PELI BIOTHERMAL™

# Options for Real-Time Transparency
## In Commercial Pharma Distribution

By: Adam Tetz, Director of Worldwide Marketing, Peli BioThermal

**For most cold chain operations, some form of real-time or just-in-time monitoring is essential in order to protect the costly, high-value payloads that require low-temperature or frozen storage. Employing track-and-trace technology for these payloads during shipping is crucial for companies looking to meet regulatory expectations, safeguard product, and understand the variables that may impact payload temperatures during transport.**

**While real-time tracking, which allows for instant or near-instant access to information regarding a package in transit, can be valuable for specific applications, its cost, coupled with the logistical challenges involved in responding to real-time data with real-time action, can limit its utility, particularly for large-scale commercial applications. Just-in-time monitoring can offer companies a reliable, cost-effective means of tracking a shipment's temperature fluctuations in transit, allowing for usable regulatory data that can inform subsequent shipping strategy.**

**The commercial shipping landscape is rife with complexity – the explosion of temperature-sensitive biologics and the emergent need for COVID-19 vaccines globally have made bulk shipments, intercontinental distribution, and near-continuous shipping the core of cold chain transport. Many new track-and-trace technologies have been introduced to the market in the last few years in direct response to the proliferation of biologics and biotherapeutics that require cold chain storage. Finding the right track-and-trace solution is critical to safeguarding these products, identifying risks, and developing strategies to improve the payload handling that is core to successful global commercial shipping operations.**

## Real-Time vs. Just-in-Time: Practical Considerations

There are many potential just-in-time monitoring solutions companies can employ to protect their cold chain drug shipments. Determining the optimal solution for a given payload hinges on several factors, including:

- payload temperature profile and value,
- compliance and regulatory requirements associated with the payload and its country of destination,
- budget, and
- organizational infrastructure and support throughout the shipment's journey.

A payload's value is not merely a monetary calculation – the complexity of the treatment's manufacture, as well as its importance in a patient's treatment plan, also determine how stringently it should be monitored. Payloads that are less expensive to produce and less critical to patient health may be better served by less cost-prohibitive just-in-time monitoring approaches. In contrast, many personalized medicine treatments, such as CAR-T therapies, which frequently require dry ice or cryopreservation techniques to maintain extremely low shipping temperatures, may necessitate real-time tracking in order to protect them.

Commensurately, track-and-trace technologies have different enabling hardware and software requirements that can impact their suitability for varying applications. Some track-and-trace solutions require digital scanning, either using a bar code reader or a mobile application, while other solutions require the data logger to be uploaded via a USB port. If these options are not practical or feasible by the shipment recipient, then an alternative solution should be considered (for example, a solution based on QR code technology).

A few commercial drug manufacturers are now employing just-in-time track-and-trace technologies and that number expands every year. Though this is chiefly to safeguard patients, it can also make it easier for companies to comply with rules from the FDA and other major drug regulators, which require processes backed by data that prove that no prolonged temperature excursions occurred during transit for drugs kept at specific temperatures. With just-in-time tracking, recipients of a package are able to access this information at the end of a shipment's journey, typically with commercial software that packages this data in a format compliant with regulations. Just-in-time technologies are evolving, particularly with regard to the software that supports them – many suppliers are working toward alerts and predictive analytics that represent a more comprehensive track-and-trace paradigm that maintains the affordability of current just-in-time platforms.

The required temperature of the shipment is another key consideration when deciding what level of track-and-trace to employ. Just-in-time solutions are typically employed for payloads kept at room, refrigerator, or freezer temperatures; this is because most deep-freeze payloads are those personalized medicine treatments that require dry ice or liquid nitrogen to maintain and can tolerate temperature excursions of very limited duration – often less than 10 minutes.

The aggregate temperature data collected over hundreds or thousands of shipments can help inform a broader strategy, but that data is frequently amassed and analyzed using antiquated "brute force" methods like manually tallied Excel spreadsheets. As with many other aspects of pharmaceutical development and distribution, the push toward more sophisticated, accessible data streams has already begun, with software platforms that help to aggregate and visualize that data faster and more accurately. Ideally, these data platforms will be largely smartphone accessible; that accessibility will, in turn, help support chain-of-custody data and improve tracing, a critical evolution for a space that is only predicted to grow as more temperature-sensitive therapeutics gain market acceptance.

## Just-in-Time Solutions, Fit-for-Purpose

The length of a shipment's journey, as well as its ultimate destination, greatly impact the decisions surrounding both the optimal shipper and tracking solution. Shipments to countries like China or Saudi Arabia, for example, must be able to be temperature tested without opening the shipper. The technological capabilities of the recipient also factor into the equation. Bluetooth track-and-trace solutions represent a relatively simple technological approach to monitoring; however, it still requires access to a mobile application to extract the necessary information, which may be infeasible for some recipients.

Dynamic QR codes can help improve this accessibility somewhat – by embedding temperature readings (taken at frequent, regular intervals) in the QR code, the recipient can verify the temperature of the shipment at its destination without the need for a specialized application. Monitoring tags that utilize RFID technology, which also records temperature at set intervals, collect this information in a credible and traceable data point – the resulting readout visualizes temperature excursions on the tag, along with the date, time, and temperature. These technologies require a specialized reader, however, which can limit their utility for recipients without access to one. Despite this, the more granular data that is often attainable with RFID tracking technology makes it an attractive solution for many companies shipping to locations with commensurate access to the required reader technology.

The ultimate goal of this monitoring is to ensure that enough temperature budget – its stability at ambient temperatures prior to the onset of degradation – remains for the patient. That temperature budget can be jeopardized by any number of factors, including mishandling during customs inspection, extreme weather conditions, transport delays, and other scenarios. With optimized just-in-time tracking, companies can investigate the root causes of a compromised shipment in order to prevent future mishaps from occurring, informing a holistic shipping strategy that can adapt to a range of challenges and shifts in market demand.

## Practical Solutions, Positive Results

Companies should look to partner with suppliers whose technologies, support, and expertise can help meet their track-and-trace needs while minimizing the amount of time, effort, and resources required to utilize these technologies effectively. Tracking solutions that are technology agnostic, easy to use, and fit-for-purpose are critical for the space; having a range of solutions that allow companies to mix and match and arrive at the level of support that is right for their shipping paradigm necessitates technologies that are as accessible as possible. For companies seeking more comprehensive support solutions, software like Peli BioThermal's Crēdo ProEnvision™ software can offer critical insights that save time, money, and resources.

In a recent case study, one of the world's largest pharmaceutical manufacturers had been shipping bulk, reusable Crēdo™ shippers to places like Australia and southeast Asia without recovering them, rationalizing that the reliability of the shippers outweighed the added cost of their irretrievability. One of the pharmaceutical company's vendors in the region, familiar with the reusable nature of Crēdo, saved the systems, storing them in their premium warehouse in Singapore. This vendor eventually contacted the local headquarters for the pharmaceutical company involved to determine how best to return them. The company's logistics manager then contacted Peli BioThermal, citing untraceable shippers, and was surprised to learn about the pallets of reusable Crēdo shippers waiting to be reclaimed but found himself unsure how to track them for reuse. At this point, the logistics manager turned to Pelican BioThermal for advice and assistance.

Pelican BioThermal elected to utilize its asset management software, Crēdo ProEnvision. With this software implemented, the company was able to access a complete picture of their inventory in this region. The company then established a consolidation facility for these shippers with their local vendor for all countries in the region. They used scans from the shippers in each country, in conjunction with Crēdo ProEnvision, to track where each shipper landed in Asia, then determined where each had been shipped from originally. Once the company established a means of tracking these adrift Crēdo shippers, their vendor sent them from each Asian country and Australia to the consolidation facility in Singapore.

Through Crēdo ProEnvision, the pharmaceutical company and their vendor monitored the returns coming to the consolidation facility and the rate at which the containers were returning to them. As a result, the collected pallets of Crēdo™ shippers were scanned upon arrival and tracked in Crēdo ProEnvision™ software. From there, Crēdo shippers sent to Asia were monitored, reclaimed at the consolidation facility, and returned to service, optimizing their utilization potential. To date, more than 1,200 Crēdo shippers have been returned to the client, saving over $120,000 in the first year of problem discovery thanks to Crēdo ProEnvision. The company estimates their savings to total $200,000 annually following the implementation of this software.

Ultimately, the utility of just-in-time tracking hinges on the software supporting it. Beyond its regulatory uses, the data collected by dynamic QR codes, RFID tags, USB technology, or Bluetooth can serve to optimize the transport paradigm for a company. The latitude to perform root cause analyses in a timely manner and with a high degree of specificity can help companies not only avoid the costs incurred from product losses and delays, but those associated with lengthy investigations that may flounder without the depth and breadth of data needed to pinpoint the problem.

## About Peli Biothermal

**Peli BioThermal – headquartered in Torrance, Calif. – is a division of Pelican Products, the global leader in design and manufacture of both high-performance case solutions and advanced portable lighting systems. Peli BioThermal is the first cold chain packaging solutions provider to offer a comprehensive portfolio of patented, award-winning single-use and reusable thermal protection packaging solutions for the safe transport of pharmaceuticals, clinical trial and diagnostic materials, tissue, vaccines, and blood supplies for the life sciences industry.**

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