

A Robust Product Delivers a Reliable Solution to the Pharmaceutical Cold Chain

Secure transit packaging is crucial to protect temperature critical pharmaceutical deliveries. Martin Hawes, Global Head of Product Development at Tower Cold Chain, explains how solutions that are built to last mean that some are still in active use after 15 years.

At its simplest, logistics is the art of getting a product from A to B. When it comes to the pharmaceutical cold chain, however, nothing is ever this simple. Factor in the high value of pharmaceutical goods, their perishable nature and susceptibility to temperature changes, the urgency of demands from healthcare practitioners to meet patient care and the numerous (often uncontrollable) complexities of the supply chain, the reality is more like getting from A to Z.

What can go wrong in transit? Containers, and their contents, might get damaged. Drugs may be subject to temperature excursions that render them ineffective. And so many stakeholders are involved that managing these elements is further challenged and the risks increase. Just to take one leg of the journey, the IATA reports that 52% of all temperature excursions occur whilst a shipment is under the control of an airline or within the airport environment.

The impact of this on the pharmaceutical industry is substantial. According to the Institute for Human Data Science, the biopharma industry loses approximately \$35 billion annually as a result of failures in temperature-controlled logistics.

Clearly, this is a situation that nobody wants – but nor is it one that any pharmaceutical manufacturer should be worrying about. The baseline requirement for pharmaceutical logistics is that goods arrive on time, undamaged and with no temperature excursions. It's here that the choice of the most appropriate cold chain solution makes all of the difference.

Understanding the Variables

Transporting pharmaceuticals requires a

container, optimised for temperature control. Said container needs to be robust enough to withstand the rigours of international air freight. It should be as lightweight as possible, to minimise its impact on the overall cargo payload. And it should maximise volumetric capacity, to enable as many products as possible to be shipped at one time.

The materials used for achieving a consistent temperature will depend on whether the container uses active control (i.e., requiring an external power source) or passive control. There are pros and cons to both approaches, but from the pharmaceutical brand's viewpoint, the critical issue is reliability, so it makes sense to base a decision on what will effectively de-risk the process.

And then there's the wider issue of sustainability. Given the growing ethical and legislative pressure to be environmentally responsible, it is worth considering the impact a solution might have. All of the points above – light weighting, volumetric efficiency, minimising wasted product – play a significant role in sustainability. Likewise, consider whether the solution is single-use or whether it has been developed with reusability in mind.

If we're to summarise this as a checklist, the solution should be robust, reliable and reusable. And that starts with getting the product right.

A Robust Product

For those operating in this sector, the critical objective is to improve the quality and consistency of pharmaceutical deliveries across a global market. This means thinking carefully about how to keep the internal contents of the container within a specific temperature range for a defined transportation time, without any requirement for active control (typically over 120 hours). The most common controlled temperatures are ambient (15 to 25°C), chilled (2 to 8°C), frozen (-15 to -25°C) and deep frozen (-60 to -80°C).

At the centre of this equation is the product, which relies heavily on the choice

of materials and components. Key criteria in any product development are quality, longevity, and performance.

Structural integrity is critical as is protection against temperature excursions. For this reason, an ideal solution is to combine outer containers constructed primarily from rotationally moulded polyethylene wall sections which, when cooled, are filled with a structural insulation foam to form a tough composite sandwich construction with high thermal barrier properties and exceptional rigidity.

This combination of rotational moulding and structural insulation foam offers the ideal balance between simplicity and long life, offering substantial protection from external shocks or impacts over an extended period of 10+ years.

Such a system is designed to hold a number of blow-moulded polyethylene plates containing phase-change materials (PCMs) to control the internal temperature and protect the contents from external extremes. These completely enclose the contents to ensure the product is fully protected with a homogenous controlled temperature within the container.

Another consideration is whether a container system offers modular design, which means that the main structural components can be reconfigured to produce up to 12 sizes of shipper to fit differing aircraft types and ISO pallet combinations. To add to the efficiency of a modular system, it's even better if every configuration requires just one size of PCM plate. How pharmaceuticals are to be transported is likely to vary considerably, so any solution must cover a wide range of transport systems including courier and articulated road vehicles, multimodal containers, and both narrow- and wide-bodied aircraft. In every case, the emphasis is on high volumetric and weight efficiency, so it's worth comparing the tare (or unladen) weight of a container against payload volume to find the right balance.

So check with a provider that can they can supply containers designed to carry EU and US part pallets, EU and US full pallets



and double EU or US pallets in the larger sizes. If the system is modular, even better – because the same structural components can produce multiple shipper sizes to fit differing aircraft types and ISO pallet combinations, requiring just one size of PCM plate regardless of configuration.

In addition, a robust design provides practical benefits to the supply chain. Containers can be moved or handled by forklift trucks; they are stackable; and they are designed for road, air and sea transport. Some designs also incorporate two doors allowing loading and unloading from either side – a feature that has significant advantages for logistics providers operating in restricted spaces.

Crucially, this bi-opening functionality doesn't compromise the container's ability to fully encapsulate the product load space with phase-change materials, delivering more homogenous temperature control of the product load area without the need for any air circulation system. As a result, a container can be loose loaded allowing more product, increased capacity and better volumetric efficiency.

A Reliable (and Reusable) Solution

A robust product on its own isn't enough, and the true performance of any solution cannot be assessed without understanding its wider benefits.

Does the system minimise the need for human intervention in the process? Once loaded, packed with PCM plates and closed, can a product be safely transported without ever needing to be opened?

Yes – but only if both the ambient and internal product temperatures are continually monitored and stored for the duration of the shipment in an integrated data logger. Any temperature excursion can be flagged precisely.

Using a solution like this brings significant sustainability benefits due to the virtual elimination of product waste. An entirely reusable system with long life, for example, delivers excellent life cycle environmental performance, particularly compared to single-use systems.

This should be supported by a global network of hubs, located to provide proximity and agility for operations. As well as reducing lead times when a container is required, these hubs also support from a sustainability viewpoint by reducing the mileage when empty, i.e., when being transported to and from the hub.

Beyond the obvious sustainability advantages, reusable passive shippers afford the lowest cost solution when compared to alternative systems. In the White Paper 'The Total Cost of Shipping,' reusable passive shippers were compared to single-use passive shippers and active shippers, on a range of cost factors. The reusable option was, respectively, 9% and 34% less expensive than the alternatives.

Maintaining Robustness in a Challenging Time

As outlined above, the right system brings many features which save customers money and allow a far higher percentage of drugs to be delivered in compliance. This benefits both patients and the pharmaceutical companies that supply them.

That said, given the current climate, amidst the ongoing pandemic and disruption to the global supply chain, it is vital that the pharmaceutical cold chain sector continues to innovate.

Arguably, there's little that needs changing. While industry demand has dramatically increased, customers' needs in essence have remained the same. They continue to require robust, reliable and reusable cold storage solutions, to provide

effective temperature sensitive control in the pharmaceutical supply chain and other life-science goods.

Nonetheless, there are always marginal gains to be made – whether that means improving volumetric efficiency, thermal barrier protection, light weighting, or the design and performance of PCM plates.

The key, of course, will be to integrate such improvements without impacting on the (literal) strength that current offerings bring to the market.

Everything else is a matter of adding further value, to help the pharmaceutical industry navigate through these challenging times. No matter what the complexity of the cold chain, customers need to be reassured that product will arrive undamaged and fit for purpose.



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