

KEEPING COOL UNDER EXTREME CONDITIONS

Examining advances in air cargo container technology that give real benefits to shipping temperature-sensitive pharmaceutical and biotech products.

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by Jonathan Neeld

Amidst all the merger and acquisition activity that seems to be holding the headlines in the pharmaceutical and healthcare sector, you may have missed an important point. A key feature of the industry's future success and growth will be the fact that in the next 2-3 years, over 50% of all newly approved medicines will be biopharmaceuticals. (1)

Why is that so important? With over 65% of biopharmaceutical products and almost all vaccines being highly temperature sensitive, their market success is completely dependent upon the ability to protect them from extremes outside their specified storage and transportation range during shipping. Exposure to temperature extremes can render biological drugs less effective, change their potency, and affect their safety to the patient.

As if maintaining product efficacy isn't enough of a challenge, consider the rapid growth of contract manufacturing (CMO) and the impact this could potentially have on the distance between point of manufacture, processing and final sale. Many of the world's CMO sites are located in regions where the local transportation infrastructure often presents a significant challenge.

But there is good news. In the air cargo sector, transportation solutions and their ability to meet new demands have moved forward. With the use of new technology and thermally superior materials, significant progress has been made in addressing those temperature control challenges.

Additionally, organisations such as the International Air Transport Association (IATA) and the Parenteral Drug Association (PDA) and US Pharmacopeia (USP) have spent considerable time reviewing and revising the various guidelines that exist internationally for the safe transportation of temperature-sensitive healthcare products.

In the case of IATA, their approval of an industry-led set of new regulations (2) for their 230+ member airlines is a major step forward in the long term improvement of transporting pharmaceutical and biotech products.

It seems therefore, that the stage may now be set for an era where manufacturers and shippers can have more confidence in the international air cargo logistics cold chain. And the timing is right because data shows that almost 50% (3) of temperature exposures above product thresholds occur when the product is in the possession of the airlines.

This article examines the significant advances that have been made in 'active' air cargo temperature control equipment and how it can now offer better protection against environmental extremes and satisfy the ever increasing importance of patient safety.

CHOOSING THE RIGHT SOLUTION

Choosing the right thermal transportation solution for your product has always been one of the most crucial decisions to be made in getting your valued product to market.

As shown in figure 1, there are many factors to consider including actual sensitivity according to the stability test data, value, seasonal and extreme temperature variations and the ability to manage unexpected delays during shipment or examination. Even shipping on the right day to avoid weekend hold-ups is a significant factor and one that plays an important role in ensuring that your shipping solution can cope.

For smaller, individual shipments over shorter distances, the use of insulated packaging solutions has a significant role to play in effective distribution. But when moving bulk, palletized shipments of temperature sensitive healthcare products, this type of packaging can become cost-inefficient, both in terms of actual shipping charges and packaging material costs. Furthermore since few passive materials are re-useable or recyclable, there is an additional environmental challenge to take into consideration.

To protect larger passively packed shipments during air transportation, thermal 'blankets' were developed but have proven to be less thermally efficient than required for sensitive, valuable shipments of pharmaceuticals. Larger,

insulated 'pallet shippers' using frozen liquid coolants or dry-ice are certainly capable of thermal protection; but because they rely heavily on a large number of cooling packs, their payload efficiency – the ratio of useable space to total volume – can be very low. And what happens when the coolant expires or the ambient environment is frozen?

In air cargo temperature controlled logistics, the 'active' container (or ULD) has been around for more than 12 years. Initially cooled by dry-ice and a thermostatically driven fan system, it has relied upon a mixture of thermal insulation construction and active cooling to maintain temperatures.

Although it has been a traditional source of cooling, dry-ice can have an inconsistent temperature tolerance and for the now more common-place longer journeys, it needs replenishment en-route. In addition, the use (and occasional loss) of the flash-light batteries used to power the fan inside the container has caused many shippers to feel that this type of equipment needed too much attention during shipment and was prone to mis-use.

Additionally, recent upgrades to the thermal insulation properties and performance of these dry-ice units have not been successful for a number of reasons including the need for the shipper to re-validate the container.

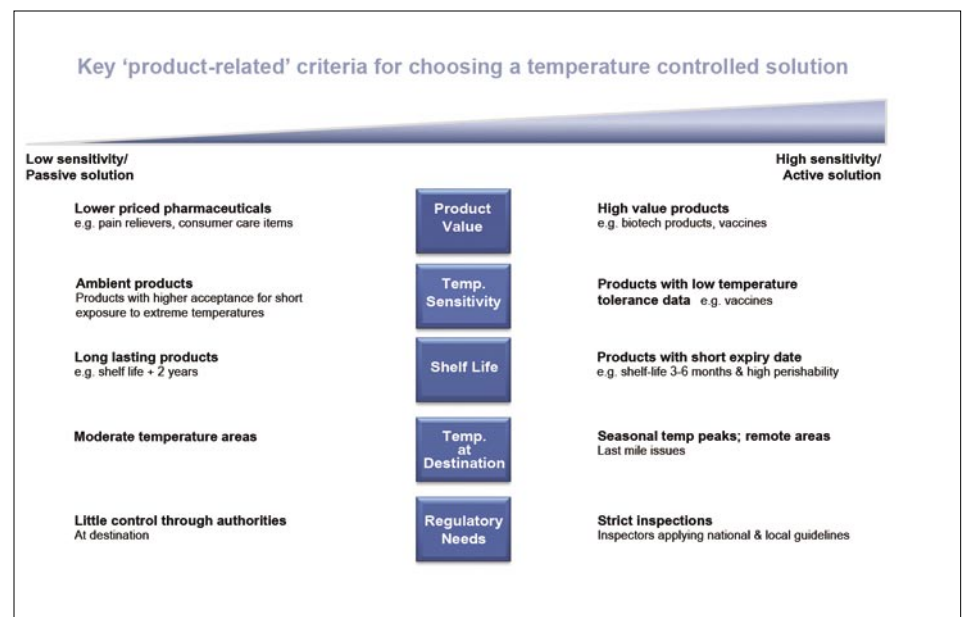


Figure 1 - Choosing a temperature controlled solution

SENSITIVE PRODUCTS NEED NEW SOLUTIONS

The need to ship sensitive products with higher or lower temperature transportation requirements (2-8°C or 12-25°C), can be a major challenge in an extreme ambient environment. Consider one of the major trade routes such as Chicago to Europe in mid-winter with very low external temperatures. Using additional 'over packing' material to protect the products from freezing inside a container cooled with dry ice can be one way forward, but this remains an unreliable method of thermal protection and uses precious internal space. More complex journeys, perhaps Australia to Europe crossing seasons and using transit points in the Middle East, are often a major challenge to traditional dry-ice cooling because of the distances involved.

To address these challenges, a new generation of air cargo transportation container was needed – one that was capable of stabilising shipping temperatures under extremes (-30°C to +49°C) without using dry-ice and that was capable of maintaining its autonomy for long periods, even in a passive state. As a result of an extensive consultation with the pharmaceutical industry, a new generation of container using compressor technology was launched to provide both cooling and heating.

More recent versions have also been combined with a significant use of much higher R value insulation for the entire container system and not just individual panel components. Using this insulation method lessens the effect of high ambient temperatures inside the cargo compartment, reduces the load on the refrigeration system and its internal power source and consequently lengthens the autonomy of the entire system. Simply put, this gives improved protection for longer periods of time and provides more exact temperature control throughout the entire payload area.

Not surprisingly, developing this type of technology for air transportation has meant satisfying diligent aviation regulators. However, there is no single global standard and although the U.S. Federal Aviation Administration (FAA) and the European EASA have differing requirements, so far only the US manufactured CSafe container has been approved by both the FAA and EASA as safe to fly.

NEW TECHNOLOGY BRINGS USER BENEFITS

With manufacturers having recognized shippers needs and developed advanced technology to meet them, this type of air cargo container is now readily available in both the US and Europe.

It has brought simpler, more user-friendly technology into the world of temperature-sensitive air cargo and created greater confidence in shipping systems for highly sensitive pharmaceutical and biotech products.

Its ease of use, with no requirement to calculate dry-ice quantities, simple controls and performance data readily available to be downloaded through USB or infrared access, has brought 'plug n' go' capabilities into reality. These advanced containers need little attention during transportation and have simple but very comprehensive alert and back-up systems giving logistical reassurance.

Battery run time has been tested at over 100 hours – long enough for most journeys even though a full charge can be given within just 8 hours.

And it's not just shippers that can realize the benefits of this new container technology. Freight forwarders, airport handling companies, airlines and many others all have a significant role to play in the global pharmaceutical supply chain and have been eager to find a solution that would meet the demands of more sensitive temperature requirements and make handling much easier.

Latest versions of these new generation containers have improved loading access allowing easier shipment of palletised goods and so reduce the potential risk of damage to the product packaging and contents through excessive handling.

In addition, there is no more handling of dry-ice and having to declare it to the airlines as a 'dangerous good' for in-flight purposes – a major step forward for all those involved in load preparation.



CONCLUSION

For manufacturers and shippers of temperature sensitive pharmaceutical and biotech products, there is keen awareness of their responsibility and the regulatory conformance attached to getting products safely to market. New healthcare items, particularly those in the biotech sector, pose new challenges to cold chain logistics especially in extreme environments, but they remain the backbone of the future success of the industry.

What all stakeholders in the supply chain need is a validated air cargo solution that will permit easier handling and need less monitoring. In other words, reassurance that advances in technology are being put to best use in providing international shipping systems that meet the ultimate goal of ensuring patient safety.

The coordinated efforts of container manufacturers, regulatory and logistics participants have advanced us a long way in being able to do exactly that.

References;

1. O'Donnell, Advanced Degrees Contract Pharma; March 2009
2. IATA Perishable Cargo Regulations Chapter 17.
3. UK MHRA statement, IQPC 2007

ABOUT THE AUTHOR



Jonathan Neeld has over 22 years experience in air transportation and mechanical engineering. He has worked at AmSafe Bridport, one of the world's largest commercial air cargo equipment manufacturers since 1997

and has recently joined the newly formed CSafe company as Engineering & Certification Manager. In this role he has had an integral part in obtaining the world's first FAA certification of a compressor driven active thermal container. He is a significant contributor within the industry and has been active with many of the technical committees involved with the safe transportation of air cargo, including the IATA ULD Technical Panel and the SAE Cargo handling subcommittee.

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