

# Transportation of TSPs: Acknowledge the Elephant

*You can transport temperature-sensitive products with confidence.*

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**W**hen writing this article, a poem by Terry Kettering came to mind: “The Elephant in the Room.” Certain lines kept whirling around my head as I tried to figure out how best to convey what we have to say:

“We all know it is there...For, you see, it is a very big elephant...But we do not talk about the elephant in the room.”

Don't you think it's time to talk about the elephant in the room? If the transportation of temperature-sensitive products (TSPs) is such a hot topic, then why are we not talking about it? Why do conferences, articles, papers, and conversations focus on the negative when there are solutions that are in practice today? Are they creating fear and adding to the confusion?

Organizations are overcoming the apparent challenges and actually transporting TSPs safely and compliantly around the world. They are confident that end-users will receive products safe and fit for their intended use. They can prove it to FDA, EMEA, USP, TGA, or to WHOMever they need.

How do these organizations do it? They acknowledge ‘the elephant in the room’—that process validation principles apply to transporting TSPs and that there is no ‘quick fix.’

Validation principles are nothing

new to those that manufacture medicinal products. GMPs require that manufacturers identify what validation work is needed to prove *control of the critical aspects* of their particular operations. Significant changes to the facilities, the equipment, and the processes that may affect product quality should be validated. A risk assessment approach should be used to determine validation scope and extent.

Product transportation falls into the category of a “process which may affect the quality of the product.” Hence, it needs to be validated. So then, what has changed?

## *Process validation principles apply to transporting TSPs.*

What has changed is that healthcare biotechnology is increasingly playing a role in conventional drug discovery. Biotech medicines such as proteins, antibodies, and enzymes now account for more than 20% of all marketed medicines and more than 50% of those in clinical trials. Because these active biological medicines are sensitive to changes in temperature and vary widely in their tolerance of short-term exposure to heat and cold, temperature has now become one of the more significant characteristics in

maintaining product quality throughout the distribution pathway. So, temperature has become a critical aspect of the supply operation that needs to be controlled in relation to the product. And the supply pathway for TSPs becomes a critical process that needs to be validated.

## **ASSESSING THE RISK**

According to the U.S. Census Bureau's industry survey of the pharmaceutical preparation and manufacturing industry, in 1997, the biotech industry shipped \$66.7 billion worth of products. In 2002 this had climbed to \$114 billion, for an annual growth rate of 11.3% per year. Projections through 2006 would result in approximately \$150 billion worth of biotech products shipped.

Given the fact that in 2002, 11 out of the 76 blockbuster products were biologicals and that biotechnology plays a key role in new drug discovery, it is no surprise that each year more and more emphasis is being placed on the importance of distributing these TSPs safely and effectively. Regulatory bodies around the globe are widening their regulatory reach. Industry observers consider the area of clinical development to be the next major area of government investigations and urge companies to focus on the design and implementation of processes and controls that will mitigate developmental risks.

This responsibility falls neatly into the lap of the organizations developing TSPs. While it is positive that risk responsibility is being assigned and that the issue is being given the attention it warrants, it is important that decisions and guidelines are not made or mandated prematurely. A deeper understanding of the myriad temperature profiles through which TSPs are transported is required, as is a more in-depth study into the complex dynamics of current distribution pathways.

For example, current practices by many cold-chain packaging providers use only generic tenuous thermal profiles to prequalify one-size-fits-all TSP packaging. At first glance, this approach may look attractive to many organizations wanting quick solutions. However, those that do research and map the thermal profiles through which their products must be distributed realize that a quick-fix generic approach falls vastly short of meeting

individual distribution requirements for each of their TSPs' unique thermal profiles.

## **RISKY BUSINESS**

Biotechnology and pharmaceutical organizations invest billions of dollars in R&D and in clinical trials annually. These companies need to move new products into the market quickly to obtain sufficient benefits from limited patent lives and to compensate for development costs. These firms are ultimately aiming to develop effective and safe treatments, while ensuring organization growth and continuity.

Given the substantial capital, the long development cycles, the value of biological products, and the risk to human lives, is a transport solution that has not been designed for your products, not developed to ensure performance throughout your thermal profile, and not thoroughly qualified as part of your master validation plan worth the risk?

A series of case studies over the next year will show how three organizations that have said 'no' to the above questions and have acknowledged the elephant in the room have implemented successful solutions for the transportation of their TSPs in partnership with EnviroCooler. The series kicks off in a future issue with a case study from Amgen.

*EnviroCooler develops and provides custom-made thermally controlled shipping solutions. Since its inception more than 12 years ago, the company has patented science-based design innovations and robustly engineered testing methodologies, extending across the portfolio of solutions, from unit vials to pallets to cryovessel loads. Current partners include Amgen, Eli Lilly, ICON, CSL, Allergan, Smith and Nephew, BioRad, Baxter, Wyeth, Cook International, Fort Dodge, Dendreon, Boehringer Ingelheim, and Cell Genesys. Future articles will explore the solutions that EnviroCooler developed for these partners. ■*