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WHITE PAPER

CEIV 2.0 PROJECT PHASE 1: EVALUATION

A project in collaboration with IATA

DECEMBER 2022

IATA PHARMA AERO

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1. Abstract

The CEIV 2.0 Project builds on the success of the 2018 CEIV 1.0 Project which evaluated the CEIV Pharma certification from the pharma shippers' perspective, three years into the program. In 2021, IATA entrusted Pharma.Aero with a broader evaluation based on the input and insights of Pharma.Aero global membership. Even more, Pharma.Aero involved its strategic pharmaceutical manufacturers members in evaluating the CEIV Pharma certification program and its impact on the quality requirements for their Life Science airfreight supply chain.

The goal of the CEIV 2.0 Project was not only to get the industry's feedback on the CEIV Pharma certification program, but also to identify potential areas of improvements and to collaborate with IATA to define an action plan to implement those improvements.

Pharma.Aero membership, together with IATA representatives, joined forces to brainstorm on how to address certain challenges by identifying the root causes and the potential solutions. Once identified, the potential solutions were ranked, prioritized, and shortlisted for further action.

2. Introduction

IATA launched the CEIV Pharma certification program specifically designed to meet the needs of aviation pharmaceutical supply chain stakeholders. Implemented in 2015, the program gains momentum, but the pharma manufacturers (pharma shippers) lag behind because they do not feel involved or insufficiently know the Program.

The CEIV Pharma certification has become a quality standard over the years, with more than 300 companies being certified or re-certified at different locations around the globe[1].

But what does the industry feel about the impact of the CEIV Pharma certification on the day-to-day business? Did the certification meet the initial expectations over the years? What are the challenges that certified companies face in relation to this program?

As a neutral global cross-industry platform that brings together pharmaceutical manufacturers and pharma air freight logistics providers, Pharma.Aero initiated the CEIV 2.0 Project to find out, together with IATA, what are the industry's sentiments on the CEIV Pharma certification program.

According to the EU Commission, transport companies do not need to hold a wholesale distribution authorisation to transport medicinal products. However, they should follow the parts of the GDP guideline relevant to their activities. In the transport industry, concerns were voiced that GDPs tend to be more focused on the storage of pharmaceutical products and not necessarily on the transport (especially on aviation). On top of that, the implementation of the guidelines into national law is left to the individual countries, resulting in national divergences in timing, interpretation and enforcement.

1 https://onesource.iata.org, December 2022

3. Methodology

The CEIV 2.0 Project started in September 2021 with the dissemination of two surveys to Pharma.Aero members, one for the pharma logistics providers, and one tailored for pharma manufacturers. The surveys aimed to identify various challenges that the companies are facing in relation with the CEIV Pharma certification program.

The results of the surveys represented the starting point, in January 2022, of a series of 8 working sessions with Pharma.Aero members and IATA representatives. The project members identified **7 areas of improvement**, with possible **root causes** and **potential solutions**.

After discussing each category using the fishbone method[2], the project group members classified and prioritized the proposed solutions. The results were presented in the last workshop of the CEIV 2.0 Project and will be the focus of the upcoming project *CEIV 2.0 – Phase 2: Implementation*.

WP1:
Surveys to Pharma.Aero members

WP2:
Analyze and summarize the surveys' findings in a clear and detailed report

WP3:
Joint Pharma.Aero - IATA workshops with Pharma.Aero members

WP4:
Share results and publish final reports

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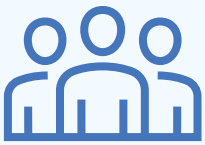
2 A fishbone diagram is a scheme that is used to interpret cause and effect. As a tool, it is commonly used in root cause analysis, which finds the root cause of a problem in order to develop better solutions to an overall system. This diagram is often used by teams for problem-solving.

4. Results

All participating Pharma.Aero members listed more than a 100 potential solutions and recommendations for IATA. They classified these in 15 categories, based on similar solutions with common characteristics and the challenge they can address.



40+
participants

7
areas of improvement

+100
ideas

15
clustered solutions

4.1 Shipper review group

Form a shipper group to involve them in the CEIV standard-setting activities such as reviewing the checklist and endorsing it, align on definitions and regulations, review the audit guidelines, etc. IATA could also provide a basic training on the program to the shippers so they have a full understanding and can advocate for it, learn the value of CEIV as compared to GDP.

4.2 Communications to the pharma community

IATA should be more active in pharma events and communities to educate them on CEIV. They could also organize regular shippers workshops with a focus on quality and procurement. Lastly, they could run a global communication campaign on CEIV Pharma.

4.3 CEIV network

Create a network of CEIV certified companies to share information, capture the lessons learnt and contribute to a continuous improvement.

4.4 CEIV database

Create a database, a shared platform of CEIV certified companies and provide access to audit results and improvements over time (with access control). This tool would also encourage companies to publish their latest risk assessments and CEIV audit reports to provide visibility.

4.5 Authority endorsement

Set up a specific task force between IATA and global health governmental authorities to seek endorsement of CEIV. Involve them in IATA/Pharma.aero fora, boards, in some publications, etc. to establish a dialogue and to build up trust. Endorsement by the authorities would create awareness and support the certified companies.

4.6 Quality of instructors and independent validators

Certified companies mentioned some inconsistencies in the interpretation from the independent validators. IATA could work on improving the quality of instructors and independent validators so that they can deliver instructions and audits more effectively.

4.7 Mid-term review prior to renewals

IATA could explore the option of offering a mid-term review/evaluation prior to renewal. This would ensure that certified companies are consistent in the implementation. They could even include the company's performance in the report, with potential improvement and recommendations, prior to the renewal of their certification.

4.8 Qualified personnel sent for training

Participating members mentioned that the turnover of the personnel can be a challenge to pass on the knowledge inside the company. It is important that the certified companies ensure that only qualified personnel are sent for training, to avoid the loss of previously acquired competencies. They should ensure consistency in the participating personnel, for example designating a "responsible person" for two consecutive years. They also could assess the personnel sent for training.

4.9 CEIV light version

The feedback received from smaller companies is that they don't see as much value in the CEIV Pharma certification program due to time restriction, frequency of audits and limited budget. There is an opportunity to create a lighter version of the CEIV that would be non-cost prohibitive for companies with limited resources. It could even be tailored based on the needs of the company and the scope could be reduced or more specific to cover the gaps.

4.10 Pre-certification program

IATA could introduce a pre-certification consultative program to educate interested applicants on the value of the CEIV Pharma. Future or potential certified companies should be aware of the program prior to certification to be able to understand the value, but also the entire process that follows up the certification (audits, QMS implementation, etc.)

This pre-Program would improve the awareness of the CEIV certification and lead to a more successful path.

4.11 CEIV certified airline group to assess Ground Handlers

As Ground Handlers work in subcontracting of airlines and different airlines may use the same Ground Handlers over their global networks, the situation urges the standardization of common Ground Handler-focused CEIV quality specifications. Forming a CEIV certified airline workgroup would help establish a set of common standards in qualifying and managing the Ground Handlers.

4.12 Recommend how to implement Quality Management System

IATA instructors and Independent Validators should focus more on the QMS (Quality Management System) implementation. They could, for instance, refer to previous reports to track the improvement based on the recommendations and the company's performance. The result would be to collate the findings and get QMS implementation failure trends.

4.13 Refresher course

The feedback received is that the refresher course is "general" and therefore not always adapted to the participants' needs. IATA could introduce a more frequent refresher course (currently only every 3 years) adapted to the needs of the organization. This would ensure that everyone is performing data collection and analysis and apply recommendations to continuously improve.

4.14 Train-the-trainer program

IATA should introduce train-the-trainer (TTT) options to allow companies to get better control over the continuation of internal trainings. Through a TTT program, further dissemination of internal quality training sessions can be improved and standardized to ensure a continuity of internal CEIV trainings to the different layers of staff inside the stakeholders of the air cargo pharma supply chain.

4.15 Consultative and risk-based approach

The certified companies should adopt a consultative and risk-based approach towards the validation exercise. This way, they would focus on what really matters, target what is critical and avoid too many (maybe unnecessary) audits.

Each solution suggested addresses different categories of improvement:

5. Conclusion

Phase 1 of the CEIV 2.0 Project was a great success in that it identified the main opportunities to advance the CEIV Pharma certification program: better supply chain management and certification standards, coverage of all relevant actors in the airline pharmaceutical supply chain, and an improved assessment process. The project provided an opportunity for relevant stakeholders to contribute extensively and re-evaluate all aspects of the program.

The final step in Phase 1 of the CEIV Pharma 2.0 project was to define the scope of the next phase of the project, Implementation.

The following potential solutions were short-listed and will be explored in the next phase of the project to enhance the CEIV Pharma certification program:

1. Authority endorsement

Seek endorsement from global health authorities to increase the credibility of the CEIV certification program.

2. Shipper Review Group

Obtain feedback on the CEIV Pharma checklist, audit guidelines/standards, and demonstrate the value of CEIV to the GDP.

3. Communications to the pharmaceutical community

Increase awareness and understanding of the CEIV Pharma certification program, through workshops, presentations and other events.

4. CEIV Pharma Database

Make audit results and improvements over time available to shippers.

5. Light version of the CEIV Pharma for companies with limited resources

Each proposed solution will have a dedicated Work Package (WP) for an in-depth assessment. Pharma. Aero and IATA are currently refining the details and the scope of each WP. The work packages will explore the integration of the proposed solutions into the CEIV Pharma certification program, to benefit both the industry and the states. Phase 2 of the CEIV 2.0 Project will start in January 2023 and unfold throughout the year.

Pharma.Aero and IATA will continue to collaborate on the CEIV 2.0 project, based on the agreement signed by both parties. IATA is committed to ensuring the implementation of the project to help provide safer, faster, more efficient and more cost-effective air cargo transportation for all stakeholders in the pharmaceutical supply chain. This is achieved through the establishment of a network of certified pharmaceutical trade lanes that meet consistent standards and ensure the integrity of pharmaceutical products.

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