and compliant practices is achieved through numerous of initiatives and [expert working groups such as IATA Healthcare Working Group](#) combined of Shippers, Airlines, Forwarders, Ground Handling Companies and all other relevant stakeholders.

IATA is [annually publishing an industry standard](#) called Temperature Control Regulations, a designated standard for the Pharmaceutical and Healthcare products in the industry.



Center of Excellence for Independent Validators (CEIV Pharma 2.0)

IATA CEIV Pharma Certification program has been endorsed by many pharmaceutical manufacturers and organizations such as MSD, Baxter, Janssen, PDA-PCCIG, Belgium regulatory authority, to name few.

Endorsements highlights are among other: ensuring safe and efficient handling of pharma products, maintaining high standards in supply chain and meeting the stringent requirements of pharmaceutical logistics.



Center of Excellence for Independent Validators (CEIV Pharma 2.0)

Is your airfreight service provider already CEIV Pharma certified?

Visit IATA's ONE Source for more information:

<https://iata.my.site.com/onesource/s/>

IATA welcomes you on our official CEIV Pharma website:

<https://www.iata.org/en/services/certification/special-cargo/ceiv-pharma/>





Thank you for your kind attention