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## Flexible Configurations Replacing Bespoke Packing In Cold Chain Distribution

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For the biopharmaceutical industry, packaging solutions that meet their needs while offering added cost benefits have become increasingly integral as more temperature-controlled biologics and cell and gene therapies begin to dominate the market. Flexible thermal packaging, which utilizes components that have been designed for their adaptability in the face of variable shipping scenarios, can facilitate the safe and efficient transport of a broad range of temperature-sensitive therapeutics through configurations performed on the fly.

In contrast, bespoke packaging, which has historically dominated the market, is just that - an individualized approach to packaging design tailored to a specific application. While it can present advantages for certain situations, the benefits of engaging in bespoke packaging design have declined as more temperature-controlled therapies have gained market acceptance. From the regulatory constraints inherent to bespoke packaging to the cost associated with designing containers from scratch, many biopharmaceutical companies have begun to recognize the value of flexible packaging in offering comparable performance without the need for extensive, expensive design and validation. More recently, the incorporation of vacuum insulation panel (VIP) technology into flexible packaging has garnered more interest and acceptance from risk-averse, strict label shipping customers, facilitating additional performance gains for these solutions.

The time and cost limitations that accompany a therapeutic's development are diverse. While shipping is just one factor impacting a drug product's long-term commercial potential, it's an important one: having the packaging solutions in place to ensure that sensitive, costly therapeutics are transported in ways that are both safe and economical is critical to achieving lasting success. By right-sizing with solutions that are fit-for-purpose, adaptable, and proven, biopharmaceutical companies can achieve their global distribution goals while maximizing their return on investment.

## Bespoke vs. Flexible: Pros and Cons

Bespoke packaging can offer companies efficiencies in a couple of key respects; by designing packaging that conforms to the specifications of a single product, companies can achieve a tighter product fit, maximizing the amount of payload that can fit inside the container while reducing its outer dimensions as much as possible. This creates a cost advantage in shipping, as companies are able to ship more product utilizing less space. But this advantage exists alongside a few comparative disadvantages, largely a result of the historical market dominance of bespoke solutions. The biggest of these are the time and costs that attend the development of a bespoke container. This development is, in essence, its own distinct R&D project - it requires thorough planning on the part of a company and its supplier, as well as significant up-front investment in tooling and manufacturing.

Ideally, undertaking the design of a bespoke packaging solution results in a container that meets a company's needs well into the future. If not, another major drawback inherent to bespoke packaging can emerge: because bespoke containers have been developed and validated for a specific application, any changes to the temperature requirements for a therapeutic, or to the regulatory standards that apply to its shipping, can force companies to redevelop their packaging, further compounding costs and delays. The combination of initial cost and time invested in these solutions, coupled with their potential invalidation in the face of shifting regulation, have made bespoke packaging a less feasible option for many companies in the long term.

Conversely, flexible thermal packaging can afford companies varying levels of customization without the need for drawn-out development or validation. Additionally, because their components and various designs have already been cleared by regulators, these systems allow companies to make tweaks to their configurations without having to resubmit to the FDA or another authority. With the ability to swap out configurations to meet differing thermal profiles and packing considerations quickly and easily, prequalified, flexible packaging solutions can afford companies a more reliable avenue for cost savings while maintaining the quality necessary for transporting time- and temperature-sensitive therapeutics.

Whether by selecting an off-the-shelf flexible packaging solution or customizing a flexible shipper and performing some additional testing, the turnaround time for flexible

shippers is markedly shorter than it is for bespoke solutions. These advantages can be compounded by transitioning from single-use shippers to multi-use systems, or even reusable shippers, to extend a shipper's usable life and promote greater resource management. These packaging solutions - both flexible containers and multi-use systems - have seen increasing market acceptance in recent years, as companies work to move beyond the status quo that drove earlier shipping paradigms. In the early days of thermal packaging, creating new tooling and cutting new sizes of containers was par for the course, but as standardization continues to evolve across various facets of the space, innovating shipping solutions that can be molded to various applications easily will afford companies an increasingly competitive edge.

## The Future of Cold Chain Shipping and Flexible Configurations

The last decade has seen a great deal of innovation for thermal shippers. The introduction of elements such as VIPs, advanced technologies that offer multifold efficiency increases when compared to conventional technologies, also affords packaging with thinner walls, helping to optimize space utilization even when compared to bespoke solutions. The modularity that has been achieved with flexible shippers has also served to strengthen their appeal; companies can now contract with the same supplier to create dozens of customized flexible shippers in a fraction of the time needed to establish a similar bespoke system portfolio.

While flexible solutions can be implemented to serve a wide range of shipping scenarios, the current reality is that a bespoke shipper, designed for a specific therapeutic, would be difficult to match point-for-point with a flexible solution. This is chiefly because the outer dimensions of flexible shippers do not change; as a result, these systems cannot always achieve the optimal internal packing structure necessary to entirely eliminate unused space, or to enhance loading for certain forms of transport. Even an inch can disqualify entire swaths of a flexible portfolio from use for a specific application; despite this, newer flexible shippers are in development that can extend the form of a box to fit atypical specifications. The internal modularity of flexible packaging affords customers the latitude to adjust the duration or internal payload space to suit low- and high-stress logistical lanes, different configurations, or the skewness of payloads. As these systems continue to evolve, the granularity achievable in the flexi-

bility is only anticipated to increase, bridging the gap and facilitating even more unique configurations.

As the biopharmaceutical space continues to progress, established companies may face increasing issues when it comes to their existing shippers. Bespoke shippers, developed for products introduced to the market years before, may represent a less optimal option when compared to more advanced packaging technologies. These solutions often possess thicker walls, the result of outdated thick foam insulation, and a company storing 10 or 20 different bespoke shippers may begin to see the value in overhauling its existing packaging portfolio. Faced with the prospect of designing and developing multiple new bespoke packages from square one, the benefits conferred by flexible thermal shippers may represent the more affordable, sustainable solution in the current market landscape.

Ultimately, partnering with a packaging supplier with the expertise and experience necessary to identify a

shipping paradigm's pain points, evaluate a product's specifications to determine its optimal container solution, and support a company's evolving needs is a critical component in achieving lasting success. Engineered, high-quality, flexible packaging products are few and far between. While there are a few packaging suppliers with flexible solutions on the market, many of these systems are not able to comply with the strict temperature thresholds necessary for the international distribution of biopharmaceuticals. The particular advantage of flexible thermal shippers lies in how quickly they can be reconfigured in the face of new information: paired with track-and-trace technologies capable of collecting the right kinds of data, companies that encounter emergent problems that require new shipper specifications can achieve them before the next shipment goes out. That level of responsiveness, coupled with the right level of support from a packaging supplier, affords companies the maximum level of adaptability in responding to the ever-shifting needs of the biopharmaceutical space.

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