PHARMA AERO

WE CONNECT PHARMA

Pharma.Aero Bedrijvenzone Machelen Cargo 706B, 1830 Machelen

WHITE PAPER

PHARMA CORRIDOR PROJECT 2.0

PROTOCOL TEMPLATE FOR VALIDATION OF AIRPORT TO AIRPORT PHARMA CORRIDORS

DECEMBER 2021

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

Pharma.Aero's primordial goal is to achieve excellence in reliable end-to-end air transportation for pharmaceutical products, by fostering collaboration between CEIV certified airport communities, manufacturers and air cargo operators.

As part of this complex mission, in 2019, Pharma.Aero took the initiative of designing, assessing and validating a protocol that provides key information on quality standards along supply chain through seamless temperature-controlled handling, visibility and traceability.

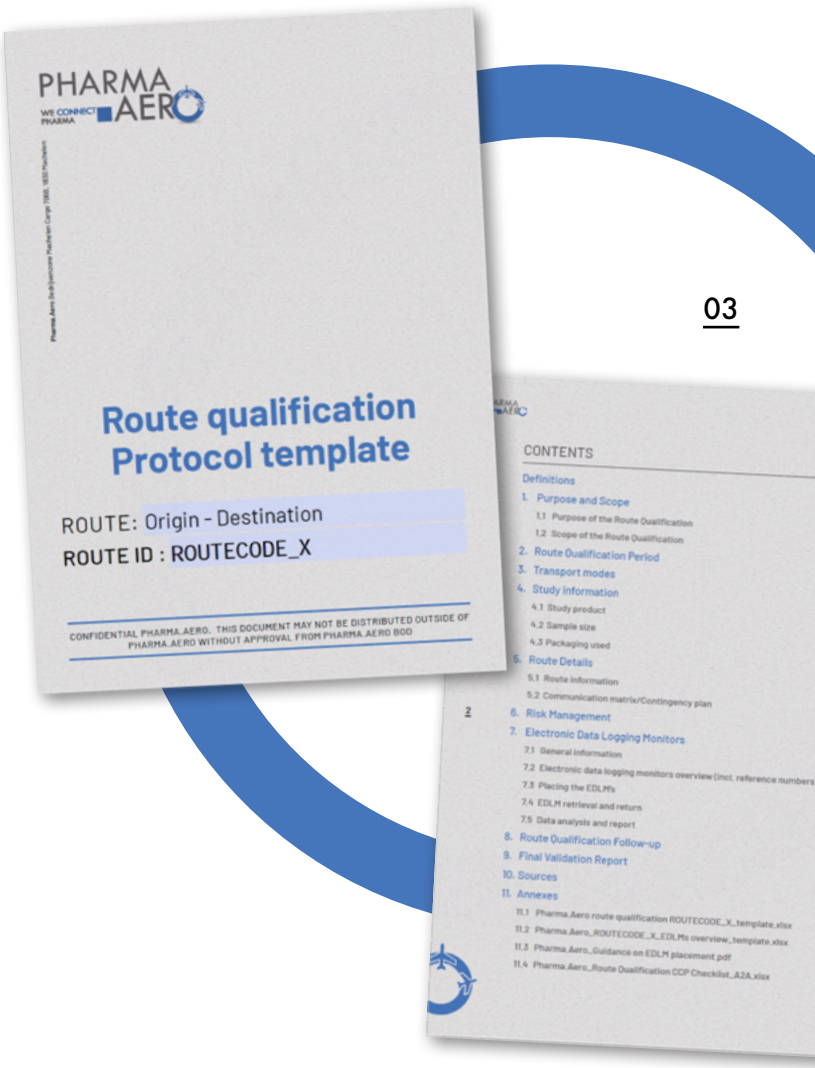
The first airport-to-airport pharma corridor protocol was successfully pioneered in 2020, between Brussels Airport Company and Hong Kong International Airport. The major objective of the Pharma Corridor Project 1.0 was to design, test and validate a standard protocol for pharmaceutical shipments along the specific corridor thus delivering unique assurance in handling quality to pharmaceutical shippers.

Now, Pharma.Aero took its mission further, and launched the Pharma Corridor Project 2.0 with the objective of designing and validating a more detailed Protocol Template for mapping, testing and validating future pharma corridors.

The Pharma Corridor Project 2.0 tested the Protocol Template on the airport-to-airport lane Brussels – Miami. The Protocol Template has been validated by all project participants and has been submitted to the shippers' community of Pharma.Aero for endorsement.

The Protocol Template is providing a clear model of all requirements and key performance indicators identified to monitor the shipment from a defined origin airport to a defined destination airport. Furthermore, the document is offering a detailed presentation of the entire operational process, including route description, transport steps, relevant stakeholders, available capabilities, communication matrix and contingency plan.

The Protocol's annexes include templates for route qualification, guidance on placing, retrieving and data analysis for the Electronic Data Logging Monitors[1] (EDLM) and checklists for Critical Control Points[2] (CCP). The Protocol Template and its annexes are now available for Pharma.Aero members only (air cargo operators, freight forwarders, handlers, trucking companies, packaging solutions providers or airlines that intend to qualify routes for time- and temperature-sensitive cargo).



1 Electronic Data Logging Monitor (EDLM) - A portable electronic device that measures and captures temperature records.
2 Critical Control Point (CCP) - In the process of transporting time- and temperature-sensitive healthcare products, CCPs are typically defined for activities where time and temperature excursions may occur or where critical processes can affect the performance of the packaging solution or containment system.

2. KEY CHALLENGES

Pharmaceuticals are particularly sensitive and exposed to risks when shipped by air. Handling issues and temperature excursions are of particular concern. Depending on the severity or the duration of the incident, a pharmaceutical product could lose its effectiveness and even become harmful.

For the past years, the industry has been calling for the creation of standard procedures, based on key performance indicators, in order to provide quality assurance for pharmaceuticals shipments.

3. MAIN OBJECTIVE: QUALITY ASSURANCE

The purpose of creating and assessing the Protocol Template is to identify, gather and verify key data in order to validate the handling quality and safety of time and temperature sensitive pharmaceutical products, thus providing shippers with an entrusted token of quality.

Today's agile environment demands a more flexible process than strict qualifications. Shippers must demonstrate visibility, traceability and control for shipments in transit. Where possible, they must apply the lane risk management process.

During the transport, the time and temperature parameters are measured, recorded and verified thus offering visibility and traceability for pharma shipments. The collected data represents the quality assurance of maintaining the mandatory standards required by pharmaceutical manufacturers and regulators.

4. PROJECT'S MILESTONES

The first step of the project was to simultaneously create the Protocol Template, identify the route, its capabilities and Critical Control Points to be monitored and tested.

Two sets of data were identified as being crucial:

- Capability information (gathered prior to the test phase)
- Operational information (collected during the test phase)

The second phase of the project was the verification and assessment of the Protocol Template through a series of test shipments over the Brussels – Miami lane.

In July 2021, the defined protocol was tested through simulated shipments over the lane Brussels – Miami and Miami - Brussels with Amerijet Airlines.

The simulated shipments had temperature ranges of +2°C to +8°C and +15°C to +25°C and were packed in va-Q-tec boxes (va-Q-proof 4 type).

5. CONCLUSIONS

The project successfully reached its objective of providing a step-by-step methodology for realizing a lane qualification study, the Template Protocol for Future Corridor Projects.

5.1 Data collection

For the first set of data (capability information or Critical Control Points), the information had to be collected from the various logistic providers involved. The manual data collection process can be lengthy. As a result, there is a risk that the data is already outdated by the time that it is aggregated to map the corridor.

For the second set of data (operational information), most information had to be recovered after the shipping and handling operations. The collection of operational data, during the test phase, was labor-intensive and prone to errors.

The key learning is that communicating clear instructions is essential: which critical milestones have to be collected, at which stage, and by whom.

For a larger-scale study of route qualification, a more automated process is recommended. Instant access to up-to-date capability information through an integrated, collaborative platform would offer the advantage of evaluating the quality and the risks for sensitive shipments in a more objective and realistic manner. In the course of this project, we relied on the capability information provided by the integrated platform that Amerijet and Aviapartner are already using for sharing data, Validaide.

5.2 Root Cause analysis and opportunities for improvement

The study allowed us to identify areas for improvement. It is essential that operators are trained in Root Cause Analysis methodologies to drive continuous improvement in their organization and consequently throughout the supply chain.

5.3 From route qualification to lane risk management

The achieved result of this project matches the objective, which was to provide a step-by-step methodology for realizing a lane qualification study, in other words, a template for future corridor projects.

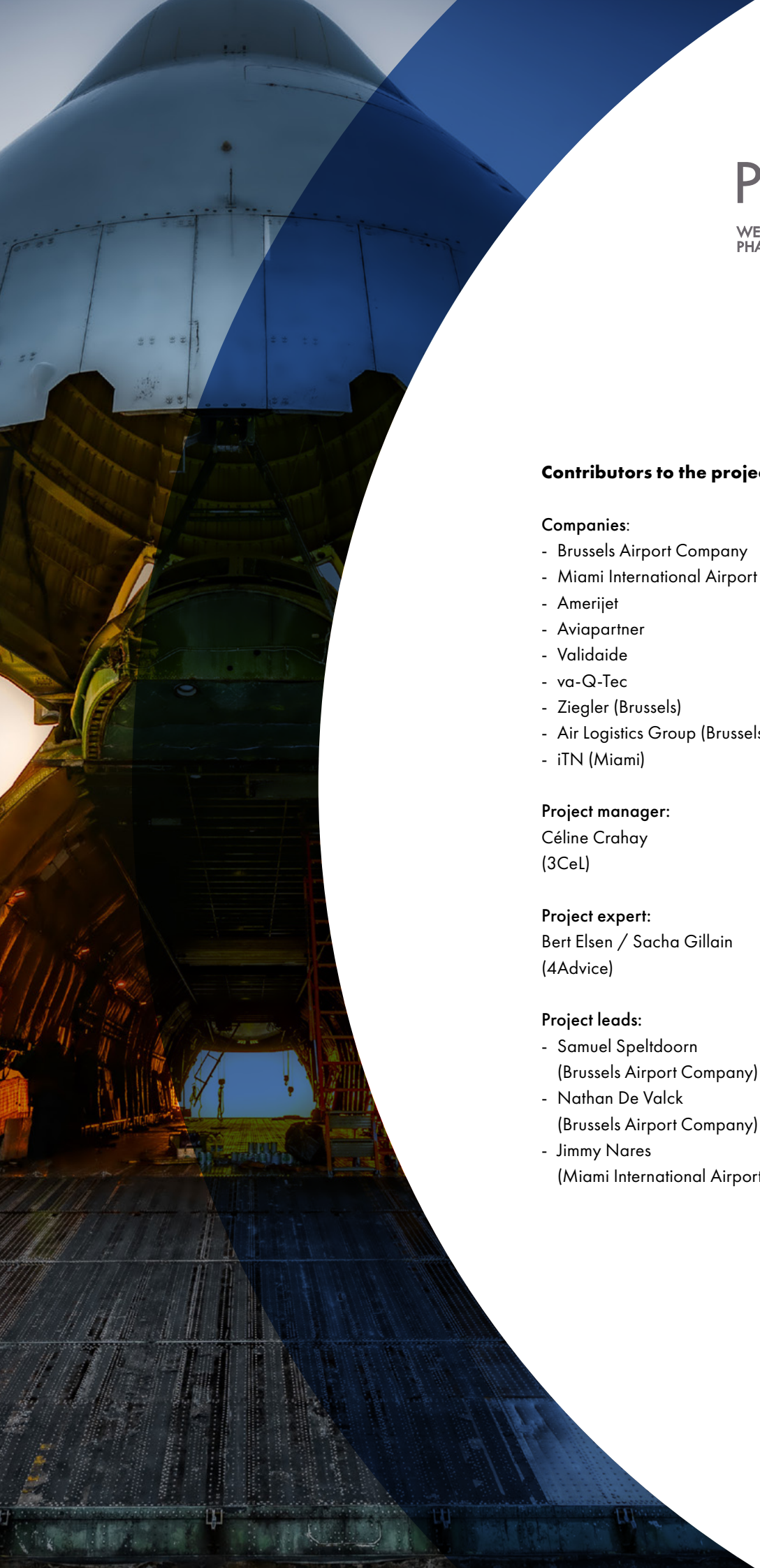
Nevertheless, it becomes clear that, in today's agile environment, the strict framework of a qualification does not fit anymore with the shippers' expectations. Shippers need to work upfront on lane risk assessments and need to demonstrate adequate mitigation plans.

The role of freight forwarders, and by extension each logistic provider, is key to the shippers in this lane risk management process:

- Firstly, by gathering and sharing capabilities, and by identifying risk drivers
- Secondly, by implementing more visibility, detectability, and control, along the entire transport lane.

In the lane risk management process, the risk mitigation part can be alleviated, when some requirements are in place, such as GDP or IATA CEIV certifications, 24-hour monitoring, shared Standard Operating Procedures, or integration programs.

It would be interesting for our industry to delve into those shippers' expectations, so that logistics providers become logistic partners in an agile, compliant, and integrated supply chain.



PHARMA AERO
WE CONNECT PHARMA

Contributors to the project:

Companies:
- Brussels Airport Company
- Miami International Airport
- Amerijet
- Aviapartner
- Validaide
- va-Q-Tec
- Ziegler (Brussels)
- Air Logistics Group (Brussels)
- iTN (Miami)

Project manager:
Céline Crahay
(3CeL)

Project expert:
Bert Elsen / Sacha Gillain
(4Advice)

Project leads:
- Samuel Speltdoorn
  (Brussels Airport Company)
- Nathan De Valck
  (Brussels Airport Company)
- Jimmy Nares
  (Miami International Airport)

Project coordinators:
- Sara Van Lerberghe
  (Pharma.Aero)
- Frank Van Gelder
  (Pharma.Aero)

Project members:
- Christine Richard
  (Amerijet)
- Ronald Irish
  (Amerijet)
- Hilde Neubourg
  (Aviapartner)
- Elfie Bal
  (Aviapartner)
- Natalie Niers
  (Validaide)
- Francois Mugie
  (Va-Q-tec)

Special thanks to MSD and GSK for suggestions and feedback and to pharma shippers members of Pharma.Aero for overall endorsement.

www.pharma.aero