PELI BIOTHERMAL™

Cold Chain Considerations
For Global Commercial Pharma Distribution

Source: Peli BioThermal

Pharmaceutical companies requiring cold chain distribution after commercial launch can maximize ROI through efficient warehousing, distribution, and packaging strategies – guided by an adept partner.

Global commercial distribution of temperature-sensitive pharmaceuticals can seem daunting for both established and emerging life sciences organizations. Cold chain packaging and shipping considerations change as an organization shifts from clinical to commercial operation, and new challenges have impacted shipping in general since the advent of COVID-19.

Implementing sustainable cold chain shipping practices that evolve alongside an organization's product portfolio and distribution footprint requires understanding the obstacles to overcome. While drugs under development historically have tended to be chemically synthesized and stable at room temperature, modern therapies are trending increasingly toward biologic derivatives – injectables and IV-infused drugs – that require constant temperature control. To operate efficiently in this environment, pharmaceutical companies must maintain minimum rigor: too little attention to temperature control can compromise a therapy, while temperature control overkill can lead to extraneous costs. Thus, "right-sizing" elements like warehousing, packaging, and shipping providers is critical.

Commercial Cold Chain ≠ Clinical Cold Chain

Stark differences exist between clinical and commercial cold chain shipping, so experience in the former does not necessarily translate to aptitude in the latter. For example, during clinical development, pharmas lack extensive data demonstrating the temperature ranges a molecule can be exposed to. So, they tend to stringently adhere to a range between -2°C and -8°C for a refrigerated drug because testing has been insufficient (to that point) to indicate the safety and efficacy repercussions of falling outside that range.

In clinical stages, that concern about temperature excursions and, to some extent, overkill relevant to thermal performance robustness, is understandable. The consequences of a cold chain excursion could be significant and lead to a domino effect. Consider the example of a clinical drug that is late to arrive, or is temperature compromised and must be re-shipped, and the patient misses a dose. As a result of clinical study protocol dictating patients must dose on certain days, the patient is dropped from the trial. The pharmaceutical company then must bear the expense of recruiting a new patient.

Conversely, commercial products generally are backed by more than a decade of research into the molecule, including acceptable temperature ranges to which it can be exposed. Hence, commercial shippers usually have more "wiggle room" related to temperature control parameters.

The scale of distribution between clinical and commercial is pronounced. Commercial distribution is intended to reach as much of the patient population as possible, whereas clinical distribution targets only individuals who agreed to participate in a given trial. Consider that, just a few years ago, one of Peli BioThermal's service centers handled about 60,000 shipments, serving multiple customers, over the course of a year. Fast-forward to 2021, when a single customer's request for proposal (RFP) concerning commercial distribution of a vaccine involved more than one million shipments annually.

Shipping at that scale demands a cold chain partner with the proper infrastructure to condition refrigerants (e.g., phase-change material) and adequate warehouse space near global shipping hubs. That partner also must have processes in place to manage conditioning, plus warehouse personnel adept in packing out those shipments quickly and accurately.

Understanding Shipping Considerations To Right-Size Services

Nearly all activities relevant to clinical development are executed with an eye toward proving a drug's safety and efficacy, with cost comprising a secondary (though still important) concern. Pharmacovigilance remains vital after commercial launch, but maximizing return on investment (ROI) also is elevated to a key concern: how will the pharmaceutical company make money back on a drug in which it has invested tens or hundreds of millions of dollars?

The answer, as it relates to cold chain shipping, usually comprises a blend of outsourcing savvy, environmental sustainability, and flexible temperature control performance commensurate with each organization's warehousing, distribution, and reverse logistics needs. In this respect, outsourcing has emerged as a best practice as pharmas seek to double down on their core competencies and increase their margins. However, pharmaceutical companies must ensure their partners can understand and adapt to their specific situation, versus trying to apply a one-size-fits-all approach.

Commercial distribution typically is staged from distribution centers located in easy-to-access, centralized hub locations (e.g., where a UPS or FedEx facility is located) and serving in-country locations, so access to recipients rarely presents a problem. Challenges are more likely to arise from extreme climate scenarios – such as Minnesota in the winter or Arizona in the summer – or locales that are traditionally tougher to access (e.g., rural Alaska) compared to the U.S.' lower 48 states. This contrasts with clinical shipping lanes, which may need to reach sites on other continents and typically feature extended transit times: 96 to 120 hours, versus the 24-to-72-hour duration typical of commercial shipping. Thus, distributors must right-size temperature control performance commensurate with those durations.

Informed by discussions and experiences with our clients, Peli BioThermal has developed the ability to scale thermal performance according to their specific needs. For example, serving a lane that only requires 24 hours of temperature control performance, we can scale the amount of phase-change material (e.g., the number of gel packs) appropriately, all the way up to 120 hours. We can customize the same box with different refrigerant sizes to avoid the use of large, heavy containers, resulting in an efficient pack-out. Further, we work with integrator carriers, using tracking systems to ensure boxes return to our service center where they can be refurbished.

With the expected 2022 launch of Peli BioThermal's newest temperature-controlled shipping solution, pharmaceutical companies no longer will have to use different shippers to accommodate situations like those described above, which is inefficient in terms

of both logistics and packaging. Additionally, always providing 96 to 120 hours of performance when only 24 to 48 hours is necessary can be costly overkill.

Related, pharmaceutical companies — especially those operating commercially, place increasing importance[1] on environmental sustainability. Most organizations now have environmental, social, and governance (ESG) initiatives aimed at achieving carbon neutrality, complete with environmental sustainability landing pages on their websites discussing conservation of water, as well as waste and carbon footprint reduction. This mindset is a driving force behind industry initiatives seeking to transition from single-use disposable packaging to reusable packaging — a significant logistical challenge when shipping and recovering packaging from more than one million shipments per year.

Finally, pharmaceutical companies must consider growing customer expectations relevant to technology integration into the commercial supply chain (e.g., real-time data for product location and package temperature). A person can get in-transit information and a picture of the package on their doorstep when ordering socks, so why is that tracking visibility not standard in commercial pharma shipping?

The economics of that tracking generally dictate which technology is integrated, when, and to what extent: what is the cost of adding that capability to the supply chain? While some early adopters have been able to cost-effectively implement such tracking technology, some years likely remain before its use is ubiquitous. In addition to more attractive implementation/operation cost, key drivers for this shift will include greater confidence in the security of data being shared and more widespread customer insistence on detailed tracking.

Final Thoughts

Vaccines developed in response to the COVID-19 pandemic (and the mRNA technology utilized) created never-before-seen demand across the industry for cold chain packaging. Additionally, investor interest in pharmaceuticals skyrocketed, with investors pulling money out of other sectors and placing it in pharma due to the immense upside potential. That interest and investment has led directly to more research, more development, and greater need for cold chain packaging and shipping.

To thrive moving forward, pharma companies want a cold chain partner that understands the scale of commercial distribution, a partner actively investing in infrastructure and manufacturing capability that supports high-scale growth. To learn more, visit us at https://pelibiothermal.com.

1 *"Environmental Sustainability in Pharma." Clinical Trials Arena, 10 Jan. 2022, https://www.clinicaltrialsarena.com/environment-sustainability-in-pharma/.*

About Peli Biothermal

Peli BioThermal — headquartered in Maple Grove, Minnesota — offers the widest range of temperature-controlled packaging and service solutions to the global life sciences industry, including a complete portfolio of services and software to support end-to-end temperature-controlled packaging asset management. Our products ensure that delicate life science materials arrive intact and effective, from discovery to distribution. Customers trust us with their most valuable health-giving and life-saving products because of our expertise in ensuring temperature stability is maintained throughout the distribution chain and for our ability to meet them wherever they operate globally. The economic value we bring our customers is total cost of ownership for all our packaging, services and technology offerings, whether owned or rented.

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