

Rising Sea Levels: The Transportation of Pharmaceuticals by Sea Continues to Gain Momentum in the Quest for Greater Supply Chain Resilience



Allan Klinge
CEO
Klinge Corporation



Alan Kennedy
Director
GDP Universal
Compliance Initiative

Sponsored by

KLINGE



Understanding the Most Well-Rounded Transport Method for Pharmaceutical Shipments

When shipping pharmaceuticals internationally, the decision of ocean shipping versus air shipping might seem obvious if speed is the only factor at play when sending sensitive medical supplies and drugs. For the last several years, however, more companies have decided to embrace ocean shipping for the delivery of their medicines. Industry experts Alan Kennedy and Allan Klinge discuss how—with more cold chain control, a lower carbon footprint, and lower costs—ocean-going vessels often have clear advantages over air freight.

PHARMACEUTICAL COMMERCE: What does a typical pharma cold chain look like and how much is moving by road, air, rail, and ocean?

ALAN KENNEDY: Firstly, there may not be such a thing as a typical pharma cold chain but if there is, it is characterized by its high degree of regulatory oversight, generally high value of the shipments, and its fragmented nature. This fragmentation makes for a high number of consignment touch points by different people during the transportation process. This brings me to the most important feature of the pharma cold chain—the extreme environmental sensitivity of many pharma products to heat or cold. Pharmaceuticals that are temperature compromised during transportation not only wastes a huge amount of money but can also lead to serious health implications if patients receive potentially dangerous medicines or are denied access to necessary treatments.

However, slightly less than half of all pharma products are currently transported in a temperature-managed environment. The proportion of cold chain amongst it is growing rapidly on account of the emergence of highly temperature-sensitive biologic drugs which are generally made, as the name suggests, from living organisms. The classic case of a biologic drug would be a vaccine, but you also have products such as gene-based therapies, recombinant proteins, stem-cell treatments and the like.

In terms of how much is currently moving by the different modes of transport, a recent research report indicates that although air freight remains the principal transportation mode for the long-distance movement of pharmaceuticals with 48% of the total involving at least an air freight leg, sea freight is now being used in 41% of pharma shipments and 17% by rail¹. Road transport on its own accounts for about 20% of all long-haul pharma freight so if a product is going from A to B across the United States for example, it might only use road. However, I want to make clear the fact that road is used in almost 100% of pharma shipments because it is used for feeder services. The

product is picked up from the factory gate and is taken to the rail head or the shipping port, or to the airport. Lastly, the proportion of pharma consignments that are now being sent by a combination of two or more freight modes is rapidly growing and that is because pharma companies are looking for additional resilience and flexibility in their transportation, as well as cost savings.

PC: What are the main benefits of air freight over ocean freight and vice versa?

ALLAN KLINGE: The main benefit of air transport most companies are considering is speed and speed means there are certain tracking items which come in to play, but also it is thought of as a risk mitigation strategy by getting a product somewhere faster. As Alan mentioned, a lot of these products are environmentally sensitive to high heat and low heat and that means companies are looking for more stable methods of transport. Speed tends to be subordinate to safety, and risk is increased during these temperature excursions that can occur during air freight. Typically, air freight is costly with a low sustainability when we talk about environmental impact. It is important to note that air freight is responsible for less than 1%, even close to 1/4 of 1% of all global freight, while ocean freight is moving 75% plus of all global freight. This is an important distinction, especially when we look at the sustainability side of things. Air freight emits approximately 50 times more CO₂ emissions than ocean freight when you look at the total footprint. It is an important task for companies to reduce their global carbon footprint and modal shifts from air to ocean can help them achieve that.

The stable temperature of ocean where the container is typically packed and not open until its final destination, offers a much better temperature profile overall for the products. While we have seen many pharma companies take advantage of this modality, there are a few challenges in the ocean freight industry. One is the shipment takes longer. Recently, there was a lot of schedule volatility in the shipping market which is slowly beginning to normalize. There is a need for increased planning and having floating inventory on these vessels for some time. There also needs to be a better and more universal Good Distribution Practice (GDP) strategy that can be applied in multiple countries and multiple jurisdictions. Most applications of ocean or air also have multi-modal aspects to them, whether that be rail or in every case, road, and these combinations can help bring a better solution than just one single mode. Companies are looking at both air and ocean and making evaluations based on product value and product sensitivity so, it is not to say one is always the right answer, but there may be different applications for both. For higher value or more sensitive cargo, Klinge Corp has been assisting a number of companies by providing refrigerated ocean transport and storage containers with automatic back-up systems and power generation in temperature ranges all the way down to -70°C

PC: How have global pharma freight operations been affected by the COVID-19 pandemic?

ALLAN KLINGE: The pandemic made everyone aware of the supply chain, whether an Amazon package didn't arrive on time, or businesses waited for containers to be cleared from the ports. Numerous challenges have driven up prices and brought logistics to the forefront in a way that it had never been before.

From a broader perspective, there have been both positive and negative effects from the pandemic. On the positive side, there is a realization of just how fragile this logistics ecosystem is, allowing for more investment. Awareness has led to cross-industry collaboration for governments and companies across the world, promoting change. There are now initiatives in place to help streamline the logistics process and avoid and mitigate risk. Consignment monitoring and traceability has grown, where new applications, new equipment, and new methods of visibility to product supply have been implemented. People have come up with creative ways to achieve the same cold chain they had before by utilizing different multi-modal and inter-modal transportation options.

In terms of negatives, there certainly has been an impact on cost. We are beginning to see normalization on the ocean side at least, but there is still cost impact for some of these newer methods of transport, and inter-modal transport. Hopefully, as they become more prevalent, those costs will reduce. Capacity constraints for companies offering these services are in effect, but we have started to see that normalize a little bit in late 2022 and 2023. The same goes for temporary relaxation of some regulations that needed to be implemented—emergency measures—which is beginning to occur. In the end, we hope to come out stronger and that is where we think we will end up.

PC: What are the main obstacles from a quality assurance perspective of moving freight by sea and how can these be overcome?

ALLAN KENNEDY: The legislation governing the safe and secure shipment of pharmaceuticals, in other words the quality of distribution, is generally enshrined in GDP. This is generic and non-prescriptive in nature, so the law is essentially telling you what you must achieve but not how you can achieve it. Furthermore, the same GDP rules apply to all modes of transport. However, these are all very different transport systems, meaning the regulations have to be interpreted and adapted to suit the mode concerned.

This creates huge problems, because different parties in different places—both companies and countries—interpret, enact, execute, and enforce the regulations in different ways and to different standards. This makes for a complex and inefficient quality process, especially as products become more sensitive and supply chains become more global and multi-modal. It is abundantly clear from research and feedback, that supply chain confusion and impediments concerning GDP remain. There is a pressing need for a completely autonomous yet industry-driven GDP support framework that covers all freight modes, is global in scope, is supported by the regulatory bodies, and is adaptable to the changing industry and regulatory needs. Such a framework is particularly needed for pharma ocean freight, where more clear-cut GDP guidelines for marine applications would undoubtedly drive more business into its hands.

A new universal GDP compliance initiative is currently taking shape, where a large number of pharmaceutical supply chain players have come together with the objective of designing and executing a global GDP compliance program that covers all freight modes. GDP Universal Compliance Initiative (GDP-UCI) will be an independent non-profit that works in collaboration with the industry to introduce GDP compliant processes and solutions, and to synchronize and standardize wherever possible—GDP training, GDP auditing, and GDP certification as examples. The launch date for this new program will be March 1st, 2023, so not very far away.

PC: Over the past few years, there have been significant developments in the industry regarding real-time shipment visibility. Can you elaborate?

ALLAN KLINGE: In response to the move—especially to ocean freight and multi-modal transport—is an increase in need for product visibility, in terms of location, but also for temperature data along the transport in the cold chain. The pharmaceutical market has responded robustly to this, where in cases there are on-board data loggers such as a Temptales that can show you the temperature at the end of the transport. Being able to see temperature data as well as make sure products were safe and ready to be distributed to the customer at the time of arrival, involve SMART Reefers and independent cellular or GSM devices and satellite devices. Reefers can monitor this data and transmit it.

The real challenge is to interpret the data and act on it. There are many ways to capture it, but what do we do with the data once we have it? Some of these newer solutions are looking to build predictive analytics where if we see a problem, based on previous shipments, it can tell us where we will see a problem based on current conditions and how we can intercede to make sure that problem is neutralized or mitigated. The main issue is coming up with a universal approach, and dealing with technical issues, such as battery life. Most problems are being tackled by individual companies and if we can achieve a universal application for how the data is reported and acted on, we will be in a very good space. Pharma companies are already working to ensure good oversight and product safety during transportation so that it gets to the patients in a way they can take it and that the temperature profile is maintained.

PC: Where do you see the pharma cold chain in five years?

ALLAN KENNEDY: There is no doubt the global consumption of drugs will expand significantly over the next five years at a general rate of about 5% annually. This growth rate is going to be dominated by the cold chain segment and this in itself is expected to expand at well over 8% per annum and represent more than 70% of total redux spend. Secondly, in terms of transport modes, the disruptions of recent years mean that going forward, pharma companies are going to remain cautious about putting all their eggs in one modal basket, and shippers will be switching freight modes much more readily.

Thirdly, pharma logistics will continue with new agile manufacturing and stock holding policies that have emerged in a world of greater uncertainty. The post pandemic logistics strategies of pharma companies will more vigorously embrace the need for resilience and agility. Fourthly, and very importantly, the environmental imperative will be an even bigger concern than it is now and will shape many technical, operational, and commercial decisions over the next five years.

Fifthly, pharma logistics will also benefit from better freight and what-if scenario planning with modeling, forecasting and early warning systems having big roles to play. As Allan explained, real-time consignment monitoring, with predictive, pre-emptive, and reactive capabilities will become the norm as communication systems improve and prices drop. Novel and innovative inventory solutions, such as a floating warehouse concept, will gain momentum too.

Finally, a new global GDP compliance program is coming into existence, which promises to ease the ability of companies to meet increasingly stringent regulatory requirements for pharma distribution. The future of the pharma cold chain over the next half-decade, is one of solid growth, increasing modal flexibility, improved regulatory conformance, and exciting technical innovation.

References

1. GDP Consultation Cluster Survey Report 2021/2022; Team Poseidon Ltd