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EDITORIAL

Filling Gaps in the Cold Chain

If you are sending products out into the cold chain, you've got to be thinking about more than just the package. Sure, your role is to ensure that your shipper maintains temperatures under extreme conditions during travel by land, air, or sea. But have you searched for any gaps in your solution? FDA just might be looking for them, warns Sanford Cook, CPP, Thermal Packaging Solutions LLC (Ocean, NJ).



Cook says that FDA is asking manufacturers to account for the gaps in their thermal packaging procedures. "What happens to drugs on the way to the packaging line? How much of the excursion temperature have you already used up to this point?" he asks. "How do you keep your gel packs frozen or chilled just before packaging? What about when they're on the shipping dock waiting for pickup? What about en route to the airport and where they're sorted before reaching the tarmac?"

Distributors can be a black hole, too, Cook says. "You cannot assume that distributors follow the same standards or will accept responsibility for handling. And what if they have to repackage it before its next journey? Product has to be protected all the way through the last mile, and repackaging is not always seamless. There are a million steps in between the manufacturer and the patient, and FDA is aware of the gaps, so you have to be able to defend how you are prepared for each of the events on the packaging line and in the supply chain."

Manufacturers should also address qualification of transport vehicles, training of delivery staff, and procedures for action when shipments deviate from required conditions. Shipment quality needs to be ensured where product is delivered to clinical settings. Qualification should include field testing of the transport channel.

Kevin O'Donnell, director and chief technical adviser to industry at SCA Packaging N.A., ThermoSafe Brands (Arlington Heights, IL), reports that distributors, wholesalers, and retailers are beginning to get involved with the Pharmaceutical Cold Chain Discussion Group (PCCDG), a working group of the Parenteral Drug Association (PDA). (For more on this group, see "Keeping Cool," beginning on page 46.) In fact, the Healthcare Distributors Management Association invited O'Donnell to help write guidelines for distributors and to speak at an upcoming committee meeting.

Additionally, O'Donnell is chairing a cross-industry committee of PCCDG members and others to write a chapter for the International Air Transport Authority's (IATA) Perishable Cargo Manual specific to the handling of pharmaceutical products.

Robust training programs will be required for parties handling product. One pharma participant at the Fourth Annual Cold Chain Distribution of Pharmaceuticals conference in Philadelphia said its company discovered that 95% of excursions stemmed from product mishandling.

Shippers have to discover how product is handled at end sites such as hospitals, whether end-users know how to store product properly, and whether they are qualified to make decisions about the temperature information they receive.

Senior editor David Vaczek contributed to this report.

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