



FROM MANUFACTURER TO FINAL MILE

Pharmaceutical Transportation Risk Mitigation Tips



Maintaining the quality and integrity of medical and biological products during transport is critical for pharmaceutical manufacturers and logistics providers. In 2020, the critical nature of vaccine transportation dominated the news cycle and took center stage as manufacturers and logistics providers worked together to overcome the challenges that came with the global transportation of a vaccine that required extreme cold storage solutions.

If the quality of a pharmaceutical product is compromised, the risk is more than the loss of cargo—it can also compromise the health and well-being of patients. Having the right solution that addresses the precise needs of the pharmaceutical industry helps ensure that products, like the COVID-19 vaccine and others that treat chronic illnesses, are transported safely around the world to the people who need it the most.



HOW TO MITIGATE RISK IN THE PHARMACEUTICAL COLD CHAIN

Pharmaceutical sales in North America are projected to be around 628 billion U.S. dollars by 2023. The pharmaceutical cold chain must be reliable so that companies can protect their patients by ensuring proper flow of materials and treatments by reducing the risk of potential logistics breakdowns.

The type of refrigeration equipment used and how it's maintained go hand-in-hand. Validation services, trailer, or truck body design, equipment age and maintenance strategies play a critical role in supporting a safe, secure, and efficient cold chain.

Validation services

One way that cold chain integrity is maintained is through validation services. Validation services provide proof that risk mitigation processes were in place and multiple redundancies are in place to increase confidence that patient's treatments will arrive on time and are properly maintained. Validation services started in Europe from

a compliance standard, good distribution practices (GDP), that is slowly becoming a global trend in ideal risk mitigation process for pharmaceutical transportation.

Validation services typically include Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). In Europe, manufacturers of refrigeration equipment and pharmaceutical logistics and shipping companies must meet these standards. This ensures that consistent quality management systems are in place throughout the entire cold chain.

Shippers that transport pharmaceutical products should have equipment serviced within a dealer network that understands the pharmaceutical industry and the regulations that must be followed to stay in compliance and maintain proper documentation for pharmaceutical audits.





Trailer, Truck, or Van Body Design

The thermal efficiency of a trailer, truck, or van body is critical. Without the proper pairing of a temperature-controlled unit and trailer body, for example, a shipper can increase potential risks during the shipment of a pharmaceutical product. When a shipper designs a temperature-controlled trailer or truck body, one of the most important things to pay attention to is the insulation quality and thickness. When a body design is not sufficiently or properly insulated the temperature-controlled unit may not have the correct cooling or heating capacity to offset various factors during shipments like rising global temperatures and extremely cold winters or fluctuations in temperature during loading and unloading. The partnership between a temperature-control unit and its truck, trailer, or van body is vital to the proper environment for pharmaceutical and life science materials.

Insulation thickness is determined by the intended operation. For trailers and trucks hauling pharmaceutical products, there are standard insulation values that are recommended. The ATP, which was adopted in 1970, provides a recommended European standard for insulation.

While it's important to understand and follow standard insulation values, the type of refrigeration unit installed on a trailer or truck also informs the amount of insulation needed. Similar to the HVAC system in your home, if the temperature-control unit is either too big or too small for the trailer size and application, it won't maintain temperature as effectively as a right-sized system.

Equipment Age

As equipment ages, it's important to track performance and the ability to keep and maintain temperature. For a refrigerated trailer, the average lifecycle is seven to 10 years. For pharmaceutical shippers, the recommended lifecycle for temperature control equipment is three to five years depending on a fleet's equipment capacity and design. Fleets can phase out trailers to non-pharmaceutical shipments that are not as temperature-sensitive. Implementing a preventative or proactive maintenance strategy will also help a carrier lengthen the life of their equipment without putting the patient at risk.



Preventative Maintenance

With everything that goes into ensuring safe and successful transport of temperature-sensitive goods, carriers shouldn't have to worry about the reliability of their temperature-controlled unit. Paying close attention to the unit and maintaining a consistent service schedule will make a difference in the lifecycle of the temperature-controlled unit.

Here are two important ways carriers can stay alert to potential problems and proactively keep fleets on the road.

- Following a good "pre-trip" inspection prior to every load helps prevent a costly repair. This type of inspection tests the functionality of the system over the course of a 15-minute comprehensive diagnostics check. The cost in time for running a pre-trip versus the cost of a load loss acts as extra insurance. The pre-trip results show a pass/check/fail code. Drivers should never clear alarms without further investigation. The standard operating procedure will determine the next steps for each fleet.
- Utilize telematics like TrackKing® to remotely monitor equipment location and health status. This allows fleets to monitor cargo temperature in real-time and take action on items immediately to prevent unscheduled breakdowns and reduce maintenance costs. Fleets that utilize telematics can monitor and react to selected codes generated by the equipment during operation. Utilizing telematics allows carriers to move from reacting to critical system issues to proactively solving problems based on warning alarms before the unit's shut down.

Fleet managers can work with their dealer to create a customized maintenance plan that not only provides a superior level of service but is also focused on what's most important to the carrier such as changing out common components ahead of schedule to reduce the risk of breakdowns. The demands on carriers have changed. A customized maintenance plan should provide solutions that address the needs and requirements of transporting pharmaceutical products.

Addressing just 35% of predicted issues could save a fleet up to [\\$490 per truck per year](#).





The United States is ranked 2nd in top countries for pharmaceutical theft with 19% of pharmaceutical theft estimated in the US, led by the UK at 29%.

[1]

PROTECT CARGO WITH TELEMATICS AND REAL-TIME DATA

Taking cargo security seriously is a full-time job and requires multiple layers of protection. Telematics provides carriers with the ability to track and trace shipments in real-time through asset location and geofencing.

With geofencing capabilities, a shipper can receive text, phone app, and email notifications when a truck or trailer leaves or enters a designated geofence. Telematics also makes it possible to easily share trip status reports from pickup to delivery so there is complete transparency between the manufacturer and the carrier.

In addition to the use of telematics, there are also a number of operating procedures carriers can put into place to mitigate the risk of cargo theft.

1. Utilize team drivers when transporting pharmaceuticals to allow for constant movement on the road.
2. Institute a policy that drivers can't make any stops in the final 100–200 miles of distribution.
3. Require drivers to utilize different routes when approaching common pick up or delivery sites or vary their distribution routes so that they are not stopping at the same truck stop or restaurant every time.
4. Use a remote door lock, such as the Mi-Jack® brand lock, which is integrated into Tracking, to remotely lock and unlock the trailer door.

Thieves overwhelmingly strike the trucks moving pharmaceutical products globally, with the trucking modality targeted in almost three quarters (75%) of thefts recorded by BSI in 2018.

[1]

The pharmaceutical industry faces many supply chain-related challenges. Foremost, and most visible, is the outright theft of pharmaceuticals, typically while in transit.

[1]

In 2009, 50 major pharma thefts occurred costing nearly \$200 million in drugs and an infamous theft of \$80 million in goods occurred in 2010. While large thefts have shrunk due to more oversight, theft is still a very real and looming threat for the pharma industry.

[2]



IMPORTANCE OF COLD STORAGE SOLUTIONS

The need for efficient, safe, and secure global transportation of the COVID-19 vaccine has served as an important reminder that the world can't afford a break in the pharmaceutical cold chain. Intelligent cold storage solutions help address transportation challenges by maintaining temperature control and tracking the integrity of vaccine shipments at all points in the final mile of distribution.

The information provided in this white paper is for general informational purposes only. If you have any questions about this information, you should consult with industry professionals to provide you with the applicable or appropriate guidance for your particular refrigerated transportation needs. The information is provided "as is" with no representations or warranties with respect to the accuracy of the information to a specific situation.



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Sources:

[1] <https://www.ttclub.com/-/media/files/tt-club/bsi-tt-club-cargo-theft-report/bsi-and-tt-club-cargo-theft-report-2019.pdf>

[2] <https://www.theverge.com/2014/5/5/5683680/after-400-million-in-heists-feds-are-cracking-down-on-medication>



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