White Paper: Safely Transporting Cold Chain Pharmaceutical Product

Dave Cranfill, Director – MD Express
1301 Perry Road, Suite 101
Plainfield IN 46168
1.317.838.8900
Introduction

As temperature sensitive biologically-based products continue to rise, experts are predicting the pharmaceutical cold chain industry will grow 65% by 2020\(^1\). This anticipated growth comes with a myriad of obstacles for freight forwarders and transportation companies, perhaps the largest one being how to safely and efficiently get temperature sensitive product to market. The growing cold chain industry calls for adaptations in pharmaceutical transportation in order to meet and exceed growing temperature requirements and safety compliance regulations.

This white paper will discuss the components to consider when defining a transportation solution for your pharmaceutical supply chain and how incorporating a third party into your solution will pay dividends.

Background: Transporting Sensitive Product

Traditionally, transportation of pharmaceuticals relied heavily on packaging to keep product both safe and within the temperature parameters set by the manufacturer. It wasn’t until the marketplace evolved from small-molecule drugs to more biologically based products when a greater emphasis was placed on cold chain transportation. Another factor behind increased supply chain complexity was the introduction of the Good Distribution Practice (GDP) by the EU in 2013. This required medicines to be obtained from a licensed supply chain and then stored, transported and handled under the correct conditions\(^2\). This added to the demand for qualified cold chain transportation providers.

Implementing a Cold Chain Transportation Solution

There are several aspects that go into a successful transportation solution. Because many pharmaceutical products require special attention and handling throughout the supply chain, companies typically consider the following attributes in a potential transportation provider.

Security

Perhaps one of the most important aspects of cold chain transportation is security. Developing a security plan which safely gets product through the supply chain and into the hands of the end user is paramount. When it comes to security, speed is not typically the only answer. Product integrity, regulatory compliance, and shipment security should be considered before speed of transportation\(^3\). With sensitive product, it is not uncommon to require team drivers on a load that will only go 250 to 300 miles. In this case, it’s not about hours of service or expediting a shipment, it’s about redundancy and mitigating risk by layering on security\(^4\). Using dedicated trucks, split shipments, expedited services and direct routes minimizes touch points and dwell time, which can be vulnerable areas when transporting high value product\(^5\).

An important aspect of providing product security is incorporating technology into your transportation solution. GPS tracking is widely used in order to keep track of high-value shipments through placing units on/in the trailer itself. Some are taking the concept of GPS a
step further by employing geofencing technology to track loads, mid-shipment. This technology uses GPS-enabled mobile devices, typically placed on the pallets of product inside the trailer, setting up virtual boundaries around designated areas. If a truck were to cross its set boundary, dispatchers are alerted and additional steps are taken. This technology also records arrival and departure times, reducing the margin for error in route planning and driver optimization. Route planning in conjunction with GPS tracking allows trucks to avoid high traffic areas, and a knowledgeable ground team can provide additional insight and alert drivers of potentially high risk situations.

**Insurance**
Pharmaceutical shipments can be the most difficult cargo to insure as they typically are a high value load. Partnering with a specialized transportation provider typically makes sense as they have extensive knowledge and industry experience in the pharmaceutical industry. They understand the importance of shipping a high-value load and take the necessary precautions to ensure product makes it safely to the final destination.

**Temperature Monitoring**
Advanced and highly expensive temperature controlled trailers and ocean containers are pertinent to ensure sensitive pharmaceutical product is kept temperature compliant no matter how long the journey. Specifically designed, refrigerated trailers ensure product is kept in compliance by means of a dedicated refrigeration unit to sustain temperature. Traffic, delayed flights, improper customs paperwork, and subpar weather conditions are all variables that arise during shipment and could detain product further. When transporting a temperature controlled product, vehicles should be equipped with continuous temperature monitoring and a data logging system, ensuring that the product is remaining within the required temperature during transport. In addition to truck requirements, it is recommended that retrievable temperature tracers are packed within the shipped product to further verify temperature compliance during shipment.

**Equipment Validation/Qualification**
All major regulatory agencies, worldwide, highly recommend equipment validation to ensure product stability during transport and eliminate the risk of temperature variance. Before loading, temperature should be confirmed as stable, and specific temperature instructions should be given to the driver, leaving no gaps in communication. The World Health Organization also recommends when loading product, to do so quickly to ensure temperature in the trailer does not deviate. Properly blocking and bracing the load allows for air circulation around all sides of the product. Standard operating procedures indicate that a temperature reading from the trailer should be obtained when a new shipment arrives, before opening the trailer doors.

**Training**
Driver training is absolutely paramount and topics should cover what to do if trailer temperatures drops, to what steps to take if a suspicious vehicle is spotted. It is also suggested to run through different scenarios with drivers to ensure they know how to respond in a given situation, for example, what security measures to take when stopping for fuel. Additional procedures and policies should be put in place detailing the routes a driver should take and where stops are
allowed to be made\textsuperscript{13}. Some transportation providers consult with local and federal law enforcement agencies to talk to drivers about safety issues that could arise\textsuperscript{14}.

\textit{Consolidation}
Freight spend is often one of the largest costs a company encounters when shipping product. In an effort to combat unused truckload space, improve efficiency, and better allocate transportation spend, many pharmaceutical companies are negotiating with specialized carriers who have the ability to consolidate similar product for like-minded customers into one shipment. Specialized carriers are also presenting the ability to create multiple temperatures zones within one shipment, resulting in increased savings and shipping efficiencies. Third Party Logistics providers and freight brokers are able to provide these services at the point of origin, minimizing unnecessary stops and in return decreasing the likely-hood of a temperature deviation or a lost shipment\textsuperscript{15}.

\textit{Trust}
When hiring independent trucking companies or contract drivers, pay special attention to driver background checks and company reputation. Cold chain pharmaceuticals carry with them a demand for a highly specialized and compliant transportation network focused on moving product efficiently while protecting integrity\textsuperscript{16}. Driver consistency and reliability are important to consider as providers who go the extra mile to build a relationship in turn become invested in the product they are carrying\textsuperscript{17}. These providers and drivers show a genuine interest in working as an extension of your team, one of the many qualities of a specialized transportation provider. And finally, perhaps most importantly, knowing (and trusting) your business partners is a major component to ensuring your commodities ship securely\textsuperscript{18}.

\textbf{Specialized Transportation Provider Benefits}
Working with a transportation provider who specializes in cold chain transportation provides many benefits when it comes to shipping temperature sensitive pharmaceuticals. As a transportation provider, MD Express (MDE) incorporates marketplace trends and nuances into their comprehensive service offering.

\textit{Qualification}
Understanding that quality and security is of upmost important to their customers, MD Express maintains a highly specialized network of carriers who have all passed a rigorous qualification process. This process not only includes driver background checks and the assessment of required certifications, but also takes a detailed look into driver training records, ensuring that the driver is properly trained on temperature and security breaches along with a multitude of other items. After ensuring that the driver is well equipped for the job, MD Express validates both truck and trailer to ensure both pieces of equipment meet strict quality standards. This process includes ensuring there are satellite GPS tracking capabilities and 24/7 monitoring.

\textit{Technology}
Given the importance of temperature control within the industry, carriers must have 24/7 temperature monitoring capabilities and consistently carry loads that do not deviate in
temperature. MD Express employs industry technology to offer their customers the capabilities of Freight Watch as an added service. Freight Watch tracks a load in progress, monitoring for situations that could lead to delays and ultimately ensuring a load is delivered safely.

**Peace of Mind**

Specialized transportation providers are able to devote quality time to tailoring their transportation solutions to fit customers’ unique freight and distribution needs. By providing brokerage services, MD Express works with a comprehensive network of qualified cold chain transportation providers who provide exceptional delivery with every transportation load. By working within a network of qualified transportation carriers, MD Express is able to provide their customers with peace of mind their product will be safely delivered to the end user.

**Conclusion**

The MD Express Team knows that transportation is not a ‘one size fits all’ solution. We work with our customers to match and tailor transportation solutions to fit their unique needs. Our Team works very closely with our customers to offer consolidated freight services, leveraging volume and combining like-minded shipments together, to reduce transportation costs and increase efficiencies. Most importantly, MD Express strives to work as an addition of your team, treating your product as our own.

**About MD Express**

MD Express is a fully licensed and insured truckload broker providing full truckload and LTL services. With a network of over 300 pieces of equipment, MDE offers validated cold chain and secured trucking services. MD Express is an affiliate company of MD Logistics.

**Resources**

1. "Innovation in Cold Chain Logistics" from Logistics Trends & Insights LLC. [http://logisticstrendsandinsights.com/reports/]
7. "Pharmacy delivery vans targeted by thieves seeking painkillers" from STAT. [https://www.statnews.com/2015/12/22/pharmacy-delivery-vans-targeted/]


