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Importance of Chain of Custody
For Commercial Pharma Distribution

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As more new biologics and cell and gene therapies enter the market, the need for reliable, demonstrable temperature control during shipping has become paramount to pharmaceutical companies' overarching strategy. Employing tracking technologies capable of monitoring a packaging solution's internal temperatures is just one facet of this strategy – equally as important is validating a shipment's integrity along every phase of its journey.

Establishing a chain of custody for temperature-controlled pharmaceutical shipments is critical to determining the root cause of a problem, which can otherwise be difficult to achieve without insight into the environmental and handling variables in play at a specific location. Track-and-trace technologies let recipients know that a temperature excursion has happened; a well-delineated chain of custody lets customers know where the problem arose, the first step to understanding how problems occur and how to fix them.

A lack of reliable data, verified along each step of the journey, is the largest challenge to achieving this understanding. Many pharmaceutical companies lack the necessary experience or expertise to consistently secure evidence for each handoff along a shipment's journey, or to implement a process that maintains chain of custody data and makes it readily available for analysis. Additionally, this lack of expertise or understanding can impact a company's perception of the true scope of a chain of custody paradigm, resulting in limited data and unnecessary risk.

In order to establish a robust, reliable chain of custody, companies must understand how a combination of macro, meso, and micro data helps contextualize the physical and procedural movements required in a shipment. Doing so often requires the support of a packaging supplier with the experience and capacity to manage complex shipping strategies, particularly in the commercial space.

The Factors That Impact Cold Chain Shipping

In an ideal world, every person who comes in contact with a temperature-controlled drug shipment understands the procedures, equipment, and qualification processes necessary to safeguard that package. The reality is often murkier: from customs to consolidation centers to airplanes, trains, and trucks, the variables that can impact a shipment's integrity are as diverse as they are damaging.

In order to fill in the blanks of where a shipper has been from the start of its journey to its conclusion, packaging supplier and pharmaceutical companies alike must develop strategies around how temperature excursions are investigated. Typically, the cause of a temperature excursion falls into one of three categories. The first is in the preparation, or the conditioning process utilized to prepare a shipper to maintain the necessary temperatures throughout transportation. Occasionally, companies will fail to recognize the limitations of a shipper, and mishandle it as a result, leading to losses in performance. Any storage outside of conditioning temperatures can begin to impair the qualified duration of a shipper. Additionally, failure to condition a shipper after the phase-change point of the phase-change material will also lead to a failed shipment. The next big pitfall that companies can run into is related to handling: damage sustained to the shipper, shippers left opened for extended periods, improperly resealed shippers, and other failures related to knowledge gaps surrounding appropriate handling procedures for refrigerated and frozen shipments can all serve to compromise a drug product.

Finally, equipment failures represent a small but significant portion of temperature excursions for these shipments. Whether it is an issue with the monitoring equipment being used to track the package, or more rarely, with the shipper itself, understanding both the root cause of equipment failures and the interactions that enable failures is key to preventing them. Facilitating an understanding around the kind of calibrations and operational ranges of the equipment, as well as the variances that can occur for equipment, depending on the temperature and external conditions involved, must occur across each interaction along a journey. Achieving a holistic view of a shipment's journey, one that incorporates human error, technological malfunction, and emergent events, can help companies optimize their shipping strategy and reap compounding benefits well into the future.

Avoiding Pitfalls Through Chain Of Custody

Having the controls and monitoring systems in place to confirm a shipper has been conditioned appropriately and maintains its temperature in transit requires a comprehensive approach. Being able to narrow down the time during which a temperature excursion occurred is the best way to gain a clearer picture of the contributing factors. This is often accomplished with a data logger or other track-and-trace technology that registers readings at regular intervals; knowing when an excursion has happened allows companies to know where it happened, and ultimately, how. Armed with information, companies and suppliers can evaluate the process to determine if new conditioning processes, payload handling guidance, or revised service-level agreements are needed to ensure a shipment's integrity.

Even the most airtight chain of custody can falter in the face of unexpected events. Customs checks can represent one of the biggest unknowns when it comes to handling – depending on the country in question and the familiarity of customs officials inspecting the package, a shipper may be open for several minutes during a customs process. Even 10 minutes in a scenario like this can compromise the payload, and increasingly stringent checks, conducted in response to the pandemic, can create the potential for more invasive customs handling. Another difficult variable to pin down is weather. Companies invariably check for the weather conditions along a given shipping route, but even knowing what to expect from the external environment can be insufficient in preventing issues. That's because it can be harder to predict how weather and inappropriate handling practices may interact: in one example, a company experiencing issues with condensation inside their shippers discovered that they were left open while being transferred to a forklift, likely compromising those loaded near the end of the process.

These types of unique scenarios represent both challenges and opportunities for companies looking to better understand the variables that impact

commercial global shipping paradigms. Companies and suppliers able to employ "lessons learned" as a result of these scenarios are well-positioned to adapt a comprehensive shipping strategy that minimizes the potential for error. Taking a risk-based approach that considers the "minutiae" present along a planned route allows for both the up-front planning and retroactive analysis needed to optimize transport.

Leveraging Data And Expertise For Commercial Success

Typically, a company has mapped its shipping paths prior to selecting a shipper for a given application, and a supplier versed in both the needs of the specific payload and the potential risks inherent to that map will then work to replicate those conditions through testing. In doing so, a supplier can establish an idea of possible "worst-case scenarios," feed those into subsequent predictive analysis, and arrive at a plan that has been vetted for as many known variables as possible.

The three key types of data central to cementing this understanding are macro, meso, and micro data. Macro data refers to the "big picture" data that defines most shipments, including pickup times and arrivals, delays, and other high-level information that forms the basis of an approach. The next level of data, meso data, refers more to the data related directly to the shipper and payload, including temperature ranges and recordings, product specifications, and conditioning data. Finally, micro data is tied to the precision and accuracy of the processes at play – this data is what ultimately indicates whether a shipping strategy is working as intended. All three are needed for a complete picture of the factors impacting a shipment, and each can be mined to various degrees to create a richer understanding.

Partnering with a supplier that can help companies identify the most valuable data points for understanding a shipment's chain of custody, as well as how to interpret them, is critical. Open communication between a company and packaging supplier is the key to achieving this – establishing the data points, necessary documentation, and training needs inherent to a shipping strategy requires an ongoing dialogue and comprehensive support. In scenarios where the cause of an issue is unclear, having that continued support from a supplier can make a big difference. A supplier may retroactively install shock loggers, for example, to determine the likeliest source of damage to a shipper when the root cause is unclear. Subsequently, once the source has been identified, that support should extend to solving the issue, likely through retraining or through revising processes.

Achieving precise, accurate monitoring for temperature-controlled pharmaceutical shipments hinges on a verifiable chain of custody. Knowing where a shipment is, who is handling it, and what factors impact its integrity along the way all comes down to this chain of custody – verifying custody at every step along a journey, collecting the right amounts of the right kind of data, and evaluating that data to solve problems are a complex but crucial need for the industry. By broadening their understanding of the chain of custody paradigm and partnering with a packaging supplier with the expertise needed to address complex chain-of-custody challenges, companies can reap compounding rewards in the commercial shipping space.

About The Author

Louis Henry is the Quality Manager for Global Services at Peli BioThermal and has over 15 years of Quality experience.

Based in the UK, he is responsible for the Quality Management System across the 19 Service Centers in the Global Services Network. Henry takes a key role in new service center development and certification, new product/service development and deployment, and works closely with clients to ensure that their requirements are met within the global services network. Prior to his current role Henry was the Quality Engineer at Peli BioThermal, arriving at the company from the food science field where he worked as a microbiologist specializing in pathogenic bacteria.

He holds an MSc Strategic Quality Management from the University of Portsmouth, in receiving distinction for his thesis on management commitment to Total Quality Management, a BA (hons) in Business and Marketing from DeMontfort University in Leicester and is a certified CQI & IRCA Lead Auditor.

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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