



## Practice Good Shipping

If you ship products along the cold chain, you need to consider more than just packaging. You need to look closely at the chain itself. And that includes your shipping partners.

USP's General Chapter <1079> Good Storage and Shipping Practices makes this pretty clear. "Shippers and distributors are to follow the proper storage and shipping requirements as indicated by the manufacturer," it reads. "Manufacturers and distributors should work together to establish proper distribution and product-handling requirements for the purpose of ensuring appropriate product maintenance in transit."

All partners have a responsibility to ensure product integrity. But manufacturers are ultimately held accountable, says Henry Ames. He serves as director of strategic marketing for Sensitech Inc. (Beverly, MA). "Auditors are looking for manufacturer documentation on supply-chain partners. They'll ask, 'Why did you choose that carrier?'"

You are responsible for educating your partners, says Ames. You need to document your expectations, including standard operating procedures (SOPs), as part of your contract with carriers, he adds. Following SOPs is critical. "Eighty-plus percent of the problems we see are a direct result of someone not following SOPs," says Ames. "The variability in the system is rarely due to equipment failure or the random ice storm, although those definitely happen. The majority of problems occur because someone failed to follow SOPs."

Setting a good example is Jim Bacon, director of global demand planning and customer operations for Talecris Biotherapeutics. "We develop comprehensive shipping procedures

and go to great lengths to develop an understanding of them among our shippers," he says. "Where you pass the baton is your area of vulnerability." He adds that regulators do ask for validation on shippers and trucking procedures. "We have to review and approve the validation protocols of our shippers."

Working together to maintain product integrity builds relationships. "We foster partnerships so we go beyond the supplier-customer relationship," says Bacon. One of his partners, UTi (Union Transport International), is working closely with Talecris to satisfy its requirements.

Another partnership has emerged between international courier service DHL (Plantation, FL) and Wyeth Pharmaceuticals. DHL will now oversee clinical trial logistics material shipments and processes throughout multiple distribution channels worldwide.

"DHL was chosen to improve Wyeth's clinical trial materials distribution. [It will] increase efficiencies by uniting the flow of information and physical goods through automation, visibility, and improved collaboration," said Robert Krautheim, president of life science and healthcare at DHL.

Nonetheless, DHL is not responsible for validating the cold chain, says a company spokesperson. Wyeth retains responsibility for validation of the cold-chain process.

The lesson? Find a good shipping partner and document your SOPs and theirs. But remember—your responsibility stretches beyond packaging and into the supply chain.

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