PELI BIOTHERMAL™

The Advantages Of Reusable Bulk Systems

For Commercial Pharma Shipping

By **Will Staddon**,
head of commercial rental services, Peli BioThermal

Enabling the commercial shipment of pharmaceuticals is rife with complexity: the logistical, economic and safety concerns that attend bulk transportation necessitate solutions optimized to simplify transfer, lower costs and extend temperature-controlled storage.

The large-scale commercial distribution of temperature-sensitive, fragile pharmaceutical products, from vaccines to biotherapeutics to other high-value pharmaceuticals, has led to unprecedented innovation for the systems used to transport them. The bulk market has historically been dominated by single-use systems, which are effectively high-grade polyethylene boxes that are discarded once they have reached their destination. This paradigm is rapidly changing, spurred by rising costs, resource scarcity and scientific innovation.

The challenges inherent to bulk shipping, already complex, have been exacerbated by the COVID-19 pandemic. Issues related to raw materials and the global supply chain, as well as the prioritization of COVID vaccines in both production and shipping, have created a paradigm that favors more sustainable, affordable shipping solutions. Passive bulk shippers have emerged to meet this need, offering companies solutions to the regulatory hurdles, supply chain disruptions and logistical challenges inherent to global commercial pharmaceutical transport.

Passive vs. Active Systems

Active systems were the first bulk storage assemblies introduced to the market; these systems traditionally possess compressors, batteries and other elements that maintain the temperature inside the unit. Passive systems, in contrast, use phase-change material, requiring no mechanical involvement, as well as vacuum insulation panels, which prevent heat from penetrating the container and cooled air from escaping it. The vacuum insulation technology employed in passive shippers has advanced precipitously over the last decade, facilitating massive reductions in heat loss and gain, vastly extending the life of the stored product. The phase-change materials used for these passive systems have also experienced marked advancement, enabling high levels of temperature specificity for the sensitive therapeutics that require it.

While active and passive systems each possess pros and cons specific to the individual shipping scenario, passive systems have evolved to present a number of advantages over active systems for comparable products and journeys. Due to their relative technological complexity, active containers are classified as "airline equipment" – these systems must follow the same repair, maintenance and handling protocols as that type of equipment, using licensed facilities and upholding the same standards. For passive systems, which are built onto aircraft PMC pallets, the logistics involved in their transfer are greatly simplified; where passive systems can be transferred directly from plane to truck and transported to their ultimate destination, active systems must first be opened, and the product shipped separately from its container.

Passive reusable bulk systems can also represent a cost savings for companies, both when compared to active systems and to their single-use counterparts. Additionally, these systems present a greater range of sizing options than active shippers, which fall into two categories: the single-pallet RKN and the RAP, a much larger four-pallet system. Conversely, most bulk passive systems are either one or two pallets in size, allowing companies to achieve more flexibility in their shipping and planning in the face of space constraints.

Because passive bulk shippers require no electricity, dry ice or batteries, these systems afford companies a wider variety of transportation choices and alleviate the payload excursion risks caused by power failure.

This has become particularly useful in bulk shipments of COVID vaccines: Because vaccines like those developed by Moderna and Pfizer require storage at temperatures below -20° C, passive shippers represent a distinct advantage over active ones, which require the addition of dry ice to sustain such extremes. The logistical problems associated with this compound as the size of a shipment grows, and the dry ice restrictions for aircraft limit the number of active containers that can be transported per flight.

Additionally, many passive system providers have incorporated other services, such as delivery or collection at destination, that have eliminated much of the rebalancing costs associated with active systems. There are, of course, scenarios in which active shippers are necessary; for example, in situations where a company may need to extend the life of a container in order to protect a product, active shippers represent the more feasible option. But for many companies, the durability, consistency, and cost of reusable passive systems have made these shippers the first choice for transporting fragile drug product.

Driving Savings, Prioritizing Sustainability, and Meeting Regulations with Reusable Systems

Recent shifts in market trends, many of them amplified by the industry's response to COVID, have caused many pharmaceutical manufacturers to turn to reusable and passive systems for their shipping. Changing regulatory standards have been one of the more pressing factors in this shift – as many companies have discovered in recent years, the increased durability and reliability of reusable systems can offer the simplest solution when it comes to meeting varying regulations.

Another critical consideration for many pharmaceutical companies is creating a shipping paradigm that prioritizes sustainability. According to Pelican BioThermal's 2020 Biopharma Cold Chain Logistics Sustainability Survey, the biopharma industry is increasingly prioritizing sustainability in business and operational strategies. Nearly half of all respondents indicated that they always factor sustainability into cold chain purchasing decisions, while 53 percent noted that it is very important to choose cold chain packaging options that advance their organization's sustainability goals.

The ecological benefits of reusable systems accrue over time: a reusable shipper used once a month for five years removes 72 single-use shippers from service and, inevitably, the landfill. Because they are frequently manufactured using metals, hard plastics, and other more recyclable materials, reusable systems confer less environmental impact than their single-use counterparts – often produced using foams that cannot be recycled easily – from the jump.

Finally, the economics of single-use systems have forced companies to explore more financially constant options; as the cost of the materials used to produce single-use shippers has increased, many companies have turned to renting reusable shippers as a more cost-effective alternative. Others have tried to overextend the utility of their single-use systems, with negative implications for the product involved – even minimal or moderate damage to a single-use shipper, or improper pre-conditioning, can compromise its utility and ruin the product.

The contrast between pre-COVID and post-COVID shipping costs are staggering – a sea freight container that cost $6,000 prior to the pandemic may now run upward of $25,000 for the same amount of space. This explosion in costs has heralded a new era for bulk reusable shipper rentals, which reduce costs, in part, by eliminating the need for companies to return the shipper from its destination. The compounding savings made possible by reusable system rentals can be difficult to convey to many companies that have historically gravitated to single-use shippers for their lower up-front cost. While this has changed significantly in recent years, a more holistic understanding of the variables that impact the ultimate cost of bulk shipping has become crucial for companies wrestling with market volatility.

Many of the misconceptions that persist regarding the comparative costs of single-use systems versus reusable ones are the result of outdated decisions. Many companies elected to use single-use shippers more than five years ago, when those systems were comparatively cheap and accessible. These companies have begun to pursue a more hybrid approach recently, using reusable rentals for the majority of their shipping, particularly to countries with more stringent regulatory guidelines, and employing single-use systems for shipments where recovery of the shipping container is unreasonably expensive or unlikely to occur.

Partnering for a Competitive Advantage

By engaging in a conversation that considers the extraneous costs of bulk shipping, from landfill costs to disposal costs and delivery costs, companies can perform a more accurate comparison of the true expense of reusable rentals and single-use systems. Similarly, an investigation of the innovations surrounding passive systems may convince many companies of their economic and logistical advantages over active systems.

At Peli BioThermal, the design of its shippers, both large and small, reusable and single use, is geared toward ensuring that valuable payloads are kept in pristine condition, regardless of external temperatures or conditions. Peli BioThermal is the first cold chain packaging solutions provider to offer a comprehensive portfolio of patented and award-winning single-use and reusable thermal protection packaging solutions for the safe transport of pharmaceuticals, clinical trial materials, diagnostics, tissue, vaccine products and blood supplies for the life sciences industry.

Its bulk passive systems are some of the most cost-competitive and reliable shippers on the market today. Peli BioThermal's Crēdo™ Cargo bulk shippers ensure high performance and consistent temperature stability in excess of 120 hours. Crēdo Cargo's lightweight, sturdy design, which features tough external wall construction that absorbs and deflects impacts, is primed for stackable, easy storage. Likewise, its Crēdo Xtreme™ bulk shippers protect high-value pharmaceutical and biotech products for 96 to 144 hours at controlled room temperature, refrigerated, frozen and deep-frozen temperature ranges. Both shippers' easy-to-use coolant loading systems help decrease labor costs and reduce the risk of temperature extremities resulting from user error.

To ensure its rental systems meet stringent quality standards globally, Peli BioThermal collaborates with healthcare, pharmaceutical, government, military and other life sciences organizations to design, develop, and qualify temperature-controlled packaging solutions. Its experienced, award-winning engineering team analyzes each project according to its schedule, product stability, mode of transport, duration requirements, required threshold and ambient temperature. Peli BioThermal then collaborates with the customer to develop a comprehensive thermal protection solution to meet those requirements.

From there, Peli BioThermal's dedicated rental team offers a wealth of technical expertise and industry experience, affording customers comprehensive support in the face of emergent shipping issues. This level of support became critical in the midst of the pandemic, when companies were scrambling for shipping alternatives in the wake of materials shortages and shipping delays. For Peli BioThermal, its primary concern was its existing customers – while many shipping suppliers chose to prioritize vaccines, Peli BioThermal elected to ensure that its customers had ready access to its rentals, helping them maintain their operations in an uncertain landscape. Since the start of the pandemic, Peli BioThermal has invested in increased capacity, particularly for its bulk shippers, in order to meet the demands of a burgeoning market.

Ultimately, the benefits of reusable passive shippers make them an invaluable component of any commercial shipping operation. Their environmental sustainability, coupled with their comprehensive cost efficiency and reliability, make them an ideal choice for surmounting regulatory challenges and creating compounding efficiencies. Peli BioThermal, which holds multiple ISO accreditations, possesses the technical capabilities and institutional expertise to accommodate a vast range of customer needs. Its reusable bulk systems offer customers consistent quality and utility, and its comprehensive support greatly simplifies many of the challenges characteristic of bulk shipping.

About the Author

Will Staddon is the head of commercial rental services for the partner management team at Peli BioThermal. He oversees and provides guidance on all areas of pricing, contracts and commercial agreements with Crēdo™ on Demand and other rental customers.

Prior to Peli BioThermal, Staddon worked at Va-Q-Tec as their Global Partner Manager – where he was responsible for all airline and freight forwarding account management and new customer implementation/onboarding. He was also responsible for updating and technical SME on items such as container handling and safety standards, etc.

Staddon started his career at British Airways (now IAG Cargo) World Cargo Graduate Program where he held roles in safety and compliance, cargo operations, regional operations management, and sales management – pharmaceuticals and life sciences for UK & Ireland.

Upon completion of the Grad Scheme, Staddon was then promoted to Global Product Manager – Pharmaceuticals and Life Sciences. He was responsible globally for the development and success of specialty products for Pharmaceuticals and Life Sciences.

Staddon holds a BSc degree in Politics & International Law.

ON THIS TOPIC OR OTHERS PLEASE CONTACT
ADAM TETZ, DIRECTOR OF WORLDWIDE MARKETING.

E: ADAM.TETZ@PELICAN.COM T: +1 763 235 6268
PELIBIOTHERMAL.COM

ISO17025, ISO14001:2015, ISO9001:2015