<1079> Good Storage and Distribution Practices for Drug Products

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Suggested audience: Drug Manufacturers, Wholesalers, Repackagers, and Pharmacies

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Background and objective(s): The sourcing and distribution of pharmaceutical materials and products, which are critical activities in any integrated pharmaceutical supply chain, involve packaging materials, active pharmaceutical ingredients, excipients, and final products such as pharmaceuticals, medical devices, and combination products.

With the globalization of the pharmaceutical industry, individuals and organizations from locations around the world are responsible for the handling, storage, and distribution of these products. Thus, it is critical to have adequate control over the entire supply chain—ranging from material procurement to manufacturing to delivery of a final product to the patient.

To maintain the quality of products, every organization involved in the supply chain should understand and comply with the applicable requirements and ensure each activity in the distribution of a product is carried out according to the principle of Good Distribution Practices (GDP).

The objective for this chapter is to identify common risks in the storage and transportation of finished drug products and recommend mitigation strategies for these risks. Instead of prescribing specific risk management approaches or discussing the regulatory framework that is currently in place, this informational chapter seeks to focus on storage and transportation risks and mitigation strategies which will enhance quality assured processes and maintain product and supply chain integrity

Anticipated proposed design phase activities: N/A

Anticipated implementation timing: Routine

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