

SAFELY TRANSPORTING MEDICINES TO PATIENTS

DE-RISKING THE SUPPLY CHAIN

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MOVING IN THE RIGHT DIRECTION

How can we improve supply chains and shipping practices to ensure that our precious medicines reach patients safely?

By Stephanie Sutton, Editor, The Medicine Maker

The cost of developing a new medicine is typically estimated to be anywhere between \$1.5 billion and over \$2.5 billion, depending on who you ask. And after all of the money (and time and effort) that goes into R&D, manufacturing, and marketing, we must not neglect the all-important and literal final leg of the drug's journey: shipping the finished product to the clinic, a patient or other destination.

When it comes to transport, some medicines are relatively straightforward, while others have strict temperature and environmental tolerances – but all must follow strict regulatory requirements. You need to ensure that your shipper understands the product and its sensitivities, so it can ensure it has the right packaging and controls in place. In short, shipping matters.

Shipping considerations must be taken into account long before commercialization takes place; for example, material for clinical trials could be traveling through supply chains years before approval. But once you reach the commercialization stage, the volumes vastly increase, significantly adding to the complexity – particularly, if the product is highly sensitive with no margin for error on storage conditions.

With the industry's increasing interest in cell and gene therapies – which have to be transported very quickly in carefully controlled conditions – there has been a corresponding growth in supply chain innovation, with companies developing better packaging solutions to protect goods during shipment, and shippers looking to offer a service better matched to high value, highly sensitive drug products.

The Medicine Maker recently partnered with Thermo Fisher Scientific to explore the industry's thoughts on pharmaceutical logistics through a survey, including what companies look for in shipping partners, and the common pain points. Within these pages, Lee Sutton, Senior Manager, Commercial Operations, at Thermo Fisher Scientific, discusses the survey and the main results, while Scott Emery, Director of Global Transportation gives his advice on what makes a good shipping partner.

SURVEYING THE LOGISTICS LANDSCAPE

Why conduct a survey into the challenges of logistics and shipping in life sciences? It's simple – we want to offer the very best service and ensure a safe and secure supply chain for our clients and the patients they serve.

> By Lee Sutton, Senior Manager, Commercial Operations at Thermo Fisher Scientific.

Logistics and transportation are crucial to the life science industry, with most investigation and finished medicines requiring some form of temperature control during shipping to maintain stability. Biopharmaceuticals, in particular, are very sensitive to temperature changes; however, some drug substance and ancillary components used to make medicines may also require a temperature-controlled supply chain. Historically, these materials have moved at ambient temperatures; however, with the emergence of Good Distribution Practices regulations globally, new requirements for temperature controls during transit are now required. Many pharma companies throughout the world are now placing more emphasis on temperature controls for all drug materials during transport. Most requests fall in the 15–30 °C profile (considered controlled ambient), or in the 2-8 °C profile (refrigerated).

Exciting innovations in cell and gene therapies have introduced new challenges in transportation and supply chain logistics. These novel therapies are generating lifesaving treatments against diseases that were incurable a few years ago. The dynamic of these therapies, and the extreme temperature ranges they must be transported in, has pushed the transportation industry to adopt new processes and control measures to ensure these critical therapies arrive on time and at temperature. Many of these drugs are also patient specific, which adds a new level of strict oversight, communication and planning throughout the supply chain. These requirements have led to improved collaboration between shipping providers and pharmaceutical companies, and, as such, have caused the industry to look at how other products are monitored and handled throughout the supply chain.

At Thermo Fisher Scientific, we want to ensure our customers are fully supported no matter what type of therapies they are manufacturing and work collaboratively with our clients to develop solutions that fit their specific needs.

Customer voices

Thank you to everyone who participated in the survey. We are grateful for the number of responses we received, as well as the diversity of the companies we received feedback from. We feel we've received a holistic view of life science transportation needs from across the globe and will take that information and build our solutions to ensure our clients and their patients remain at the center of what we do.

There were many interesting responses to our survey, but one of the key takeaways was that service and transparency are crucial when working with supply chain partners. I feel this also emphasizes how important it is for us as an organization to check in with customers to ensure they are getting what they need on a regular cadence. Another result that really stood out to me was the percentage of time that people spend interacting with their logistics provider. Many of the responses were around the 20 percent mark but, in an ideal world, this number should be higher. You may ask, "Why?" I feel the answer is simple in that there is real value in working with a company that uses a consultative approach in the market. We have found that by sitting with our customers and listening to their needs, we're able to provide better overall service in transporting their product, but also planning for future growth and exploring ways of offsetting costs, especially if growth mandates entry into international markets.

I also found the comments in the survey that called out lack of communication, visibility and delays to be interesting. When companies utilize premium couriers, they are used to paying a "premium" price for their services. One of our organization's primary values is our communication. We pride ourselves in establishing oneto-one relationships with our clients, as well as setting up specific client work instructions or SOPs that dictate



how we interact with our clients. Our belief is that you can never communicate too much when it comes to pharmaceutical logistics. We incorporate that belief into our day-to-day global operations.

Supply chain solutions

Large companies typically have direct oversight and control over their supply chain. Often times, companies allocate specific groups or departments to manage their supply chains, which are supported by a significant budget to buy services that fit their needs. Given how well-established these companies are, they also possess long-term relationships with their supply chain partners. We do a great deal of work with large companies, but I've found it is often the emerging and mid-tier companies that gain the most benefit from a premium logistics partner, due to their need for additional how-to and guidance. For smaller companies, the transport of their molecule and materials can sometimes be an afterthought, as the main focus is on developing the drug. It's not uncommon for employees in companies of this size to juggle different roles outside of their primary job function. A partner like Thermo Fisher adds tremendous value to companies who operate in this environment by effectively listening to their needs and becoming an extension of their supply chain. We provide end-to-end support for our clients' shipments and have the ability to provide guidance on shipment requirements when moving internationally, as well as provide preconditioned qualified shippers across multiple temperature ranges. We proactively research potential challenges from a transportation perspective, such as customs regulations, duty and tax (VAT) requirements, as well as airline or port of entry infrastructure to support temperature-controlled shipments.

By combining Thermo Fisher Scientific's end-toend solutions for development, clinical trials and manufacturing, life science companies across the globe are able to utilize one company for all their clinical and commercial needs. The use of a single partner allows our clients to de-risk their supply chain by working with one partner, one quality system and one individual in mind: the patient.

GETTING AROUND

MEDICINES NEED TO REACH ALL CORNERS OF THE GLOBE, BUT MANAGING THE LOGISTICS AND TRANSPORT – WITHOUT COMPROMISING ON QUALITY – CAN BE A SIGNIFICANT CHALLENGE.

When pharma companies are looking for a premium courier to aid with transportation and logistics, a consultative approach and adherence to a quality system are vital.





transports and

Not being proactive when documentation is required from custom officers Lack of understanding of the unique requirements of biological samples

> Finding a reliable partner with a global scale

GETTING FROM A TO B

Shipping pharmaceuticals is about more than getting from A to B – pharmaceuticals often require specific handling and storage during transport, and must follow exacting regulations. Scott Emery explains how communication and planning – and experienced life sciences shippers – can help mitigate the potential risks.

By Scott Emery, Director of Global Transportation at Thermo Fisher Scientific.

From your perspective, what are the main pain points when it comes to shipping pharma products?

On the one hand, the logistics of transporting drug products and materials seems simple: it's about getting the right package to the right people at the right time. But on the other hand, it takes a lot of organization to do this effectively. Packages may be moving just a few hours down the road, or may need to get on a 16-hour flight and vour shipping partners need to be able to cope with both. As supply chains expand with globalization, packages are often moving more frequently and over greater distances, which adds to the challenge. Delivering a package from its point of origin to its end point, while ensuring the correct temperature is maintained, is a real pain point for many companies. Supply chains are dynamic and there are a lot of factors outside of your control, such as traffic on the roads, flight delays, unexpected weather, and staff at airports or ports accidentally mishandling packages that could lead to shipment damage.

What is the best way to mitigate potential risks during shipping?

It is the role of your logistics partner to mitigate transport risks as much as possible. I believe it is very important to pay close attention to the package during its entire journey (having information available in real time about the location and temperature of a shipment is a huge help) – and then be ready to intervene as soon as possible if a problem looks likely or starts to arise. There is as much art as science to this aspect; it really comes down to experience with shipping. For example, an experienced team will know the locations with the highest potential for problems – and they will book with higher service airlines accordingly to avoid risk. But the same experience will also allow them to identify more easily and earlier when something is going awry and requires action.

Before shipping, it is crucial to understand the customer's product and to plan for its movement. The shipping partner should ensure there is ample time to prepare the shipment, which could be 24 hours, 30 days, or longer depending on the complexity of the product (see sidebar, "Planning for Success," for an example). The more information the transport partner has upfront, the better prepared they will be.

How important is communication?

In the survey, many respondents talked about problems with communication. This did not surprise me – I've heard it all before! We have so many different ways of communicating today, but most exchanges are through written emails or text messages, which can create a lot of "noise." It's too easy for real issues to get buried in an email thread that veers off on a tangent. As a society, I think we too often shun the use of phone communication – and often it's a quick five-minute phone call that can clear up a lot of problems! And that's something I emphasize to my team.

What should pharma companies be looking for when choosing shipping partners?

My advice is to ask a lot of questions. Ask the provider how they are going to manage a shipment – "We'll pick it up at this time and deliver it at that time" is not what



PLANNING FOR SUCCESS

Thermo Fisher Scientific has worked with many different customers – all with different needs. One specific example: we worked with a cell therapy company that needed to export a product from the US to China. Cell therapy products and materials are notoriously challenging because of their sensitivity. The company had never shipped to China before and nor did they have the relevant expertise with regards to Chinese regulations. They also had no experience in the movement and use of dry vapor shippers.

Three months before shipping, we reached out to our network in China and determined what was required from a paperwork and registration perspective – it's important to get such information early. We then helped the client to prepare the paperwork, which was verified by our network in China to ensure that the material would clear customs upon entry without problems. As for the actual shipping, we used a dry vapor shipper and had to maintain ultra-cold temperatures. The material was placed correctly inside the shipper and then taken on the first available flight to China. The physical shipping process took around 72 hours and was straightforward. The keys to success? i) Asking the right questions of the customer early on to properly define the project, and ii) planning well ahead to complete the appropriate paperwork and registration.



you want to hear! Ask for more in-depth information. If the shipment is going to move from the UK to Australia, ask how it will get there – what planes will they use? How will the material be picked up? How will they monitor the condition of materials inside of the shipment box? What temperature controls will they use? Ask probing questions to test their knowledge.

The more information the provider has, the better the chances of successful and pain-free transport. If they can't go into detail or don't seem confident in their responses when asked a question, it highlights a lack of knowledge. You also need to ensure that the shipper can cope with changing scales. What happens when 100 shipments for a clinical trial becomes thousands of shipments for commercialization? Or when a one-off highly specialized move for a sensitive cell therapy needs to scale up? Ask your potential partner how they might address increasing shipments in the future with tighter timelines, and how they will help you commercialize your therapy.

Pharmaceutical products are highly valuable. Damaged products can cost thousands of dollars – and can also negatively impact patient lives through shortages. When choosing a partner to transport these products, you need to be sure that they understand the value of what they are handling – and that they have the right packaging, shipping vessels (such as dry vapor shippers), and paperwork. Pharmaceuticals make up only a small percentage of the total goods being transported across the globe, but they are some of the most complicated. They must be segregated from other products, vehicles and facilities must be cleaned to specific standards, and all suppliers must be qualified. If you do choose a standard courier with little understanding of life sciences material before, then you need to be cautious. Do they understand the needs of pharma products? Do they understand the regulations? Are they prepared to handle problems that may arise? In my world, life science expertise makes a huge difference when mitigating risks during transport.

What is Thermo Fisher Scientific's approach to transporting pharmaceutical products?

First of all, communication is crucial! Our approach is consultative. We enter into dialogue with our customers to ensure we have the right information upfront prior to shipping so that we can mitigate any potential risks and identify the potential pain points that may occur once we start moving the packages. In this business, I think it's important to be a partner rather than a provider – and this is something we take pride in. In terms of capabilities, we have facilities globally and the ability to store and distribute at multiple temperature ranges and shipment volumes.

Shipping and logistics can be an afterthought in drug development, as it's "simply" about getting the product out of the door after the hard work has been done. But it deserves attention. When we are hired, we are hired as experts to help mitigate risks. We want to collaborate with our partner and ensure there are as few issues as possible. A huge amount of time, effort and expense goes into making drug products and we want to make sure they reach the final destination safely. We do this with great attention to detail and with great care. In short, we take a very defensive approach.

Thermo Fisher

Marcus Roberts Senior Manager, Quality, Pharma Services Memphis, TN

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Find out more at thermofisher.com/patheon

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+1 919 226 3200 • pharmaservices@thermofisher.com • thermofisher.com/patheon © 2019 Thermo Fisher Scientific Inc. All rights reserved. Published 12/19 PSG0938

