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Pharma.Aero Bedrijvenzone Machelen Cargo 706B, 1830 Machelen

FINAL TECHNICAL REPORT

CEIV VALIDATION PROJECT PHARMA.AERO

JULY 2018

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1. Project outline

1.1 Project charter

IATA CEIV Pharma Shippers Validation

Project Authors:
Nathan De Valck, Brussels Airport
Geert Verniers, 4Advice

1.2 Project purpose

The CEIV pharma certification standard has become an industry standard, which is being implemented by any air cargo stakeholders. A validation of the checklist by pharma shippers can result in a simplified and reduced audit frequency of certified stakeholders.

1.3 Project description

Pharma.Aero will invite its pharma shipper members to participate and involve their Quality Agreement experts to review and validate the CEIV checklist. The group will evaluate to which extent pharmaceutical manufacturers can validate the checklist and the audit methodology, aiming at obtaining an endorsed audit format.

- The project group will work with the pharmaceutical shippers to validate and endorse the existing IATA CEIV Pharma checklist and audit methodology.
- CEIV version 2.0: resulting in a shipper endorsed audit format, reducing audit workload and streamlining the audit process by the shippers.

1.4 Project lead

Brussels Airport

1.5 Project manager

Mr. Geert Verniers, BD Director, 4Advice
IATA CEIV Independent Validator

1.6 Project participants

Brussels Airport Company:
Mr. Nathan De Valck
Cargo & Logistics Product Development Manager - Strategic Development

Johnson & Johnson / Janssen Pharmaceutica:
Mrs. Alexandra Kaempf
Senior Manager Q & C Temperature Control - Transport & Temperature Q & C

Mr. Gino Vleugels
Senior Manager EMEA Temperature Control - CLS Transportation EMEA

Mr. Pieter Doms
Air & Ocean Freight Operations Manager - CLS Transportation EMEA

MSD - Merck & Co:
Mr. Ruud Vander Geer
Assoc. Director, SCM Deliver CoE - EMEA Product Handling

Mrs. Debora Mattys
Associate Director – Compliance Operations EMEA - Global Logistics

Miri Leezer
Assoc. Director External Quality Assurance - Global Transportation EMEA

Pfizer:
Mr. Eddy Weygaerts
Intercompany Operations - Sr Manager Logistic delivery

1.7 Project planning

- Project charter: 29/06/2017
- 1st meeting 4/08/2017: kick-off
- Conference call 12/09/2017: follow-up of input by shippers
- 2nd meeting 6/10/2017: audit methodology & priorities
- 3rd meeting 14/11/2017: challenges & audit checklist
- 4th meeting 11/12/2017: validation of audit checklist
- 5th meeting 23/01/2018: discuss report with IATA
- 6th meeting 09/02/2018: discuss report with IATA

2. Report

2.1 Audit Finding Methodology: Classification Minor-Major-Critical

1. There is a need to add 'critical' as an extra classification of findings. It is a matter of definition, clearly defined to avoid confusion.

Recommended action:
Refine the critical/major/minor. Shippers to provide specific definition. IATA will cross-check and the circulate to finalize the definition.

2. The observation represents the complete absence of one or more QMS element or system component necessary to meet regulatory requirements, including failure to comply with the requirements of the CEIV program and/or established standards. Linked to the "Critical" issue.

Recommended action:
Same Recommended action on point 1.

3. IATA should give reliable transparency about who's already certified and for which specific temperature ranges. CEIV stakeholders, who are not certified yet, should not have any visibility on the IATA CEIV website. How to update information if there are any changes? Pharma shippers can help to provide / verify that information as they are seen as a credible source.

Recommended action:
CEIV Capacity Database to be shared with Shippers. Define methodology on how to update information, discuss with shippers and publish process on the website.

4. The Independent Validator should respect all requirements identified and linked to the specific stakeholder (columns on the right on the CEIV checklist), and should not be changed into N/A. It needs to be clearly specified why it is N/A, because a simple N/A is not acceptable. Also shippers suggest that certain actions should be qualified as mandatory.

Recommended action:
Inform Independent Validators that they need to provide a reason when they declare something as N/A.

5. Each CEIV stakeholder should be able to become CEIV Certified within a maximum period of 1,5 years. Need to give timelines to frame the program.

Recommended action:
Evaluate the timeframe and decide the starting point. Timeline aspect to include into the contract.

Note:
The difference between 'critical' and 'major' in this instance is that for 'critical' observation the quality issue will or already has occurred.

2.2 Audit Finding Methodology: Frequency of Supplier audit

1. All CEIV Stakeholders must present a signed CEIV compliant Quality Agreement with all Critical suppliers and Subcontractors (coming out of the risk matrix). Pharma Shippers want to see the internal audit reports the certified companies have created when inspecting their subcontractors to ensure they are compliant with the requirements by using the same checklist to ensure consistency of the program. Look at and to do a risk assessment on the most critical ones (e.g. maintenance contract).

Recommended action:
Inform Independent Validators, needs to be rated as a Major and companies need to prove they performed these audits based on the CEIV Checklist. This by update of the CEIV Pharma guidelines.

2. Based upon the Quality Agreement, each critical supplier should be audited at least once a year How to guarantee the changes are controlled?

Recommended action:
Inform Independent Validators. Needs to be rated as a major and companies need to perform these audits. Update the CEIV Pharma guidelines and suggest that these audits shall be performed at least once a year.

3. A pharma shipper should be able to receive the Audit results of stakeholders further down the supply chain. Audit reports cannot be published. What can the companies show the auditors?

Recommended action:
Need to evaluate what the right recommendation would be.

4. There is a need of a transparency from IATA towards the Pharma shipper when a CEIV certified stakeholder has made significant changes (new warehouse, new premises,...) See procedure of change control. What is considered as significant change (e.g. in case of merger, new type of aircraft, infrastructure, expanding the cold room – are mapping/calibration performed?).

Recommended action:
Include in the contract that the companies need to inform IATA if these changes take place. Look for opportunity to inform Pharma shippers about changes (e.g. mass mailing, newsletter, shippers can register on the website to receive updates) Shippers should also inform IATA of changes they need. Update the CEIV Pharma guidelines in defining what significant changes are.

5. When a Critical supplier or Subcontractor is CEIV certified, the pharma Shipper agrees upon the fact that those suppliers don't have to be audited again by the pharma shipper. Shipper will simplify their audit base on the CEIV certified audit.

Note:
- *Based upon the Quality Agreement with its Freight Forwarder and Airline, a pharma shipper should be able to perform audits at a Ground Handling station or obtain the Audit results.*
- *When a Critical supplier or Subcontractor is CEIV certified, the pharma Shipper agrees upon the fact that those suppliers should be audited only once every 2 years.*

2.3 Audit Finding Methodology: Recertification CEIV stakeholders

1. The Recertification should focus on showing proof that the stakeholders have maintained the CEIV requirements during the last 3 years. Recertification is a complete audit as well as refresher training Show proof, by showing what else they have been doing.

Recommended action:
Update the CEIV Pharma guidelines in providing more information.

2. For all major and critical findings during a recertification the CEIV stakeholders have max 6 months to close all findings. Findings have to be closed by the time the certificate expires.

Recommended action:
No Recommended action defined.

3. The duration of a recertification audit should be at least 2 full days. It is 2 days.

4. There is a need to focus on Change Management and follow up of the CAPA (Corrective and Preventive Action) process of the previous audit. Focus on recommendations as well. Is the scope still the same? Linked to significant changes.

Recommended action:
Need to send prior reports.

5. The Independent Validator who has carried out the Validation audit, cannot be the Validator for the Recertification Audit. IATA will take it as a recommendation but will not commit.

Recommended action:
No Recommended action defined.

6. The Recertification should be done based upon the entire CEIV checklist for the concerning stakeholder. Assessment is being done based on the entire checklist.

Recommended action:
No Recommended action defined.

7. The content of the refresher 2-day IATA CEIV training should be reviewed and checked by all stakeholders. Companies provide feedback on the refresher training which will re-define the content.

Recommended action:
Share content with Shippers to have their expectations and/or define specific topics to address.

8. In order to prepare the Recertification Audit, the CEIV certified stakeholder should send a file with the following topics:
   - Local regulations customs & health regulations & operations.
   - Redefine the scope (new services, new equipment, ...).
   - All change controls carried out during the last 3 years.
   - Current organizational chart.
   - All training records.
   - Future vision of the CEIV stakeholder.

9. Recommended practices airline: sensors linked at random pharma shipments = relevant historic data set for lane profiling.
   - If applicable, all carried out lane validations and studies carried out to support those lanes (lane simulations).
   - If applicable, all carried out temperature mappings & cooling compartments.

10. The CEIV stakeholder presents all signed CEIV compliant Quality Agreements with the Customers and Critical suppliers of the previous 3 years.

11. The consequence of not having respected the CEIV requirements is that the certification status changes immediately to expired until the independent validator has approved a corrective recommended plan. The company could be suspended on spot checks. The terminology of a company failing the certification is different from a company not wanting to continue CEIV.

Recommended action:
Define the terminology. Check how IATA deal with cargo agents and travel agencies.

12. Based on the recertification audit, IATA should share the information that the CEIV stakeholder's certification has expired (possible status valid/ expired/in progress).

2.4 Audit Finding Methodology: Define which stakeholders should be CEIV audited in the Cool Chain

1. There is a need to integrate the Pharma Shipper and appointed Distribution Centres part of the Cold airfreight supply chain in the CEIV program as a stakeholder, with a 'light version training and audit – Certification" It is recognized that the Shippers should be part of the program. The idea has merit but there cannot be a light version audit. Methodology needs to be the same otherwise the industry will question it. Training could be adapted for Shippers and assessing Shipper's distribution center/facility and handover activity could be considered. A combination of self-assessment and formal IATA-audit. Good opportunity for raising awareness and knowledge in the shippers community. Align internal shipper with global standards which would define the frequency of the audit as a risk based approach. Guidelines by IATA with the right framework, practical focused.

Recommended action:
Check feasibility and design pharma training. Include into the checklist the expectation for each question. Check the feasibility and define a Business Case to frame a possible trial the self-assessment and/or a physical IATA audit. Frequency of the audit.

2. Pharma shippers perform self-assessments based on the CEIV checklist completed with a remediation plan which will be shared with CEIV auditors (IATA should provide a template for the self-assessments and remediation plan).

Recommended action:
Alignment Pharma shipper methodology and IATA methodology.

3. The CEIV program should focus more on the stakeholders of the final destinations, such as local agents, ... taking the last mile.

4. The CEIV program should focus more on the tarmac transport service provider. The CEIV program should guarantee that this stakeholder is also CEIV certified. Focus on ground handlers (cargo and ramp) but IATA cannot impose the stakeholders to get into the CEIV Certifications. Airline need to ensure their

sub-contractor are risk assessed. Mitigation the exposure of product to weather conditions (e.g. Tarmac time, thermal cover, to mitigate to risk).

Recommended action:
Keep pushing on the GHA (push through airlines to sub-contractors).

2.5 Challenges: Identify Challenges

1. In the CEIV checklist, there should be a separate chapter on Road Feeder Service transport, highlighting all relevant procedures and requirements if the Airlines organizes Road Feeder Service transport. The RFS should always be included in the scope of the CEIV scope. It is like any other transportation leg. The CEIV Checklist includes Road transportation but not always refers to RFS, depending on the company's scope of the certification.

Recommended action:
Provide clarity in the program that RFS is required in the program when the service available.

2. In the CEIV checklist, there should be more focus on visibility and checks on final destinations and possible risks at handover points. Last mile is essential. Import shipments are often not stored in temperature controlled areas. Incoterms play a big part in the transportation liability. Airline/GHA should report if at destination there is something going wrong. Do shipper ensure their origin freight forwarder?

Recommended action:
To be further investigated on the start/end responsibility in the supply chain to identify Recommendeds. IATA to include information in the Guidelines on the escalation process by different stakeholder.

3. Role and responsibilities of the tarmac handover point, for both import and export processes, should be clearly and completely be defined by the different parties. Warehouse handler and tarmac handlers can be different. Handover points are looked at in the checklist, verifying the companies ensure the handovers are done in a correct way.

Recommended action:
Ensure the checklist is covering the handover point I a complete manner especially between the warehouse handler and tarmac handlers.

4. In the CEIV checklist, the handover point "loading/ unloading aircrafts" should be checked more thoroughly: who does what, based upon Quality Agreements. There is a need for additional specific questions. Warehouse handler, tarmac handlers and in addition there is the unloading/loading handler. Ensure the checklist is covering the handover point. Handover points are looked at in the checklist, verifying the companies ensure the handovers are done in a correct way.

Recommended action:
Ensure the checklist is covering the handover point in a complete manner especially between the handlers.

5. As the Ground Handler has no direct contact with the Freight Forwarder, the CEIV program should foresee a mandatory communication procedure in which Pharma shipments can only be unblocked via a written approval via the Freight Forwarder and not the Airline. That's not how the industry works in terms of contractual relationship. In addition, this cannot be imposed and it remains with the Shipper to decide to hold, return or release the product. IATA can address it more on the escalation process.

Recommended action:
Update CEIV pharma guidelines (section 7.1) focusing more on the escalation process. Find a way where stakeholders could report to IATA (report mechanism) on anonymous way that certified companies are not performing or there are issues on compliance. This is a monitoring process where companies could get spot checks in case of non-compliant. IATA would do spot checks and potential suspend the company depending on the issue.

6. There is a need to implement transparency in the entire Cold Supply Chain for the Pharma Shipper for at least Temperature excursions and relevant incidents. Performance and if something is going wrong. CAPA should be initiated. Alignment between freight forwarder and airlines on what information can be shared. Pharma-Aero lane validation/ digitization project / historic aspect (performance indicators). Actual situation – aligning CAPA procedure (report methodology – GDPR in mind)

Recommended action:
IATA to include in the guidelines on what minimum information should be included into a CAPA report.

7. Major Change Controls of CEIV stakeholders is key for a Pharma Shipper: there is a need to create visibility on capabilities via the IATA CEIV website (chronological log of changes) What is currently in place and how to log the change. What is being audited and if something is changing how to make this visible. Critical changes need to be reported – What is significant change, means that this should be included in the initial contract to be advised by the contracted company. Visibility via the website.

Recommended action:
Shipper can share with IATA what significant/relevant change occur (e.g. capabilities, changes of the building, design, racks, cooling installation, mapping of update cool room, moving building, supplier change)In quality management change control in their system and be able to report it. IATA to see how in the Capability Database the possible changes can be reported to the industry (triggering something?).

8. There is a need to create more transparency on the capacity of the required temperature ranges of each stakeholder via the IATA CEIV website. IATA Capability Database.

Recommended action:
IATA Capability Database information to be shared.

9. Key Performance Indicators and performance within the CEIV compliant Supply Chain is key. CargoIQ methodology. Internal messaging today but next step, where shippers can access the information and potential trends. Quality shipment in BRU Pharma quality dashboard included into their platform. Intention to have it accessible for the shipper to track performance of the Freight forwarder and airline. Definition compliant supply chain, no real KPI defined aligned with CargoIQ (19 MS), 3 levels of data (in the dashboard) quality of the shipment check at delivery to ground handler.

Recommended action:
Share more information with Shipper on CargoIQ. Share with CargoIQ team the shipper request to have the information and how pharma milestone can be included.

10. The CEIV required handover point checks via the IATA checklist should be gathered and digitalized via a central website: The IATA CEIV website? Pharma.aero website? This would be BRUCloud data sharing platform and IATA IQ.

11. Recalls and falsified pharma shipments: MSD has a PowerPoint study, which will be shared and discussed next workshop: this should be part of the CEIV checklist and its linked specific questions. Falls under quarantine shipment. Points to potentially removed, share with IATA, to enrich the checklist.

Recommended action:
Discard point 11, to be checked.

12. Pest control: Birds and bats should also become a focus as they also carry diseases and parasites. Animal are region dependent and a list should not be restrictive.

Recommended action:
Review 6.1.21 and 6.1.22 on the checklist, question and guidelines and ensure it refers to all animals in pest control.

13. Dry ice solutions: There should be more focus on this topic in the CEIV checklist: classifications/ Dangerous Goods/ security procedures/ capacity/... The IATA checklist has included some questions on ACT (active containers) some related to dry-ice. Volume calculations, HIS people protection all covered by IATA

Recommended action:
Reviewed the dry-ice requirement are covered in the checklist, responsibility of protection for sub-contractor, following the DGR.

14. Active containers: idem previous point. The IATA checklist has included ACT information questions. Add-on on Lithium batteries, part of the dangerous goods further to educate.

Recommended action:
Reviewed the ACT requirement are completed covered in the checklist.

15. Temperature excursions during flight: each airline should show proof of performing continuous studies on how to improve the stability of the required temperature ranges. Best practice where an airline have randomly used a device for temperature

monitoring. Temp mapping of the cargo hold is not supported (many uncontrollable factors) indication of regular routs – same type AC. Provide the airline with a minimum standard way, based on a mindset risk based approach.

Recommended action:
Continue the discussion on the TTWG on Temperature Mapping recommendation to have these included in the TCR.

16. We need to create a shortlist of which Dangerous Goods can or cannot be consolidated on a Unit Load Device with Pharma shipments. Importance to distinguish co-loading and incompatible load. Segregation chart for Pharma, from out of the shipper industry recommendation guideline to go for compatibility.

Recommended action:
Insert in the TCR Regulation an incompatibility chart.

17. There is a need to focus more on the specific capacity of each Stakeholder, on its 2-8 and 15-25 cooling rooms. CEIV Capability Database. When doubling the volume for a company, what should be reported to IATA. Is this under informing about significant change. Needed matrix, capacity management – spot check IATA.

Recommended action:
Spot check if noncompliance reported by shippers for example.

18. There is a need to focus on the integrity of the pharma shipments: partial loads / split shipments are strictly forbidden. This should be included in the IATA training courses and checked via the CEIV checklist. Split shipment is a critical issue for shippers. Issue with monitoring shipment, clearance, storage, split shipment of narcotics and regulators not accepting split shipment. FF managing the booking and information is not shared.

Recommended action:
Communication flow from Airline – FF – shipper to be emphasized and optimized. IATA will prepare an agenda action for the next TTWG meeting to share concern and opportunities. Training to shippers.

2.6 Topics that should receive more attention in the CEIV checklist

1. Responsible person vs organizational chart
   - The authority and position in the organizational structure of the CEIV stakeholder.
2. Security
   - Security of the premises, pharma shipments and their supply chain (X-ray).
3. GDP guidelines
   - GDP and CEIV awareness.
4. Storage
   - The many challenges of how to manage and bring transparency in storage of pharma shipments.
5. Information
   - How is the required information on the pharma shipments shared and guaranteed throughout the Supply Chain?
6. Checklist at handover points tarmac
   - There is a need to implement a strict check at the handover point on TARMAC- Ground Handling. See checklist.
7. Road feeders
   - There should be more relevant questions on Road Feeders, as this is a standard transportation mode for pharma shipments as well.
8. Lithium batteries
   - There is a need to focus on the specific regulations regarding lithium batteries inside the temperature loggers.
9. Cool dolly tarmac transport
   - There is a need to standardize this new added value into the CEIV program.
10. Active packaging solutions - dry ice?
   - There should be more relevant questions on Road Feeders, as this is a standard procedure for pharma shipments as well.
   - This comment is copied from question 7.

Recommended action:
Modify the comment.

11. Change management

    - There is a need to focus more on the specific changes implemented by the CEIV stakeholders.

12. Continuous improvement

    - The CEIV program and GDP guidelines are based upon the desire to implement Continuous Improvement: this should be measured during the CEIV audits.

13. Lane validations

    - The only few questions are not meeting the CEIV and GDP requirements.

14. Internal procedures X-ray

    - There is no question regarding the mandatory internal operational procedures.

3. Addendum: remarks and questions

1. Checks or minor audits during the 3-year period by the Independent Validators.

2. List of the real scope of the audit - What is checked during the Validation (Standard list)?

3. Day-to-day operational control.
   - Forwarder / handler how to manage the trajectory?
   - 17 points story - what is most important for the group?
     → When arrived?
     → Which conditions (temp)?
     → When departure?
     → When doors closed aircraft?
     → When doors open aircraft?
   - Within the industry, what is possible?
     → Start is crucial.
     → Data collection can go on (participants).
   - Project charter (Nathan - Eddy) / Proof of concept (content).
     → Check procedure - different steps.
   - What? What if x, y, z is changing? Positive or negative.
     → Handler direct line - use of the checklist but then during the complete trajectory.

4. Short legend concerning the training - clear content.

5. Description "PIL" when to place with a code.
   - Some Airlines are still bypassing - until now no compliance due to the fact that PIL codes are not accepted in general.

6. Shipper info - guideline is a must.

7. What is required from the shipper regarding training:
   - Content from the air waybill (content and standard).
   - Label - clear guideline.

8. In the standardization no transparency regarding:
   - Risk details.
   - Lane info needs to get back to the shipper.

9. 'Temperature Control Regulations' book - overview of the changes should be a must.

10. Mapping requirements - winter/summer Start up operations major changes based on airflow - isolation impact.

11. Information flow - Documentation is of great importance but also operational information.
    - a good flow of information for both parties - what is coming from the freight forwarder also partially comes from the airlines.

12. Requirements for deviations concerning temperature - clear explanation -how should handlers deal with this?

13. Handover points - checklist not standard only for Dangerous Goods (ADR[1]) there is a clear regulation but for Pharma this is not really clear. The IATA Dangerous Good Regulations (DGR) requires a checklist and provides a template for shipment by air, whereas the ADR has no such requirement nor has a template for transport by road.
    - Airlines are not linked to a clear regulation in this matter, but are on the contrary binded by the ITATA DGR.
    - Recommendation is to scan the label and adding some data (temp 2 - 25°C).
    - IATA label driver for transportation in the air industry.
    - Missing of duration of loading / unloading (documented).

14. Security regulation when Tapa - this action is OK.
    - If not - need to have a 10 points question overview.
    - Regulated agent.
    - AEO[2].

15. Dry ice - active packaging.
    - More details regarding the different steps of the procedure.

16. Cool dolly tarmac transport.
    - Is not included in the list.
    - Also need for a procedure concerning how it is working.
17. Road feeders.
    - Responsibility of the airline.
    - Should be announced upfront - in scope or not.
18. Lithium batteries (loggers).
    - Check where we can put this on the list.
19. Business Continuity Plan.
    - Need to specify more in detail.
20. Screening personal full background.
21. Customs time needed per country.

1 Accord européen relatif au transports international des marchandises Dangereuses par Route. - Europees verdrag betreffende het INTERNATIONAAL vervoer van gevaarlijke stoffen over de weg.
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