

HELPING PHARMACEUTICALS KEEP THEIR COOL

Innovative solutions help pharmaceutical manufacturers safely transport temperature-sensitive drugs under new guidelines

In pharmaceuticals, the ingredients that pack the most power can also be among the most temperature sensitive. Accordingly, they require consistent temperatures from production through delivery to the final customer. But until recently, this end-to-end supply chain standard covered a limited range of medications, and the requirement to manage drugs at ideal temperatures often applied only to the storage, but not the transport, of those goods.

That's changing as the patchwork of pharmaceutical transportation regulations across the globe continues to evolve. One example is the European Union's guidelines on Good Distribution Practice (GDP) for medicinal products for human use¹, which went into effect in November 2013. The guidelines extend adherence to storage conditions as indicated on the packaging to the transportation leg of the journey. This compliance requirement has long been adhered to with cold chain products - generally anything below 8°C. It is, however, new for the majority of the drugs found in most medicine cabinets, often labeled for 25°C. In practice, the GDP guidelines now apply to about 80 percent of pharma products in the EU.



¹ European Commission, "Guidelines on 5 Nov 2013 Distribution Practice (GDP) for medicinal products for human use," November 2013

To ensure they stay in compliance with these new requirements through every step of the supply chain, manufacturers will rely on their logistics partners to provide fully compliant temperature-controlled transport.

Sensitivity, distance increasing

As the requirement for more stringent adherence to temperature conditions increases, so too is the distance these products travel as they move through the supply chain to market. This adds greater risk of disruption from events like natural disasters and transport delays.

Moreover, manufacturers are turning their research and development efforts toward more targeted therapies, customized treatments for rare diseases, and second- or third-line therapy uses, meaning that their products now contain more high-value active ingredients with shorter shelf lives and strict temperature requirements. At the same time, the markets for these drugs are expanding geographically, increasing the need for compliance in countries with varying requirements. As those drugs travel across international borders, they must stay in compliance no matter what disruptive events occur.

The new EU law states that wholesale distributors are required to “maintain the quality of the product, to protect against breakage, adulteration, and theft, and to ensure appropriate environmental conditions are maintained during transport” according to packaging guidelines. For many drugs, this means remaining below 25°C, while some require transportation at 2 to 8°C.

The good news is that governments are working to make their laws more alike. Several recent revisions in various countries’ guidelines focus on the same issues, including quality agreements, contracts, supply chain integrity, and temperature management.

No matter which set of regulations apply, pharmaceutical manufacturers depend heavily on their logistics partners to ensure that their goods remain compliant once they leave their dock doors. In fact, in some instances manufacturers rely on these partnerships to stay ahead of legislation in their respective countries of operation. These requirements add new layers of complexity to already sophisticated supply chain operations. Third-party logistics companies (3PLs) are playing a key role in helping pharmaceutical manufacturers implement, monitor, and report on compliance with temperature-assurance regulations.

Overcoming temperature challenges “Down Under”

One example of this beneficial relationship can be found in Australia, where transport is strongly affected by high temperatures. Third-party logistics provider, DHL Supply Chain handles a large volume of pharmaceutical shipments in that country.

“Australia has similar regulations [to those in other countries], but at present they do allow for temperatures outside of target temperature range on a temporary basis,” explains Saul Resnick, DHL Supply Chain’s Australia Managing Director. “Our customers have parent companies in the U.S. and Europe, so they are looking to adopt higher, global standards.”

With that in mind, a DHL team set out to measure the conditions experienced by pharmaceuticals in various modes of transport, including interstate line hauls, local delivery

fleets, air shipments, and handling at transport hubs. They found that 100 percent of delivery vehicles had loads exceeding 25°C in the summer and shoulder (adjacent) months, where temperatures in the vehicles sometimes exceeded 50°C. Local delivery vehicles showed the greatest variation, and even line-haul vehicles consistently exceeded 25°C at some point in the delivery. They also learned that transport hubs could not be configured to guarantee compliance with requirements below 25°C due to the nature of the operations with such high flow of traffic. Similarly, air shipments were exposed to high temperatures before and after the aircraft segment of their journey.

After evaluating many possible solutions, DHL determined that air conditioning of vehicles and trailers, with monitors feeding temperature data back to a central point, would be the most cost-effective approach. Working with pharmaceutical manufacturers, planners developed a “direct flow” model that avoids the use of transport hubs whenever possible, instead moving pharmaceutical products directly from temperature controlled warehouses into air-conditioned trucks for direct delivery to the final destination. By collaborating with manufacturers on order profiles and schedules, including consolidating orders and setting dedicated delivery days and time slots, the team brought delivery timetables into closer alignment across its healthcare customers, reducing time in transit. The solution is being phased in across Australia throughout 2015.

As the dominant provider to the Australian pharmaceutical industry, “DHL is able to work with wholesale distributors to coordinate deliveries into their warehouses for an end-to-end solution, versus just addressing our part of the supply chain,” Resnick says. “We’ve been able to deliver value while minimizing costs and adhering to strict global standards.”

Patients rely on powerful, often temperature-sensitive pharmaceuticals to restore them to good health. As this example shows, by working with their supply chain partners to craft innovative solutions, pharmaceutical manufacturers can deliver those drugs safely into patients’ hands.