

Packaging/Drug Delivery

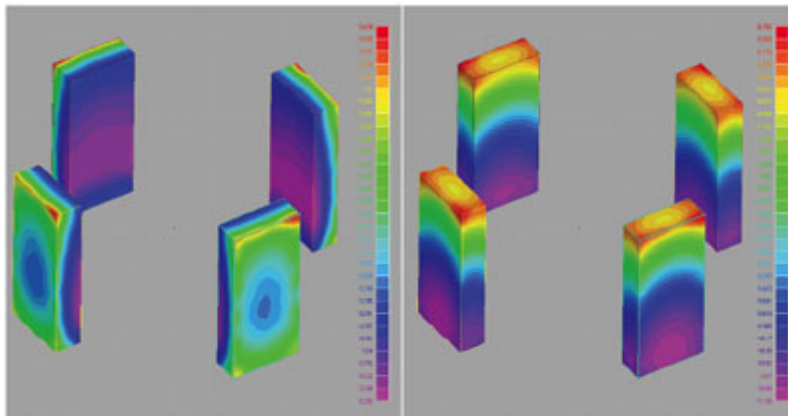
Temperature-Controlled Shipping Options Multiply

By: F.J. Quinn Date: 2008-12-26

New phase-change materials offer more choices for delivering fragile pharmaceuticals and biomaterials

Even as the biopharma industry is paying closer attention to quality assurance and protocol compliance in temperature-controlled shipping, vendors of packaging systems and services are rolling out a broader array of product offerings. At this fall's IQPC Cold Chain Distribution conference (Philadelphia; Sept. 22-25), exhibitors were showing new insulating and temperature-control materials; new packaging; and a wider array of shipping container services.

Perhaps the one area of most intense development is the growing variety of phase-change materials (PCMs) to provide a predictable, reliable temperature during shipping, even over extended periods of time. Traditionally, the industry has depended on water-based gel packs for cooling for higher temperature ranges, and dry ice for lower ranges, or, alternatively, the use of "active control" via battery-powered cooling and heating systems. Now, PCMs are reshuffling the industry options.



Thermal modeling of a packed-out container, showing the progression over time as the container warms. Credit: Cold Chain Technologies

Temperature-sensitive drugs represent about 10% of the roughly \$240-billion pharmaceutical distribution industry, according to the Healthcare Distribution Management Association (Arlington, VA). A wider variety of diagnostic or clinical-trial materials are also coming under more demanding temperature-controlled shipping requirements, as are **blood products** (see p. 1) and vaccines. In most cases, these products are shipped in an insulated container which uses ice, gel packs, and other materials that help maintain the required temperature. "Within the pharma community, temperature-sensitive drugs and clinical trial materials can lose their effectiveness when subjected to temperatures outside the predetermined acceptable ranges," says Karl Schlenker, VP, Minnesota Thermal Science (MTS; Plymouth, MN). "The PCM working with other insulators can minimize the risk and provide a safe shipping alternative to carriers or refrigerated trucks."

A case in point is MTS, which claims to have launched the first -50° shipping

container, called Credo Series 50M, to ensure contents for long-duration shipping remain frozen within temperature-range requirements. "We're very excited to introduce a container that will preserve medical samples better than any other option in the marketplace and cut down on exorbitant shipping costs," Schlenker says. "Another advantage is that the container will hold payloads at -50°C for three days, but after five days it will still be below -18°, which is still viable for most frozen medical requirements."

Rethinking how to get there, in a temperature-controlled way

A temperature-controlled supply chain depends on a lot more than selecting a suitable container, insulation and cooling agent. Pharma shippers—and industry regulators—are paying more attention to variations within shipping vehicles (particularly refrigerated trucks) and to storage conditions at transit points. As supply chains for both commercial and clinical product deliveries get longer and more complex, the challenges rise commensurately.

Like most industry problems, if you throw enough money at your temperature-controlled supply chain, problems will be diminished. But the more preferable action is to analyze the economics of shipping materials and transportation methods, and devise a transportation solution that meets requirements and is cost-effective.

PCM specs are often driven by the protocol of the product being shipped, including allowable excursions, as a result of the pharma/bioscience manufacturer's qualification and validation processes. "Handling and ease of use need to be considered," MTS' Schlenker says. "If the selected PCM is a hazardous material, it may not be the best choice for medical supplies."

Minnesota Thermal Science, which cut its developmental teeth on portable containers for blood factors and other pharmaceuticals to be used under battlefield conditions by the U.S. Army, has an S-Series container that has a 3.6-cu.-in. payload and can maintain temperature for up to 72 hours.