DIGI 1.0 : CERTIFICATION OF PHARMACEUTICALS AIR TRADE LANES THROUGH DIGITISATION

White Paper

PHARMA AERO

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PHARMA.AERO

The objective of Pharma.Aero is to achieve excellence in reliable end-to-end air transportation for pharma shippers, by fostering collaboration between CEIV certified airport communities dedicated in developing and pioneering when it comes to handling, storage and air transportation of pharmaceuticals.

Pharma.Aero's goal is to create more transparency and to improve performance of the supply chain. The ability to collect, unify and leverage data across the multiple participants in a pharma supply chain is instrumental in achieving the Pharma.Aero mission.

EXECUTIVE SUMMARY

Temperature excursions during the air transportation of pharmaceutical shipments carry a big cost to the pharma industry. To minimise and prevent such excursions, shippers want a greater transparency throughout the supply chain. They want to be able to know where and when excursions occurred, but in the present situation, they lack the means to monitor where and when their shipment was exposed to undesired weather elements.

Shippers rely to a large extent on data provided by the other stakeholders in the supply chain, but these data are currently recorded and monitored in silos by the individual supply chain player. On top of that, such data may not be shared across the supply chain. Adding to the complexity, supply chain players use different IT systems and the data is stored in different formats.

Within the pharmaceutical industry, the idea was raised that a coherent and uniform door-to-door data stream on shipment level being hosted on a common data sharing platform could be a solution. It would not only increase the visibility and traceability throughout the supply chain, but also be a tool to assess and certify the air cargo trade lanes for pharmaceutical products.

This single platform should be accessible in a controlled manner to the various stakeholders of the supply chain who embrace the IATA CEIV certification and should enable the monitoring and tracking of temperature controlled pharmaceutical shipments from the start to the end.

Pharma.Aero emerged as the organization capable of developing the platform and of bringing the various stakeholders around the table. In September 2017, it launched the project "Certification of Pharmaceuticals Air Trade Lanes through Digitisation", known as Digi 1.0.

Its aim of Digi 1.0 was to prove that data from different systems and in different formats can be ingested and displayed on a dashboard to enhance the visibility throughout the supply chain. A prerequisite is that the different stakeholders must be willing to work together and to share data. This can be achieved by giving each data provider or authorities the ability to control which part of their data are accessible to which stakeholders under a specific situation. Another key aspect of the sharing concept is that the platform should be cloud-hosted and rely on blockchain to prevent tempering of data.

The project group developed a demo-version that proved it is possible to collect and combine standardized cargo documents, shipment status data, sensor data and quality control data into a coherent and uniform data stream on shipment level on a single data sharing platform.

This model was subsequently presented to Pharma.Aero strategic pharma shippers members and received their acceptance. They signalled that they agree this is the way to go.

As a result, the Pharma.Aero project group prepared recommendations for the development and implementation of the next step, known as 'Digi 2.0'. This prototype will use real data of actual pharmaceutical shipments. The intention is to test and implement the tool on a small number of pharmaceutical trade lanes, including Brussels-Singapore-Sydney. If successful, this proof of concept could consequently be rolled out to other lanes.

1 WHAT IS THE PROBLEM?

Compared to sea freight, transportation of pharmaceutical products via airfreight tend to experience a higher occurrence of temperature excursions. According to the International Air Transport Association (IATA), the annual losses of pharmaceutical products due to the excursions range between USD 2.5 and 12.5 billion. According to some estimates, the cost might be even higher.

To minimise and prevent such excursions, shippers want higher track and traceability, as well as greater transparency by being able to know where and when excursions occurred. To this end, data availability and visibility are essential. However, shippers are not always fully aware on how their cargo is being handled in the airport environment. For example, they are unable to monitor whether their shipment was exposed to undesired weather elements. In addition, the Key Performance Indicators (KPIs) set by the shippers may not be cascaded across the supply chain as these KPIs are difficult to measure throughout the chain.

Data loggers

Data loggers accompanying the pharmaceutical shipments can be a solution, but most of them are passive devices- devices that are not able to transmit real-time data. These data are only available upon downloading at the destination. By then, it too late to take corrective measures. It is also challenging to determine where the excursion occurred and establish protocols to prevent future excursions. Active loggers – devices which transmit real time data, be it location or temperature - do exist, but they would require the airlines' approval to be carried on board, as they transmit signals that could interfere with aircraft communications during take-off and landing.

Hence, shippers rely to a large extent on data provided by the other stakeholders in the supply chain. In addition, the data relevant to investigations on temperature excursions and other incidences (e.g. duration on tarmac or in warehouse, temperature of cold room, handover of responsibility from one party to another, etc.) are recorded and monitored in silos by the individual supply chain player. Unfortunately, such data is currently not shared across the supply chain. Adding to the complexity, supply chain players use different systems and the data is stored in different formats.

This lack of communication and sharing of data among the players hinder the improvement of air transportation quality throughout the supply chain and prevents the identification of the weak links and areas of improvement. Within the pharmaceutical industry, the idea was raised that a coherent and uniform data stream (on shipment level) being hosted on a common data sharing platform could be a solution. Such a platform could not only increase the visibility and traceability throughout the supply chain, but also be a tool to assess and certify the air cargo trade lanes for pharmaceutical products.

Pharma.Aero

Pharma.Aero rapidly emerged as the organization capable of developing the platform and, above all, of bringing the various stakeholders across the supply chain around the table.

Pharma.Aero developed a vision of a digital platform to collect and combine standardized cargo documents, shipment status data, sensor data and information on the quality of handling into a coherent and uniform data stream on shipment level. This single platform should be accessible in a controlled manner to the various stakeholders of the supply chain who embrace the IATA CEIV certification and should enable the monitoring and tracking of temperature controlled pharmaceutical shipments from the start to the end.

Two main levers

To develop this platform and establish transparent and certified pharma trade lanes, Pharma. Aero determined two main levers:

- The identification of data (e.g. common KPIs) that must be collected amongst stakeholders during the airport to airport transportation process
- The definition of the required technologies to collect, integrate and share these data in the form of a dashboard whilst protecting their integrity

Pharma.Aero launched the project - called Digi 1.0 – that eventually was concluded with a demo version to prove the feasibility of such a platform.

2 HOW DID PHARMA.AERO PROCEED?

In September 2017, Pharma.Aero launched the project charter "Certification of Pharmaceuticals Air Trade Lanes through Digitisation". This later became known as the Digi 1.0, with Changi Airport Group (CAG) and Pfizer designated as the project co-leads. They coordinated the identification of common KPIs and requirements for the common data sharing platform.

Together with Brussels Airport Company (BAC), the parties identified critical data IT requirements, as well as existing technologies and potential partners in the market.

Mr. Geert Leroy, an external consultant from Eureachi, was appointed as project manager.

Participants to the project were a unique mix of companies representing the different stakeholders in the industry:

The participants involved in the project took the following successive actions:

- Define and confirm the scope of the project
- Collect inputs on information that are currently captured under the respective milestones in the IATA Cargo IQ Master Operating Plan (MOP)
- Identify the types of data required to create more transparency in the supply chain
- Identify the data and IT requirements
- Identify technologies that can monitor and publish these data
- Finalise a list of data points to captured (and identify a list of other potential data sets)
- Present a demonstration version of the data sharing platform
- Publish a technical report

3 THE CONCEPT

In a typical air cargo supply chain, even for a direct flight, many stakeholders are involved: the shipper, the freight forwarder, the ground handlers (on departure and arrival), the carrier, in some cases another freight forwarder on arrival, and the consignee.

Although some stakeholders do share their data openly, but it is not a common practice. The implication for shippers is the inability monitor their shipment on a real-time basis and to obtain the relevant data in a timely manner during a temperature excursion investigation. By combining data from different stakeholders on a single platform and by matching them, it is possible to achieve greater visibility and insights throughout the supply chain. Ultimately, it would enable the shippers to determine where and when an excursion occurred. Combined with live temperature monitoring, the platform would be able to send immediate notifications to the appropriate stakeholders.

The aim of the Digi 1.0 project is to prove that data from different systems and in different formats can be ingested and displayed on a dashboard to enhance the visibility throughout the supply chain. The participants involved in the project identified three main sets of data that should be consolidated on that single platform. These are:

- Data on location and status of the cargo
- Data on temperature of the cargo
- Data on the quality of shipment

Status and location data

Presently, shippers have to rely mainly on the forwarders for the status and location of their product. These forwarders in turn get their tracking information mainly from carriers and their respective Cargo Community Systems. However, most shippers do not have direct access to this information.

The working party identified common key milestones based on the flight status update (FSU) messages, which are currently being time-stamped by the airlines. These milestones allow one to interpret the location of a shipment at a given time.

Quality data

Typical examples of quality data are CEIV Pharma Acceptance Checklists and other Quality Analysis (QA) checks. Presently, shippers only get access to these quality data after an excursion or a QA issue and during a CAPA investigation. It is thus hard for them to assess the overall quality of a transportation operation or a specific trade lane.

These data could be fed into the data platform at relevant milestones during cargo movement. Ideally, the data platform should also be able to register photos or checklists, such as the IATA Acceptance Checklist.

Temperature data

Shippers often use data loggers that travel with the shipments. However, with passive data loggers, the information on temperature can only be collected after arrival at the destination country. Although the data would indicate any excursions, they do not indicate where they occurred along the supply chain. CEIV certified operators do monitor the temperature of their transport or storage activities, but these data are only shared in case of a CAPA investigation (CAPA: Corrective And Preventive Action).

The data sharing concept

The Pharma.Aero project group came to the conclusion that when stand-alone data from different sources are combined onto a single platform, they can provide a higher track and traceability and better transparency to the supply chain, thus leading to the ability to take actions in achieving better control of the supply chain.

To achieve this, different stakeholders must be willing to work together and to share data.

That willingness would be boosted by giving each data provider or authorities the ability to control which part of their data are accessible to which stakeholders under a specific situation (e.g. data that are accessible for all shipments or only during excursions).

Another key aspect of the sharing concept is that the platform should be cloud-hosted, enabling any stakeholder to access the information in real time, from wherever in the world. Additionally, it should rely on blockchain to prevent tempering of data.

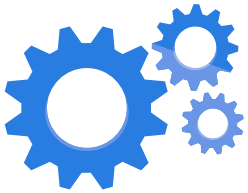
4 DEVELOPMENT OF A DEMO VERSION

As data come in different formats and resides in different systems, a prerequisite for the creation of this platform is a demonstration that this challenge can be addressed. The project group thus decided to create a demo version to proof this point and establish some of the key functionalities and capabilities of a cloud-based and blockchain-enabled data platform. For this demo version, actual but historical data were used.

Guiding principles

Two guiding principles were formulated in the elaboration process:

The data platform should be open, both towards the data providers (offering a wide range of data entry points) and to the data consumers (in order to offer them the possibility to develop value added services and applications)

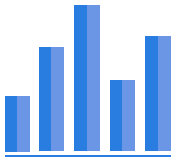


It should also be interoperable, since many of the existing data related to cargo movements may be available in other systems and/or platforms.

Essential conditions

The tool to be developed should also meet several basic conditions:

It must allow for automatic detection of deviations from the planned route, stating the time, location, temperature and quality status (accordance to CEIV requirements) of the product when the deviation occurs. For example, it should detect non-conformances such as temperature excursions, quality issues or delays. It should also be able to identify relevant parties to notify based on cargo documents and to alert them in case of non-conformance.



It must allow the use of the data to review performance, facilitate the risk assessment and validation of a pharmaceutical trade lane. The system thus should enable visualisation and statistical analysis of cargo movements and quality metrics. It should also allow parties to extract the dataset to perform additional business intelligence analysis or report.

As the data being collected are sensitive by nature, data contributors need to be able to trust that the information they provide will only be used for its intended purpose; they must also be assured that their data will be shared only with those who are permitted to see them.

In addition, the information provided needs to be reliable and tamper-free. Providing proof of compliance for interested parties and auditors is a must.

Outcome

The result of this effort was a demo model that proved it is possible to collect and combine standardized cargo documents, shipment status data, sensor data and quality control data into a coherent and uniform data stream on shipment level on a single data sharing platform.

With this demo version, the Pharma.Aero project group managed to prove that relevant information can be collected and shared with various logistics stakeholders by using existing data sharing technology and a single data platform.

This model was subsequently presented to Pharma.Aero strategic pharma shippers members - who are key players - and received their acceptance. They signalled that they agree this is the way to go.

5 THE NEXT STEPS

As a result of this successful demo, the Pharma.Aero project group prepared recommendations for the development and implementation of the next step, known as 'Digi 2.0'. In this second phase, the platform will a be prototype that goes further than the demo version.

With this Digi 2.0 project, Pharma.Aero and its members go for the real test, using real data of actual pharmaceutical shipments. The intention is to trial and implement the tool on a few pharmaceutical trade lanes, including Brussels-Singapore-Sydney. If successful, this proof of concept could consequently be rolled out to other lanes.

The platform prototype will combine different data channels, allowing the ground handlers to send their data automatically.

The potential advantages of air trade lanes certification through this digital central platform are extensive, as it introduces a "single version of truth". For instance, based on evaluation of trade lanes and on the observation from repetitive shipments, a shipper can determine the lane performance. Other features can also include an early warning message to relevant parties that a shipment is about to reach the temperature threshold. Ultimately, shippers can reduce the cost of damaged cargo and the manhours spent on investigations.

This White Paper is based on the technical report "Digi 1.0 : Certification of Pharmaceutical Air Trade Lanes through Digitisation", which summarizes the requirements identified in the project group for a start-to-end monitoring and tracking of temperature controlled pharma shipments and the elaboration of the demo model.

This technical report can be accessed for free by Pharma.Aero members only. Non members should envisage membership to read the technical report.

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