



Trial Run



Dan Catizone at QuickSTAT explores the territory of shipping logistics and their pivotal role in the efficient conduct of clinical trials

Dan Catizone is the Vice President for Business Development of QuickSTAT, a division of Quick International Courier. A 19-year veteran of the transportation industry, Dan previously worked in many different capacities for TNT Express Worldwide. He is a graduate of Pace University, where he received a Bachelor of Business Administration. Dan helps to provide QuickSTAT customers with door-to-door cold chain logistics solutions to ensure the safe transport of investigational products and clinical specimens for both the pharmaceutical and biotech community worldwide.

From the first kernel of an idea in a researcher's mind to a drug or therapy coming to market, the clinical trial process is an arduous and expensive undertaking. Along the way, any number of issues can derail the process, with cost overruns, flawed trial designs or the plain fact that a scientific hypotheses has turned out to be wrong, being among the most common culprits. But there is another bogeyman stalking clinical trials that frequently gets short shrift: shipping logistics.

Lost amidst the excitement of research and discovery, is the fact that clinical specimens have to be transported to far-flung corners of the globe, often under strictly controlled temperature conditions. Commonly referred to as 'cold chain management', which encompasses all the storage, transport, paperwork and logistical capabilities needed to ship your specimen, this is an absolutely crucial element of keeping clinical trials on time and on budget.

Cold chain management should be considered from the outset of the discovery process, because the viability of your trial may depend on it. A specialised life science courier is best equipped to deal with cold chain complexities and, though many clinical staffers, marketers and other interested parties will not be on the frontline of the shipping process, everyone should be cognisant of the basics. Once you have ascertained the site locations, quantity of drug to be transported, depots, number of specimens to be shipped and destination lab, you should involve your courier.

If you want to plan appropriately, you must look at the shipping process from the very beginning and consider specimen packaging, communications with the courier, and the impact of commercial airlines on the overall project.

PACKAGING

The packaging configuration chosen for cold chain distribution should be qualified or validated by your packaging provider. You can purchase pre-qualified packaging systems – those that will sustain the desired temperature of your specimen for a specified period of time, or have the system qualified based on what you are shipping.

The initial consideration when choosing a packaging solution for your specimen is whether you need an active or passive system. In layman's terms, think of an active system like a refrigerator, which can be adjusted to maintain a desired temperature, and a passive system like a beer cooler, which uses a combination of frozen and refrigerated gel packs to keep something sufficiently cold.

If you are selecting a passive packaging system, polystyrene or polyurethane insulated box, you should work with a testing lab that has experience in thermal design and package testing. Considerations for testing your packaging system include the locations you will be shipping product and specimens to and from, the target temperature of the commodity, volume of product to be transported and the expected number of hours the product will be inside the package. Variations in temperature during transit should be considered, especially if you are shipping from a summer environment to a winter one.

If you are shipping larger volumes of drug product, you may look towards an active, validated packaging system. These systems protect product integrity, reduce labour-intensive packaging, lower consumption of non-usable material and reduce the risk of tampering. To better assess the right solution, consider the pros and cons of active and passive systems (see below).

Pros and Cons of Active and Passive Systems	
Active Systems	
Pros	Cons
No warehousing	Availability
Secure	Limited lane segments
Leased not purchased	Mechanical issues
Quick loading/unloading	Winter use may be risky
Passive Systems	
Pros	Cons
Hold tighter temperatures	Warehousing
Can ship anywhere	Conditioning refrigerant
Reusable	Longer assembly
Year-round use	

