Security & Temperature Control in the Cold Chain

With the increase in global pharmaceutical shipments, driven by the aging of the world’s population and the increase in available therapies, many pharmaceutical and biotech executives are hindered in their attempts to provide an accurate cost-benefit analysis of the transport of their drugs to market.

Two distinct yet inter-related aspects must be considered when analyzing transportation within the cold chain: 1.) the physical security of the drugs being moved 2.) the temperature “security” or control of the drugs being shipped.

Adding further complexity to the cost-benefit analysis, the design of pharmaceuticals and biologics are becoming more complex (and therefore potentially unstable), and regulatory authorities around the globe are demanding a greater degree of proof concerning drugs’ identity, strength, quality and purity. Regardless of the needed temperature setting (deep cold, 2-8°C, or room temperature) or the degree of security oversight, these factors combined have driven the need for a wiser evaluation of transport partners within the cold chain and their capabilities.

Security in the Cold Chain
The security aspect of selecting a transport provider within the cold chain should include the following considerations. Although many of the specific points refer to truck transport, much of the knowledge can be considered good advice among other modes of transport as well:

1.) Does the carrier schedule an appropriate pick up and delivery?
This factor is equally contingent upon the business hiring the carrier as it is on the carrier itself. A truck hauling your shipment is at its most secure when it remains in motion. When a truck becomes a “warehouse on wheels” parked somewhere with your shipment on board, there is a greater risk of theft.

Many times a truck is in this situation because of inappropriate scheduling. Sometimes a pick up is scheduled at a time that makes it impossible for the shipment to arrive at its destination when the recipient is still open. In instances like this, the truck becomes parked with cargo. With the vehicle parked, the risk of the driver leaving the shipment unattended increases. This leaves the vehicle at risk of either being broken into or stolen. Even a parked vehicle with an attendant driver is still at risk of potential hijacking.
2.) Does the carrier have a “safe parking” program?
Recognizing that having a truck parked with your shipment is a likelihood that can be unavoidable at times. In such instances, does your transportation provider have a “safe parking” program? Ideally, a vehicle would be parked within an enclosed facility. Additionally, such a facility would be fenced off with barbed wire, monitored by closed-circuit TV, have a locked gate and a security guard on duty 24/7. The same attributes that make for an adequate “safe parking” environment are good guidelines for consideration for one’s warehousing and distribution facilities as well.

3.) Is the carrier aware of crime levels in your shipment's geographic area?
Is your transportation provider aware of risks of criminal activity within select areas?

This knowledge is not only relevant to the immediate area where the pickup or delivery is occurring, but for the regional area as well. Portions of select metropolitan areas are known high-risk locales for cargo theft and vehicle hijackings. Does your transportation provider have the insight to route around such areas?

4.) What is the carrier's relationship with law enforcement?
Does your transportation provider have an ongoing relationship with law enforcement? Much of the knowledge gained about crime in certain areas comes from an ongoing dialogue with law enforcement.

5.) Does your carrier have a security contingency plan?
Make sure your transportation provider has a security plan and standard operating procedures in place to deal with any needed security levels your shipment requires. Additionally, make sure they have the capability to implement those security procedures. Are drivers handling secure shipments appropriately trained in those protocols?

Ask yourself the following questions:

- What is the transportation provider’s response if the vehicle carrying your shipment breaks down?
- Do they have the capability to dispatch another vehicle immediately to pick up your cargo and continue with the transit?
- If so, is the driver of that vehicle trained in the security protocol?
- Are there processes in place to notify you of such service disruptions?
- Are there procedures in place to move the vehicle to a “safe parking” environment where a cargo transfer could be done securely?
Do not allow a carrier to confuse the issues regarding a security protocol. A carrier may state that they are “hazmat certified.” This refers to their ability to handle hazardous materials, but it has nothing to do with their degree of security.

Another security claim some carriers make is that they are “C-TPAT certified.” This is a voluntary government-business partnership with U.S. Customs and Border Protection that allows trucks to cross the border more quickly. While it is good to have, it does not denote the quality of a carrier’s security plan or its capability to implement it.

6.) Who is handling your shipment?
Are you provided any advance identification on the driver(s) handling your shipment?

7.) What security technology and backup systems are in place?
Does the carrier have such security technology as satellite tracking of the vehicle, electronic alert button (the driver of the vehicle could push a button that alerts local law enforcement of an emergency) and other such efforts?

Additionally, do backup systems and protocols exist if such technology fails? Simple protocols can make a big difference. For example, ensuring a driver has a cell phone turned on can make sure he or she can be contacted if their satellite tracking malfunctioned. Backup plans like this separate transportation companies who can ensure security of your shipment from those who merely claim they do.

Temperature Control in Cold Chain Transport
Before we delve further into a discussion on cost-benefit analysis, we need to have an understanding of the mechanics involved and the conditions encountered that can affect temperature control. Transport conditions are dependant on many factors including available technology, seasonal heat/cold and random severe weather events. There are several layers of protection that should be considered when shipping that are related to time, mode, and monitoring and intervention capability.

This portion of the article addresses considerations for transporting temperature sensitive products by air or truck.

Aircraft conditions
Many aircraft are equipped with air conditioning ability, but standard passenger and cargo aircraft are not designed for temperature control. Air temperature inside the cargo areas on properly equipped aircraft can be monitored and influenced, but not controlled in the way that a temperature control unit (TCU) can control the temperatures in a truck or compressor-powered container. The aircraft does have some ability to warm the cargo area using engine heat. Pressure in all three cargo holds during flight can be set to a comfortable level for living creatures.
Due to the tremendous mass of an airframe, generating enough heat to sufficiently warm each entire cargo hold has a high cost in fuel and time. Because of this, an aircraft will be conditioned during the ongoing conduct of its flight operations and not prior to loading/departure, as is common with other modes of transport.

Generally, aircraft that are equipped with some temperature control capability are able to warm the cargo areas with enough speed to minimize impact on active dry-ice containers and passive packaging so that product within them is protected for the duration of the flight. Newer technology active containers that are controlled by battery-powered compressors have shown to be able to maintain a stable temperature within the container without regard to the variations of temperature within the cargo hold of the aircraft.

Implications of weather
Freight shipped by air may experience different conditions due to vulnerability to the impacts of weather. The most common challenges are in the transfer of freight between modes of transport during the course of the shipment from pick up to delivery. For example: a truck will pick up the product, the truck moves the product to the airport, and the freight is processed and loaded onto an airplane. At the destination airport, the freight is removed from the airplane, processed, loaded onto a truck, and moved to final delivery. Conditions including weather and time exposed must be considered for all of the following events:

- Loading/pick up – the conditions on your dock/loading area
- Truck movement – can be controlled by using a properly qualified refrigerated truck
- Processing (Export) – may include open inspections or extended wait times. These can often be reduced with prior planning and coordination.
- Processing (loading aircraft) – Container may be exposed to weather
- Flight – consider route/duration of transport and temperature depending on the container system being used. Time of flight may also be a factor for the leg of the shipment your product is on. An aircraft used for the first time that day will be conditioned to weather temperatures. For example: during the winter, it may take several hours of flight time to condition the airframe to stabilize at a comfortable temperature as the warm air from the conditioning system works to warm the existing cold air and cold aircraft.
- Unloading – exposed to weather
- Processing (Import) – may include open inspections or extended wait times. These can often be reduced with prior planning and coordination.
- Processing (loading truck) – exposed to weather
- Truck movement – during the last mile, a properly qualified refrigerated truck may not be available.
- Unloading/delivery – for the last mile, this may often involve exposure to weather or worse, left inside a mailbox or other unprotected container for several hours.
The length of time outside of a controlled environment and ambient conditions at each of these stages must be considered and planned for in order to successfully transport temperature-sensitive products by air. By coordinating with a carrier that understands pharmaceutical transportation requirements, transport systems can be designed to significantly reduce the risks to the freight at each stage. Contingency plans can be developed to effectively address risk areas where design is unable to sufficiently mitigate.

**Shipping containers**

Three major categories of shipping container are available for use in air or ground transportation:

1.) Passive containers/packaging
2.) Active containers (dry-ice cooled)
3.) Active containers (compressor powered)

Any of these can be used effectively when their use is considered within the context of the chosen transportation plan and product requirements. Active or passive wraps / blankets can also be used as required to protect against the effects of a particular weather condition or when exposure cannot be sufficiently reduced.

**Movement by truck**

Areas of consideration specific to ground-truck transportation are:

1.) type of truck (temperature control “reefer” or dry van) vs. the expenses associated with protective packaging
2.) refrigerated truck specifications/qualifications
3.) monitoring methods
4.) cargo load configuration
5.) route
6.) length of shipment
7.) contingency plans

When a refrigerated truck is used, ensure it is well maintained and qualified to be able to control temperatures within the required range. When practical, also consider the truck’s ability to operate in the ambient conditions it will encounter on the specified route. Then select a monitoring technique to ensure accurate temperature data is obtained. Coordinate monitoring and shipment procedures carefully with your selected carrier.

Load planning is essential. The efficient operation of truck refrigeration systems depends on unimpeded airflow around the entire load, including both sides, underneath, in front, and at the rear of the cargo hold. Without constant and unimpeded airflow to all areas around the cargo, the truck’s ability to control air temperature stability is reduced. This increases the likelihood of unplanned variations of temperature within the cargo area and impact to the cargo itself.
A well-planned route can reduce the extremes of ambient heat and cold that might otherwise be encountered. In seasons of peak heat or cold, consider timing routes, including load and unload events, so that the truck avoids the peak heat / cold of the day. Another option to consider is routing around desert or high mountain environments when appropriate.

Finally, prior to beginning a movement, plan for contingencies along the route to complete your due diligence. Pre-define contingency events, for example: vehicle breakdown, TCU malfunction and temperature excursions. Consider how decision makers will know when a contingency event has occurred and what options are available for responding depending on where the event occurred along the route. Depending on the level of risk, consider pre-coordinating with service locations along the route when possible to ensure a complete understanding of the service they offer and to obtain contact information, particularly for after-hours events, to enable timely action.

**Risks**
Prior to doing a cost-benefit analysis as it relates to transportation within the cold chain, recognition of the risks of domestic or international transport need to be discussed.

Risk factors to be considered include:
- Exposure to ambient weather: How often is the cargo exposed to multiple handoffs, mode transfers, customs, or en route storage that could impact the length and degree of ambient temperature exposure?
- What is the travel time and temperature profile of each mode of transport?
- How often will the cargo be handled?
- Security: How is the cargo guarded from theft or the introduction of counterfeits?
- Documentation: Can the transporter provide an unbroken audit trail verifying the location and temperature setting of the cargo throughout its transport?

**Quality Management**
To minimize the risks involved, carriers and their pharmaceutical clients should work together to apply the same principles of quality management that occur in other aspects of the industry to the design and operation of the cold chain transport system.

After evaluating the environment and the time and temperature demands of the cargo and the transit involved, design a transportation system to handle that environment. Test the transportation system and establish controls based on the test results and train people to implement the controls. Monitoring the process and providing ongoing feedback related to its performance is essential for a continuously improving system.
Transport Criteria for the Cold Chain
Determining a list of critical factors for your temperature-controlled cargo is key in evaluating the effectiveness of a transport service provider in meeting your needs. Guidance set forth in the Parenteral Drug Association’s Technical Report 39 urges the following considerations when hiring a transport service provider for your temperature sensitive product. The facts that you need in order to assess the qualifications of your potential carrier include:

- Are you as the shipper able to have an agreement with the transport service provider verifying their ability to maintain temperature controls?

- Are you able to audit the transport service provider concerning their quality controls? Will the carrier provide you with quality statistics for your on-time delivery, temperature excursions and claims/loss history?

- Does the transport service provider have a quality management system? Is there a specific individual responsible for quality management?

- Does the transport service provider have a tracking and tracing system implemented that not only tracks the cargo location but monitors temperature as well?

- Regarding temperature measurements, what is the carrier’s monitoring method, the sensitivity of temperature measurements and the frequency of temperature readings?  
  *Note: The carrier will need to provide the specifics on frequency, sensitivity, and monitoring.*

- Does the transport provider have a contingency plan in the event that a cold-chain shipment fails to maintain temperature control? What is their reaction speed in determining a failure and implementing a contingency?  
  *Note: The contingency plan should be specific to your cargo. The carrier should also be able to answer how quickly they can become aware of a service failure.*

- Does the transport service provider provide training to its personnel and subcontractors concerning appropriate care of temperature-controlled cargo? Is that training documented?

- Will you be informed in advance of any changes that materially affect the terms of transport?

- If the transport service provider needs to utilize a subcontractor, do the subcontractor and the service provider have a transport agreement? Does the subcontractor adhere to the same quality management system that the transport provider has?
A Final Note on Security & Temperature Control

Cost control is a factor that is of interest to nearly every decision-maker. In evaluating the cost of cold chain shipping, consider also the cost of your own past losses, excursion management expenses (including quarantine delays) and packaging costs. Also consider the sensitivity of the freight, your tolerance for loss (either through theft or temperature failure) and the quality assurance/regulatory environment.

It may be that the most cost-effective solution does not have the least cost per mile or per weight.