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PDA at the Forefront of Meeting Temp Sensitive Challenges

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Can your company identify all the nodes of the supply chain for its temperature-controlled products? Can it describe its risk mitigation strategies to prevent damage to the product, theft, counterfeiting and a whole host of supply chain risks? Does it have a stability budget in place to assure the quality of product from the beginning of the distribution process to when it arrives in patients' hands?

Product integrity and supply chain visibility are of vital importance for manufacturers and suppliers of medicinal products to provide the right product with the right quality and quantity at the right time and place. During manufacturing, handling, storage and distribution these medicinal products are exposed to risk of damage, theft, temperature extremes, counterfeiting, tampering, and other conditions which might impact the product avail-

ability, efficacy, and quality to the end user: the patient. Application of risk mitigation actions should protect the patient, the product and the supply chain. Other solutions include implementation of good distribution practices (GDPs) related to regulation, contract management, temperature control and transport integrity and serialization of products.

PDA's Pharmaceutical Cold Chain Interest Group (PCCIG) has been at the forefront of many of these changes. Additional answers to your pressing question for distribution of temperature-controlled products can be found in many of the interest group's efforts, including *Technical Report No. 39 (Revised 2007): Guidance for Temperature-Controlled Medicinal Products*, *Technical Report No. 46: Last Mile*, *Technical Report No. 52: Guidance for Good Distribution Practices (GDPs) for the Pharmaceu-*

tical Supply Chain, *Technical Report No. 53: Guidance for Industry: Stability Testing to Support Distribution of New Products*, *Technical Report No. 58: Risk Management for Temperature-Controlled Distribution*, and *Technical Report No. 64: Active Temperature-Controlled Systems*.

In addition, to encourage additional dialogue on the topic, PDA Europe will hold a conference dedicated to supply chain and temperature-controlled product logistics in Berlin, Germany, Oct. 14–17. Representatives from numerous supply chain- and pharma-oriented organizations, along with international regulators and PCCIG members, will discuss current issues and help find solutions for common supply chain concerns.

For more information about this event, please visit the PDA Europe website at europe.pda.org/supplychain2014. 🍷