



↘ Cool runnings

The air cargo industry is calling for higher standards when transporting temperature sensitive pharmaceuticals, as seen by the surge in demand for CEIV certification.

Keith Mwanalushi checks in on progress

Flying pharmaceuticals requires strict processes
(photo: LATAM Cargo)

In order to fly pharmaceuticals to where they need to go there are strict processes in place to maintain the cold chain of the product. As outlined by IATA, transporting healthcare products by air demands a rigorous logistical approach. If mishandled, the intactness of these products can be compromised by temperature changes during transportation.



François - CEIV is not a goal on its own, it's a tool
(photo: Brussels Airlines)

With the pharmaceutical industry moving over one trillion dollars worth of cargo every year, [IATA] upholding a shipment's quality requires specific equipment, storage facilities, harmonised handling procedures and, above all, strong cooperation among the cold chain partners.

There has been a growing expectation to see compliance, standardisation, accountability and transparency across the supply chain and since 2014, IATA has developed standards that address these needs to ensure regulatory compliance and quality services. Enter the CEIV Pharma programme – it is a globally consistent, recognised and standardised certification for pharma shipments in air freight.

Brussels Airport played an active role in the creation and implementation of CEIV Pharma. "We co-developed the quality standards in collaboration with some of the big pharma shippers based in Belgium," reveals Nathan De Valck, Cargo Business and Product Development Manager, Strategic Development at Brussels Airport Company.

With CEIV certification De Valck feels it gives a clear guideline to all the air cargo stakeholders on how to implement the shipper's requirements. He says, especially in a community certification setup, like the BRUcargo community at the airport. "The programme helps to standardise and align all the companies involved in the cool chain at the airport."

It's important to note that Belgium is well known in the pharmaceuticals industry, as pharmaceuticals account for over 10% of Belgium's total exports, according to Alban François, VP Cargo at Brussels Airlines. The Brussels-based carrier's pharmaceutical transport activities grew by 56% in 2017 and now consist of 10% of the airline's cargo activities. "With the CEIV certificate, we look to further expand our pharma activities in the future," he says.

François adds that the biggest investment during the CEIV Pharma validation process is an investment in time. "Moreover, Brussels Airlines Cargo has invested in a quality management system and has joined the Brussels Airport's initiatives to use the airside pharma transportation dollies for all temperature sensitive pharmaceutical shipments."

Being placed right in the middle of one of Europe's strongest life science cluster, Medicon Valley, the safe transportation of pharmaceutical products has always been a top priority for SAS Cargo. Leif Rasmussen, CEO for the SAS Cargo Group says air freight should expect to gain its fair share in pharma transport as global regulations become mandatory and as it continues to meet the required standards to safely transport temperature sensitive products.



Rasmussen says air freight should expect to gain its fair share in pharma transport (photo: SAS Cargo)



Huizing says pharma has become more easily identifiable (photo: Swissport)

"The growing pharma market quite rightly expects that pharmaceutical transport should follow global standard and strict temperature control guidelines as well as transparency in transportation at all stages, traceability and execution of an unbroken temperature control logistics chain," Rasmussen mentions.

In addition to making sure that its services meet global regulations, SAS have launched a new pharma product – SAS Pharma Cargo. "This offers our customers the ideal environment for handling temperature-sensitive cargo across the entire supply chain."

Thierry Huizing, Project Manager at Swissport in the Netherlands recalls the pharma journey when it started, just a few years ago. "The pharma volumes were there, but they were not very visible to us as a cargo handling provider," he admits.

"Ever since the industry started using a broad range of special handling codes for pharmaceutical goods, pharma has become more easily identifiable. This helped us track the flows through our facilities," he adds. ▶

Brussels Airlines pharma transport activities grew by 56% in 2017 (photo: Brussels Airlines)



Huizing reckons the CEIV programme is a real added value to standardisation of the handling procedures in pharmaceuticals at a global level. The Swissport Amsterdam cargo warehouse, for instance, can now handle pharmaceuticals at all the required levels.

“If just one step is not executed with the necessary expertise and care then it can compromise the integrity of a shipment,” warns Huizing.

In preparation for CEIV validation, Swissport started by evaluating its then current handling procedures for pharmaceutical shipments. “Some procedures were already set up quite well, others had to be enhanced by adding additional control loops.”

Furthermore, the introduction of the IATA pharmaceutical acceptance check should help organisations ensure that the shipments are correctly labelled and provided with the right information. “This is a prerequisite. If the information is incomplete or even wrong, the next steps in the supply chain cannot be executed as required and the goods may be compromised as a result,” says Huizing.

In addition to adapting procedures, Swissport started analysing the volumes that were flowing through their facilities. “We realised that a large share of the shipments in fact required storage in temperature-controlled areas.”

This led to the construction of dedicated storage rooms for 15-25°C and 2-8°C in all their terminals at Schiphol Airport. Huizing states the storage rooms are equipped with back-up heating and cooling systems and an extensive amount of temperature loggers to ensure the right climate and a high-tech pest control system.

The primary driving factors for growth in pharma air freight are the new regulations in the form of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Even more, IATA elevated the industry expertise by introducing the CEIV standard.

“Before CEIV certification, there was no global standard,” notes Ferry van der Ent, Director for Business Development at Amsterdam Airport Schiphol. “GDP rules often have their own local interpretation and has less focus on transport, especially at the apron. GDP is mandatory, CEIV is not. In general, every certification programme which creates higher awareness for pharma is a plus,” says van der Ent.

AirBridgeCargo (ABC) was the first Russian airline and the seventh in the world to be CEIV certified and was able to complete its preparation for CEIV certification within just four months and successfully passed the IATA audit in November 2016. As part of this, the company has also delivered specialist pharma training to 200 of its employees – this is the biggest investment part of the whole project. ABC states that it has demonstrated the required processes that meet IATA’s global standard and to provide the level of quality and consistency that is of paramount importance for shipping healthcare products.

The whole process of CEIV certification includes five stages: preparation, assessment, validation, training and certification. While preparation deals with documentary side from both parties (IATA and the carrier being certified), assessment and validation are the most active stages and cover on-site assessment (against minimum IATA temperature-controlled checklist), establishment

SAS is strategically placed for pharma transport
(photo: SAS Cargo)





ABC's receipt of its CEIV certificate
[photo: AirBridgeCargo]

of findings with recommendations, development of implementation plan, and on-site visit by an independent validator to review if all the recommendations are met. After that the report is drafted and in 6-8 weeks the certificate is granted in case audit is a success. During these stages, employees of the operating carrier will take a special IATA training course in handling of pharmaceuticals.

In 2017, Changi Airport in Singapore became the first airport community in Asia-Pacific to attain the CEIV. "The value of establishing a CEIV certified community is that at least one company at each node of the supply chain is able to meet the stringent standards," contributes Mr Lim Ching Kiat, Managing Director, Air Hub Development, Changi Airport Group.

At Changi Airport, they have taken the CEIV certification even further. The airport launched its 'Pharma@Changi' initiative in October 2017. Comprising of nine CEIV certified companies that span across each node of the air cargo supply chain. Lim says Pharma@Changi advocates the sharing of best practices for transport, storage and handling of pharmaceutical air cargo, as well as assessing new and emerging pharmaceutical logistics trends and technologies.

LATAM Cargo launched its pharma products in 2015. "The money spent in pharmaceutical's logistics is increasing," declares Cristina Oñate, VP, LATAM Cargo Marketing and Product Development.

According to Oñate, from a volume point of view, ocean freight still accounts for most of the pharma business versus air cargo. The main reasons for choosing one mode over the other are the nature of the goods and the reliability of the service needed.

"The growth that we are seeing in the air industry is driven partly by new demand and because of the shift that some pharmaceuticals are doing from shipping as general cargo to specific pharma products," she notes.

LATAM went through two different CEIV validation processes: one for its global procedures and processes as an airline and another one for the ground handling operation at MIA [Miami]. "Both of them are very thorough and required the dedication of a multidisciplinary task force team for several months."

Oñate explains that the first certification scrutinises multiple global internal processes such as documentation and other procedures, training, and internal audits. The second one audits the local handling processes and capabilities. "Certifications are a good way to complement your internal efforts. Thanks to CEIV, we improved our mapping procedure and we decided to fast-track certain improvements to our cooler facilities in MIA."

In February 2016, Air France KLM became the first major airline group to be awarded the CEIV certificate for its hub operations in Amsterdam and Paris, as well as the Air France and KLM airline processes. ▶



Oñate - Certifications are a good way to complement your internal efforts
[photo: LATAM Cargo]

Amsterdam handles pharma at all levels (photo: Swissport)



"We started the validation process a year before, However, it has not been easy; like any major plan, it requires a lot of focus, communication, training, change of processes, eliminating 'old habits' and change management," says Enrica Calongh, Global Head Pharmaceutical Logistics at Air France KLM Martinair Cargo.

There are some aviation companies however that have chosen not to attain CEIV accreditation and of concern is that differing standards in the supply chain might compromise the integrity of pharma shipments.

"The standards in the supply chain are defined by the needs of the products," says Oñate. "The different pharma certifications not only help the industry establish better and stricter processes to handle pharmaceutical products, but also help shippers identify industry players that meet the highest global standards more easily," she adds.

Air France KLM Martinair Cargo was and is still not satisfied with GDP alone – "CEIV provides more stringent regulations than GDP regarding both the temporary storage and transport of pharmaceutical goods. It spells out what each party must do to be in compliance with the regulations. It is up to the pharmaceutical industry to decide. I personally aim at a community of CEIV certified parties where quality and standards are common denominators and we all strive for one goal," explains Calongh.

Huizing from Swissport weighs in and argues that by choosing local or even region-specific accreditations, there are possibilities that procedures may differ on different quality levels. He says in

the end this would not help establish trust in air transport logistics as the preferred way for moving pharma shipments.

"Hopefully they will at least go for some of the other well recognised accreditations that are there," Huizing suggests.

With the Airport Authority Hong Kong for instance, besides CEIV Pharma, the three cargo terminals at Hong Kong International Airport (HKIA) are also certified with GDP. The airport authorities say while all the seven air cargo operators have obtained CEIV, it means they are proven to be capable to handling the pharmaceutical products during the whole transportation process at HKIA.

As efficient delivery and temperature control are the key challenges in handling pharmaceutical products, two kinds of devices are deployed at HKIA to protect the products against temperature excursion. They are temperature-controlled Unit Load Devices (ULDs) and cool dollies. Cool dollies maintain pharmaceutical products at their specified temperatures against the ambient temperature during ramp transportation.

François from Brussels Airlines stresses that the CEIV Pharma programme is not a goal on its own, it's a tool. He says by using the same standard it allows the different parties in the chain to "speak the same language," and make things easier for everyone.

"Though, using differing standards is not insurmountable provided that the other stakeholders have also invested the right resources to safeguard the integrity of the products when in their custody," François concludes. ■