

Introduction to Cold Chain Management–Part II

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Cold chain is the supply and distribution chain for products that must be kept within a specific temperature range. Compliance practitioners must be aware of the regulatory requirements and appropriate practices to ensure that the handling and distribution of drug products and their components are under good control. Government agencies and industry organizations intend to assure the quality, efficacy, and safety of the drug products being distributed to the public. PDA Technical Reports No. 39 and No. 46 provide guidance for the quality of temperature sensitive drug products through the supply...

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