

Pharmaceutical Cold Chain Risks and How to Mitigate Them

Shipping temperature sensitive pharmaceuticals involves a range of risks that can impact the quality, safety, and availability of life saving treatments for patients. Nick Gilmore, Global Head of Sales and Marketing of Tower Cold Chain, explores how risk can be mitigated through strategic partnerships with specialist temperature-controlled packaging suppliers.

The pharmaceutical industry is growing at a rapid rate, and as the most current data from Statista has demonstrated, it has now surpassed the \$1.48 trillion mark in revenue. With such growth comes an increased level of complexity in the pharmaceutical supply chain, and thus, the reason why implementing best practices for managing risk is crucial.

Securing the integrity and quality of medical and biological products during transportation stands as a pivotal challenge for both pharmaceutical manufacturers and logistics providers. With many biopharmaceuticals requiring strict temperature control from manufacturer to patient, precise handling and storage is essential. The potential loss of cargo poses a significant risk to patient health and wellness. Coupled with increasing regulatory requirements whilst serving an international market, players need to implement robust quality assurance practices to mitigate these risks and ensure products are transported reliably across the supply chain.

Reliable Shipping

Timely delivery, intact condition, security and a stable temperature – these are the fundamentals required for successful pharmaceutical shipping, and it's here that the choice of temperature-controlled solution and supplier makes all the difference.

Manufacturers require a container robust enough to safeguard its contents, and eliminate breakage, throughout the various pressures faced during international freight. Such container needs to effectively regulate temperature, remove manual intervention, and prevent excursions that



might compromise the efficacy of the cargo. And finally, an optimal packaging-to-payload ratio is required, adhering to transport safety regulations.

Yet fundamentally, every solution available on the market does the same thing. The use of temperature-controlled containers ensures palletised delivery of pharmaceutical shipments, in a way that keeps the product safe from physical damage and temperature excursions. Yet the distinction lies between the suppliers, in terms of how well-equipped they are to mitigating risk.

Increasingly, pharmaceutical manufacturers are partnering with cold chain shipping providers with risk-first mindsets. Knowledge of the nature of the supply chain's risks is the first step in establishing supply-chain resilience.

Cold Chain Weak Spots

Transfer points where multiple stakeholders are involved in the handover and stopover elevates the chance of damage and/or temperature excursion. This often occurs during the unloading and loading process, through either improper handling or through delayed shipments sitting on tarmac or storage depots.

Further to this, the distribution of vaccines during the COVID-19 pandemic

brought forth a number of issues with the global cold chain, not least the fact that many developing nations are not as prepared to receive and transport temperature-sensitive products. Airports often have less capacity or lack of on-site temperature-controlled facilities. There is also often limited knowledge on the ground, which can lead to serious errors leading to spoiled shipments, pilferage, or mishandled packaging.

Beyond major transport hubs, the issue of delivering vaccines, medicines and other temperature-sensitive payloads to rural areas in developing nations is a challenge. Road infrastructure is often poorly maintained, and in many places not passable for many delivery vehicles.

And, as we see more extreme weather conditions due to climate change, with natural disasters and power cuts becoming more prominent, the focus on how packaging performs will intensify.

Delays in customs clearance can be another reason for deviations and the damage caused to temperature sensitive goods. The import of pharmaceutical products often requires various permits and extensive documentation, the incompleteness of which can quickly lead to queries and delays, which in turn pose a risk to the goods.



However, the right combination of suitable packaging and a specialist cold chain shipping partner can significantly reduce the risk of weak points in the cold chain. Passive containers offering both internal temperature control and robust external protection can provide up to 5 days' worth of contingency and are built to be fully reusable, withstanding 10+ years of freighting. Providing peace of mind in cases of disruption, whether this be diversions, breakdown or even labour strikes, passive containers consist of materials intended to keep the internal contents of the package within a specific temperature range for a defined period of transport without any means of manual intervention or power source.

In comparison, active containers use mechanical and electric systems powered by an energy source, combined with thermostatic control in order to maintain proper product temperatures.

From the pharmaceutical brand's viewpoint, the critical issue is reliability, and some understandably take comfort in having a powered solution. Yet, as advances in passive technology have progressed, and we continue to face supply chain challenges, passive containers are quickly becoming a sensible choice to mitigate risk in the industry.

Regulatory Compliance

Pharmaceuticals are a highly regulated

industry for a good reason: safety, effectiveness, and the wider impact medicines can have on patient's lives. The ramifications of not complying with regulatory affairs can profoundly impact a company's reputation, finances, and customers, and can cause significant legal implications and criminal consequences. Thus, compliance is a top priority for manufacturers.

Due to the risk of non-compliance, players in the pharmaceutical cold chain should have a sound understanding of the varying regulatory bodies that govern them and be aware of new guidance and how it applies to them.

To build up a successful and sustainable pharma-distribution operation, the nuances and key characteristics per country and region need to be handled bi-laterally. Logistic providers must provide the agility and flexibility demanded of them, offering a global network for localised deliveries – all whilst complying with each country's regulations. Investment in Good Distribution Practice (GDP) training for local teams, enables organisations to tailor to the needs of specific regional markets guaranteeing compliance with all pharmaceutical regulations within all market geographies.

And, as sustainable supply chain management comes to the fore, the pharmaceutical industry is under pressure to

optimise environmental performance, whilst still meeting stringent safety standards. The implementation of environmental, social and corporate governance (ESG), combined with increasing consumer struggles with single-use plastics, has led pharmaceutical companies to favour sustainability focused packaging and transport partners, which can not only provide robust and reliable solutions, but ones that are fully reusable too.

Quality Control

As more and more pressure is put on global cold chains, the higher the stakes become for those responsible for delivering safe and secure logistics networks and cold chain processes.

The risks of cross contamination and mishandling can lead to physical damage, contamination, or tampering of pharmaceutical products which ultimately compromises product quality and safety. Cold chain container providers safeguard against temperature fluctuations, assuring the stability of temperature-sensitive drug, with tracking and tamper-evident features to deter any form of unauthorised access or damage.

And whilst training and investment in infrastructure are key, a move to more automated processes and the deployment of technology will ultimately reduce risk from human error in cold chain logistics. Implementation of tracking tools such as internal data loggers provide peace of mind



by monitoring the internal temperature of the shipment and can notify users in the rare case of a temperature excursion, as well as providing automatic data downloads throughout the transit. By using Bluetooth Low Energy Technology, each logger communicates wirelessly, sending accurate data to the cloud. This digital innovation allows for accurate compliance checks and on-delivery sign-off, empowering operations with clear, transparent information no matter the mode of transport used.

Companies who invest in digitalisation are likely to see the clear benefits of time, cost and resource savings in addition to customer satisfaction and most importantly, patient safety.

Experts in Risk Mitigation

Evidentially, the potential pitfalls in the pharmaceutical cold chain are multifarious. Containers and their contents can suffer damage during cargo handling. Pharmaceuticals may endure temperature excursions due to extreme weather, improper storage or training, that undermine their efficacy. The involvement of numerous stakeholders further complicates the management of these factors, intensifying the associated risks. For instance, research by the Institute for Human Data Science found that approximately \$35 billion is lost annually to failures in temperature-controlled logistics.

Certainly, this is a scenario nobody desires and so it is vital pharmaceutical companies

implement robust quality assurance practices. Partnering with experts in cold chain shipping is a sure way to mitigate risk, helping businesses adhere to regulatory guidelines, use validated packaging and shipping methods and ultimately, ensure that pharmaceutical products are delivered to patients, safely and securely.

In short, by looking carefully at the options available on the market, you can find the container and dedicated supplier that meets all of your needs and simultaneously helps mitigate risk in the pharmaceutical cold chain.



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Nick Gilmore has 24 years sales and marketing experience in international public and private equity owned companies. He is an energetic business leader working cross-functionally and with boards to deliver winning commercial strategies delivering long term, sustainable growth for multi-site manufacturing facilities supplying global customers.