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Pharma.Aero Bedrijvenzone Machelen Cargo 706B, 1830 Machelen

WHITE PAPER

CEIV 2.0 PROJECT

PHASE 2: IMPLEMENTATION

February 2024

A project in collaboration with IATA

IATA

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Table of Contents

1. Abstract

The pharmaceutical industry is a rapidly evolving sector, necessitating continuous evaluation and adaptation of industry standards. This white paper presents the findings and outcomes of the *CEIV 2.0 Phase 2: Implementation* project, a collaborative effort between Pharma.Aero and IATA, aimed at enhancing IATA's CEIV Pharma certification program.

The project, spanning two years from 2022 to 2024, involved a comprehensive assessment of the existing certification program. *Phase 1* identified challenges and proposed solutions, leading to the initiation of *Phase 2*, focusing on six key directions.

The Methodology section of this white paper details the structure of the project with seven work packages, each addressing specific aspects.

The Conclusions section highlights the need for increased support in consolidating the certification process after a decade of IATA CEIV Pharma certification. The project emphasizes improvements in engagement with authorities, enhancements to the Independent Validators' qualification process, postponing light certification until the core process is robust, and the importance of shared databases for industry transparency.

The paper concludes with a call for continuous efforts to increase visibility for IATA CEIV Pharma within the life science manufacturing sector and a refreshed visual identity to signify a commitment to the program.

IATA launched the CEIV Pharma certification program specifically designed to meet the needs of aviation pharmaceutical supply chain stakeholders. Implemented in 2015, the program has become a quality standard over the years, with over 500 companies being certified or re-certified at different locations around the globe.

2. Introduction

The *CEIV 2.0 Phase 2: Implementation* project conducted by Pharma.Aero in collaboration with IATA is the final part of a 2-year endeavour that started in 2022 with a thorough evaluation of IATA's Pharma CEIV Certification Program, based on the input and insights provided by Pharma.Aero's global community of end-to-end pharma-certified logistics providers.

The initial part of the project, *Phase 1: Evaluation*, involved a thorough assessment of how CEIV Pharma-certified companies perceive the impact and the value of the certification on their daily.

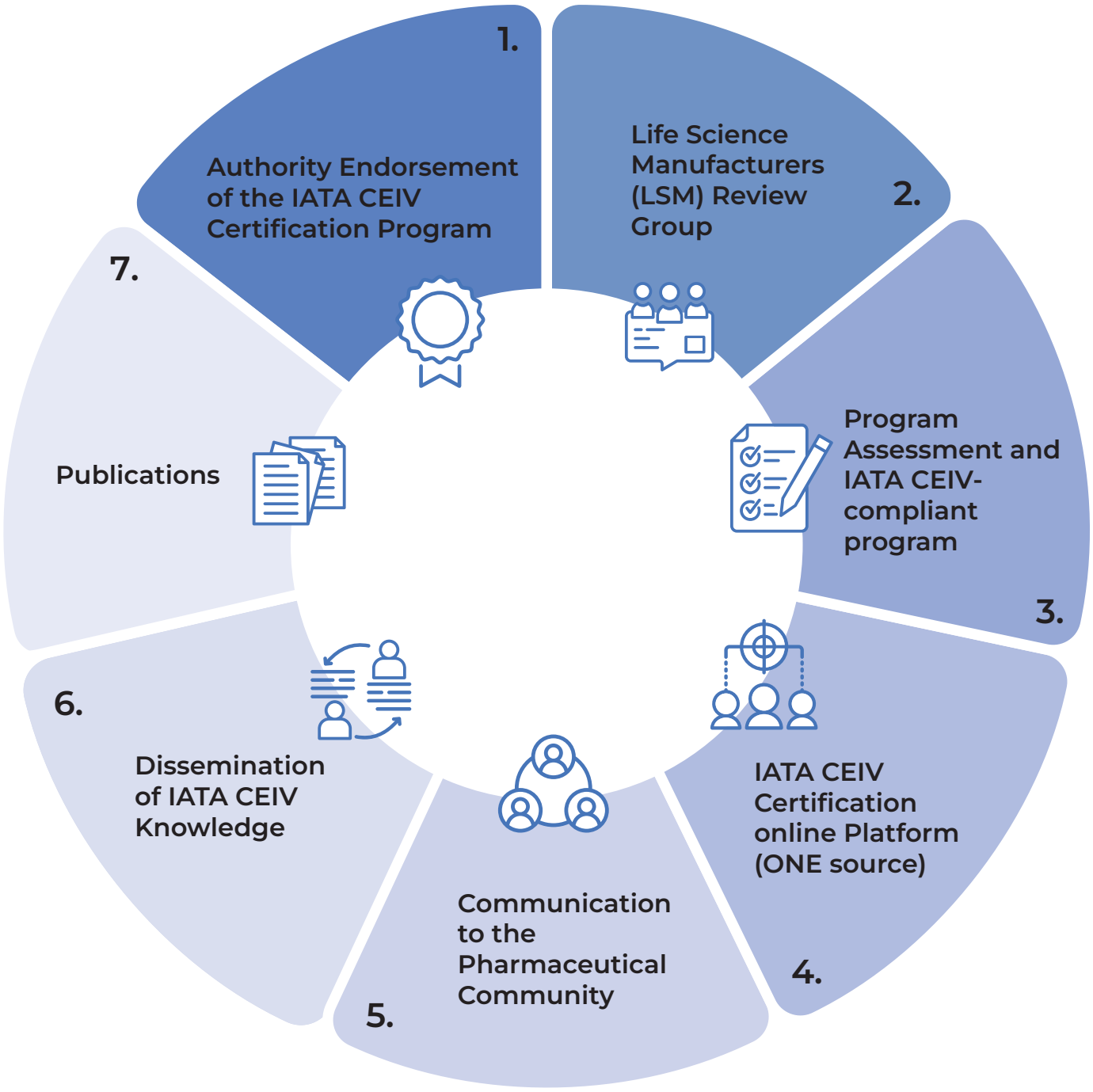
The project members identified the challenges faced, with possible root causes and suggested potential solutions[1]. In cooperation with IATA, Pharma.Aero's project team decided to further build on the results by implementing part of the proposed solutions. A follow-up phase of the project was launched, *CEIV 2.0 Phase 2: Implementation*, to explore six concrete directions:

- Authority Endorsement of the IATA CEIV Certification Program
- Life Science Manufacturers (LSM) Review Group
- IATA CEIV-Compliant Program
- IATA CEIV Certification online Platform (ONE Source)
- Communication to the Pharmaceutical Community
- Dissemination of IATA CEIV Knowledge

1. White Paper: CEIV 2.0 Project Phase 1: Evaluation

3. Methodology

The project was structured into seven Work Packages and ran from March to December 2023.



WP1

Authority Endorsement of the IATA CEIV Certification Program

The scope of this work package was to identify actions aimed at obtaining recognition of the IATA CEIV Pharma Program by authorities and regulatory agencies at the global, European, and national levels. The objective is to position the certification as equivalent to or integrated with the GDP certification in the airfreight industry.

WP2

Life Science Manufacturers (LSM) Review Group

The main objective of this Work Package was to establish a group of life science manufacturers to review the IATA CEIV Pharma Certification and provide feedback to enhance and update the program. In collaboration with the LSM Review Group, Pharma.Aero addressed several aspects to gain better insights into the industry's needs and requirements:

- Is the IATA CEIV Pharma Certification Program known by the pharma industry?
- Has the introduction of the IATA CEIV Program resulted in measurable improvements?
- Were there any noticeable changes in the quality level?
- What could be added or modified to the Program to be more inclusive?
- How can we obtain more support, buy-in and endorsement from the industry (both pharmaceutical manufacturers and airfreight stakeholders)?

WP3

Program Assessment and IATA CEIV-compliant program

The goal of Work Package 3 was to investigate different aspects: Independent Validators' profile requirements, consistency and control, light IATA CEIV capability check, training process, and checklist content. Two surveys were conducted within Pharma.Aero membership - one tailored for Life Science manufacturers and another one for non-LSM stakeholders - to gather insights on independent validators, focusing on potential enhancements to their profiles and competencies. The division of target companies into these two groups was essential, considering the varied industry sectors and differing opinions on pharmaceutical requirements. Some overlapping questions were included to assess potential divergent perspectives.

WP4

IATA CEIV Certification online Platform (ONE Source)

The objective of this Work Package was to raise awareness of the IATA ONE Source Program within the Pharma.Aero membership and assess its potential utility for the industry. In collaboration with an IATA representative, an interactive webinar was conducted to present the current and future features of the program and address queries from participants.

WP5

Communication to the Pharmaceutical Community

Pharma.Aero organized a dedicated webinar where two IATA representatives presented the IATA CEIV Pharma program. The aim was to discuss the future enhancements of the program and explore strategies to address the needs of the pharmaceutical industry.

WP6

Dissemination of IATA CEIV Knowledge

The goal of this Work Package was to highlight the significance of various roles within companies involved in the pharmaceutical transportation process. The technical report detailed essential personnel, requirements and training pathways pertinent to the industry.

WP7

Publications

A comprehensive Technical Report was distributed among Pharma.Aero members in December 2023, marking the conclusion of the CEIV 2.0 project. This White Paper serves as the final documentation for the project.

Project Team

Samuel Speltdoorn
Brussels Airport
Pharma.Aero Board Liaison

Andy Faes
Expeditors
Project Lead

Chrystelle Haddad
Dnata
Project Lead

Pieter Huyghens
4Advice
Project Manager

Bert Elsen
4Advice
Project Expert

Marco del Giudice
MdG Consulting
Project Expert

Sara Van Lerberghe
Pharma.Aero
Project Coordinator

Frank Van Gelder
Pharma.Aero
Secretary General

4. Results

WP1: Authority Endorsement of the IATA CEIV Certification Program

One of the main concerns expressed by the Pharma IATA CEIV-certified companies participating in the assessment phase of the project was to gain more recognition from the authorities and regulatory agencies so that the IATA CEIV Pharma certification would be recognized worldwide as equivalent to the GDP (EU Good Distribution Practice of medicines) for the aviation sector.

This would increase visibility for the certification among LSM and expand its recognition within the industry. Acknowledging the complexity and time-intensive nature of this task, project participants proposed a series of specific actions of IATA to engage with organizations and associations, aiming to feature their IATA CEIV Pharma Program in official pharmaceutical publications.

WHO (World Health Organization)

IATA should engage with the WHO Expert Committee to introduce the IATA CEIV Pharma certification process and requirements, proposing its inclusion in a revised version of Annex 9[2].
If the WHO were to officially recognize this certification, it would signify to the global healthcare industry that the airfreight sector has a distinguished certification for the transportation of pharmaceutical products.

FDA (Food and Drug Administration)

IATA should initiate discussions with the FDA to seek recognition for the CEIV certification program.
A recognition from the FDA would be highly advantageous for US logistics providers and pharmaceutical manufacturers engaged in international trade with the US.

EMA (European Medicines Agency)

The EMA is dedicated to upholding scientific excellence in evaluating and overseeing medicines within the European Union (EU), for the betterment of public and animal health.

MoHs (Ministries of Health)

MoHs provide direction and vision for the health systems and are central to regulation and managing essential public health functions.

European GDP Association

IATA should engage with the GDP workgroup to disseminate information about the CEIV Pharma certification process and the relevant checklists.

2. WHO Technical Report Series, No.961, 2011 - Annex 9: Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products

WP2: Life Science Manufacturers Review Group

1. Awareness level

Most industry members are aware of the certification but express concerns about its global coverage, noting a focus on specific entities.

2. Additions and changes to the program

Respondents suggested potential additions like data security, handling dangerous shipments, inclusion of medical devices, etc.

"Data security becomes more and more important as shipments will contain more sensitive information."

"CEIV is not up-to-date with what is happening in the pharmaceutical industry. It should include everything that is shipped by air."

3. Changes in quality level

Most pharma companies have their own, internal quality check procedures, and therefore there cannot be made a direct correlation between the quality improvement and the IATA CEIV Pharma Program. Nevertheless, the overall quality is positive and confirmed by the participants.

"If you go through the CEIV program, especially companies who go down the path for the first time, it is very robust, all operational people need to be trained in various sessions, etc. I would really recommend it to whom didn't do it yet. It really increases awareness, and ensures that people are trained and retrained again. It definitely has a positive impact."

4. Measurable improvements

Participants were not able to show a direct link between the introduction of the IATA Certification Program and the improvements due to a lack of quantifiable data.

"With all the data available, there should be an objective data report on CEIV improvements. There is currently no KPI, no measurements to see the difference between certified and non-certified companies. There is no direct correlation between the certification and the improvement."

5. Support and endorsement by the manufacturers

The pharmaceutical manufacturers are willing to endorse the program but they require proof of correlation between the program and the quality improvement (quantifiable data). They also seek assurance that their opinions and suggestions will be acknowledged and implemented.

"The program is valuable but it needs to be more thought in the practicalities and content."

WP3: Program Assessment and CEIV-Compliant Program

Members Survey: Key Findings from the Pharmaceutical Industry and the Logistics Providers

1. Improvement of Independent Validators (IV)

Clearly Defined IV Profile Requirements
IATA should establish a clear IV profile, requiring minimal previous experience in both airfreight and pharmaceutical (or GDP) audits. This experience should be supported by verifiable training records.

Customer Feedback Surveys
Implement a post-audit survey for final customers, sharing the feedback with the IV for improvement. IATA should utilize these surveys to evaluate the effectiveness and competencies of the IV.

Monitoring and Evaluation
IATA should actively monitor auditing activities, assessing consultancy service levels after each audit, to ensure accountability and uphold a high standard of service in the auditing process.

Transparency and Documentation
Upon customer request, IATA should make available the entire professional CV, training records, previous audit projects and customer surveys for IVs.

Conflict of Interest Prevention
IVs should ideally be free from employment affiliations with companies that may have potential commercial ties with the audited customer, to avoid conflict of interests.

2. Certification Process and Structure

Annual Remote Maintenance Audit
This audit should particularly focus on aspects such as non-conformities, customer complaints, risk management, and, where applicable, encompass change control and temperature excursions related to infrastructure.

Mandatory Onsite Visit
The initial assessment should be based on an onsite visit resulting in a comprehensive report with detailed descriptions and images of the facility.

Validation Procedures
Validation Procedures can be executed either onsite or remotely, contingent upon the absence of a facility.

Recertification
Irrespective of the facility's presence, the recertification must consistently be carried out onsite.

Enhanced Transparency
To enhance the transparency of certified companies' accreditation (scope of certification), improvements should be implemented to offer LSM a more intricate understanding of the specific activities for which these companies are endorsed.

3. Training of Staff

Training Attendee Database
Establishing a database is crucial for tailoring training experiences to individual knowledge levels, ensuring precision and efficacy irrespective of a company's recertification status.

Certified Schools
Emulating the IATA-accredited schools for Dangerous Goods model, with certified schools in each country providing training in the trainees' native language, could lead to significant cost savings. This approach enhances comprehension and engagement, aligning with efficiency and cost-effectiveness while fostering a deeper understanding of the training content.

4. Members Opinion Regarding a Light Version of the IATA CEIV Pharma Program

The first survey tested the sentiment regarding a lighter IATA CEIV certification, prompted by concerns expressed by participating companies. The primary worry centers around the absence of a simplified version for Good Distribution Practices in the pharmaceutical sector. Given the critical reliance of pharmaceutical companies on certification, there is a perceived risk that the credibility of the entire IATA CEIV Pharma certification may be compromised. This concern extends to the potential hesitancy of LSM to trust the lighter version, casting doubts on its effectiveness and, by extension, the standard IATA CEIV Pharma certification.

The ambiguity surrounding the content of the light IATA CEIV Pharma version further exacerbates the risk, creating uncertainty and potentially eroding trust among LSM. To mitigate this, a clear and distinguishable certificate, logo, and process must accompany any simplified version. The certification process should be meticulously detailed, specifying which companies and contexts are eligible.
Respondents indicated that a simplified version should be applicable only to companies not involved in managing infrastructures and vehicles for pharmaceutical product transport.
Importantly, the survey emphasizes that the development of a simplified IATA CEIV version should only proceed if concurrent efforts significantly enhance the original certification process and the qualification of Independent Validators (IVs). This holistic approach is essential to maintain the integrity and reliability of the IATA CEIV Pharma program.
This divergence underscores the importance of adopting a nuanced and balanced approach. It highlights the necessity of carefully weighing potential benefits against the imperative of preserving the program's credibility. Half of the respondents conditionally support a simplified version, but only under strict conditions.
To address these differing perspectives, it becomes crucial to prioritize enhancing the current certification process, by strengthening its robustness, aligning its content with industry requirements, and improving qualification aspects.

5. Certification Process and Structure

Diversify and Tailor Checklists
to accommodate the specific pharmaceutical requirements of various logistics providers, create distinct checklists for different types of providers (such as airlines, ground handlers, freight forwarders, and trucking companies) or incorporate distinctive sections within a unified checklist.

Increase Transparency in Auditing Procedures to have clearer indications of certified companies' certifications for specific activities or logistic services.

The new checklist (1.7) could include medical devices and veterinary products.

WP4: IATA CEIV Certification Online Platform (ONE Source)

The ONE Source Program is IATA's free aviation industry platform enabling different service providers across the transportation chain to list their company profiles and highlight their IATA certifications and validated aviation capability & infrastructure information. During the interactive webinar conducted by Pharma.Aero, an IATA representative presented the program and responded to participants queries regarding the present and upcoming features of the platform.

The discussion revolved around ensuring accuracy, reliability, and accessibility of information related to industry standards, certification programs, and locations within the platform.

WP5: Communication to the Pharmaceutical Community

As part of the webinar addressing the communication aspects, IATA's representatives provided information about the Healthcare Cargo Working Group, dedicated to ensuring the safe and efficient transport of healthcare shipments and actively working on updating and improving the regulations. This working group has been involved in revising and updating various chapters of the regulations, focusing on responsibilities, packaging, tracking, and monitoring, among other aspects.

- **Responsibilities for LSM and Operators**
  This includes proper packaging, routes assessment, sharing information, obtaining necessary certificates and licenses, compliance with marking and labelling requirements.
- **Temperature Control Regulations**
- **Packing**
  Chapter 5 has been restructured and revised to introduce four main types of packing and temperature control containers. The group has provided considerations for choosing packing and container solutions and emphasizes the importance of following the manufacturer's instructions and using authorized equipment.
- **Shipment Tracking and Monitoring**
  The group has introduced standard operating procedures for data sharing and the approval of tracking devices, with responsibilities assigned to both LSM and operators.

- **Future Editions**
  The group plans to merge content related to subcontracting into relevant sections for the 2025 edition and continues to work on updating other sections, such as documentation, labelling, marking, and handling procedures.
- **Collaboration and Standards**
  The working group collaborates with standard-setting organizations to develop and improve standards related to safety, security, efficiency, and sustainability.
- **Board Composition**
  The board of this group is composed of airline representatives, ensuring representation across the entire supply chain.
- **Focus on 2025 Edition**
  The current focus of the group is aligning with the IATA Master Operating Plan and detailing specific requirements for time and temperature-sensitive healthcare shipments in the updated handling procedures chapter for the 2025 edition.

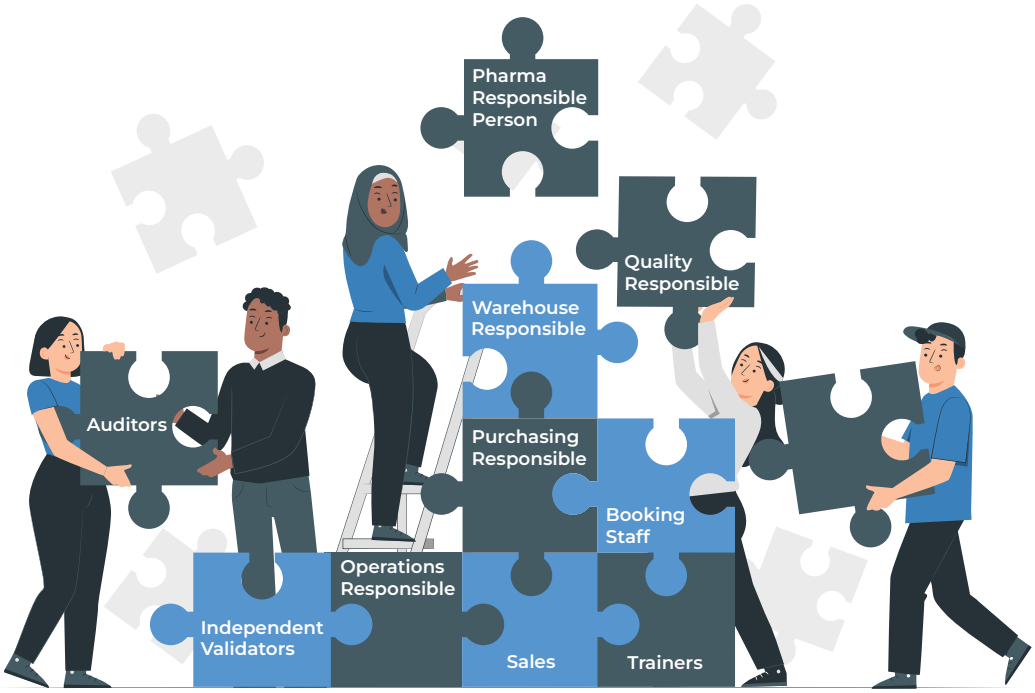
Also during this webinar, a second IATA representative presented the IATA CEIV Pharma certification and its implementation within the aviation and pharmaceutical transport industry:

- **Area of Specialization**
  It includes operation safety and security, environment and sustainability, training and development, and special cargo (live animals, perishables, pharmaceuticals, healthcare, and lithium shipments).
- **Future Enhancements in 2024**
  Seeking endorsements from competent authorities, better engagement with LSM, enhancing communication and visibility, improving the IATA ONE source, and making the certification more accessible to non-developed countries and small enterprises.

WP6: Dissemination of IATA CEIV Knowledge

Effective personnel training is crucial in pharmaceutical logistics, mandated by Good Distribution Practices for medicines and the IATA CEIV Pharma Program. Ensuring a meticulous and efficient training process is fundamental to preventing errors in pharmaceutical handling.
However, creating and implementing a comprehensive training program poses significant challenges to logistics companies. Accurate training modules, tailored to the right staff, must be developed based on risk and training needs analyses. These programs should cover a spectrum of pharmaceutical activities, including operations, transportation, critical equipment, quality and audit activities, warehouse management and supplier qualification. Given the diverse challenges associated with each activity, staff members require adequate and regular training updates. To establish an efficient training structure, logistic operators need an updated training database, a clear training matrix aligning the job functions with courses and systematic monitoring of the recurrent training to ensure overall efficiency.

Deployment methods, such as e-learning, webinars, classrooms, or on-the-job training, should be structured based on organization's size and specific training needs.
In the following section we will outline some of the typical key job functions within a logistics company, specifying their respective training requirements. In some cases, these responsibilities may be held by one individual or they may be distributed among various roles across different companies.



Pharma Responsible Person
Key figure for activities aligning with internal and external pharma compliance.
Training requirements include broad pharmaceutical knowledge, GDP, IATA CEIV, WHO, and national regulatory requirements. Additionally, technical expertise, Quality Management knowledge, internal audit techniques, and self-inspection training are essential.

Warehouse Responsible
Meticulous training is mandatory, guided by a careful risk analysis and subsequent training needs analysis for each critical control point (acceptance of shipments, storage, temperature-sensitive shipments, loading, handing over).

Quality Responsible
A key role in the logistics organization, requiring comprehensive knowledge of pharmaceutical product integrity beyond the traditional quality management system.

Auditors
Responsible for internal audits, ensuring alignment with the quality management system. Requires knowledge of audit techniques, quality system requirements, and pharmaceutical technical requirements.

Trainers
Training for pharmaceutical management courses necessitates prior 'train-the-trainer' sessions and specific technical training.

Purchasing Responsible
Requires basic training on pharmaceutical requirements and relevant experience to support the purchasing process.

Operations Responsible
Subject to risk and training needs analysis, operations staff should undergo various training modules based on scopes, activities, and equipment used.

Sales Representatives
Need a clear understanding of pharmaceutical logistics requirements and customer needs.

Booking Staff
Training for booking and operational aspects requires thorough risk analysis, with a defined pharma training module.

Independent Validators
This role demands specific skills and knowledge, including confidence with checklist questions. IVs should possess detailed knowledge about the structure and commercial relationships of airlines, cargo handlers, freight forwarders, and ramp handlers, including technical documents from WHO.

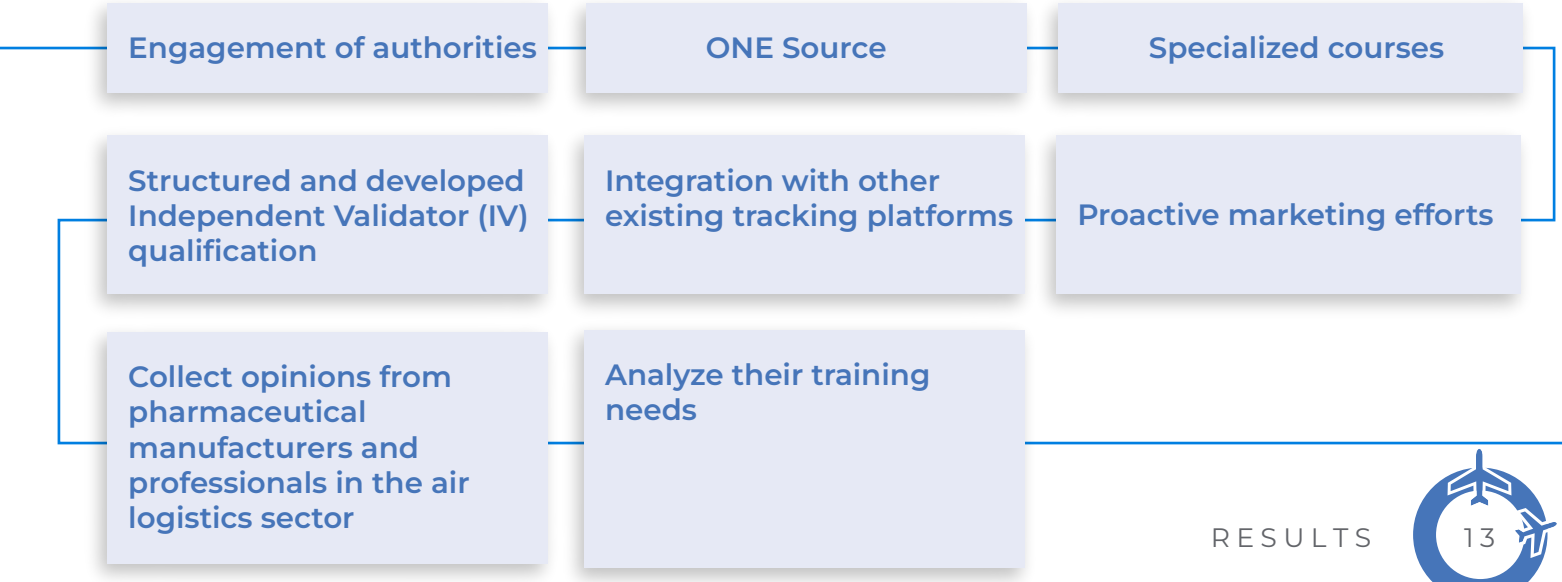
5. Conclusions

After almost a decade of IATA CEIV Pharma certification and accrediting hundreds of companies worldwide, the logistics market signals a need for additional support to consolidate the certification process. This consolidation is crucial for sustaining continuous growth, and preventing stagnation or routine certification procedures that could jeopardize the entire program.
This project underscored the potential benefits of enhancing the entire IATA CEIV Pharma program, particularly through engagement of authorities and the integration of their best practices on both a global and local scale. This engagement indirectly amplifies visibility for the entire pharmaceutical industry.
Surveys conducted with certified logistic companies clearly revealed the need for a more structured and developed Independent Validator (IV) qualification, improvements in the certification process, subsequent IATA training modules, and adjustments to the checklist layout. The feedback emphasizes that any light certification should be postponed until the core process is robust enough.

Another valuable outcome of this project is the ability to collect opinions from pharmaceutical manufacturers and professionals in the air logistics sector through webinars and surveys. Their inputs are pivotal for consolidating and enhancing the certification process.

The ONE Source Program, a shared platform, proves beneficial for the entire industry, providing visibility and transparency on essential information. However, further enhancements and integration with other existing tracking platforms could optimize its utility.
To further increase pharmaceutical knowledge, logistics companies involved should analyze their training needs and provide specialized courses beyond mandatory training for the staff involved in the process.

The IATA CEIV certification plays a crucial role in the broader landscape of pharmaceutical airfreight transportation. While it can be integrated into the GDP certification, it often lacks recognition within the LSM sector. Addressing this requires proactive marketing efforts by IATA, including its participation in conferences and pharmaceutical logistics events. Promotional activities and demonstrations showcasing the ONE Source online Program and the transparent certification process are key initiatives that demand further development.
A refreshed visual identity, symbolizing a renewed commitment to IATA CEIV, would be beneficial. Involving all stakeholders in this renewal process could once again capture the attention of the entire aviation and pharmaceutical industry.



6. Acknowledgements

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