

New Regulations for Frozen Shipping

“Maintaining the cold chain is the number one priority for life science companies operating in the Middle East,” Mohamed Nasser, M.D., managing director of Eli Lilly in Saudi Arabia, said in an interview. Maintaining the cold chain is a global concern with some two dozen nations recently developing or revising their pharmaceutical guidance for good distribution practices.

For example, Health Canada updated its temperature-controlled transportation guidelines (GUI-0069) in January 2011, calling for companies to develop written procedures for shipping pharmaceuticals, accounting for the nature of the products, local conditions, modes of transport and seasonal variations as well as any special handling requirements. The U.S. Pharmacopeia has similar guidance, and the PDA Technical Reports 39, 46, 52 and 53, covering transportation, last mile, good distribution practices and stability testing, have been updated in recent years.

Globally, regulators are focusing on packaging materials, data monitoring and innovation, according to Rafik H. Bishara, Ph.D., speaking at a Frozen Shipping Summit. Temperature monitoring and data logging are key criteria for many of the guidelines, as nations want assurance that pharmaceuticals and clinical samples do not experience temperature excursions that make them unusable, ineffective or dangerous.

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