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ISPE recognized the need for guidance in this area a dedicated team of subject matters experts from across the pharmaceutical and biopharmaceutical industries developed the ISPE Good Practice Guide: Cold Chain Management. This Guide provides tools and strategies for Cold Chain Management and to complement work by the Guidance for Temperature Controlled Medicinal Products. It helps to develop, establish, document, implement, maintain and improve industry good practice for product requiring ...

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ISPE recognized the need for guidance in this area a dedicated team of subject matters experts from across the pharmaceutical and biopharmaceutical industries developed the ISPE Good Practice Guide: Cold Chain Management. This Guide provides tools and strategies for Cold Chain Management and to complement work by the Guidance for Temperature Controlled Medicinal Products.

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The approach described is consistent with that described in the ISPE Good Practice Guide: Cold Chain Management. Guidance is provided on Controlled Temperature Chambers used to store raw material, work in progress, or finished product, and which operate under current Good Manufacturing Practices (cGMPs).

~~Good Practice Guide: Controlled Temperature Chamber~~

Full Title: ISPE Good Practice Guide: Cold Chain Management . Pages: 140 . Published: 2011-05-09 . Good Practice Guide: Commissioning & Qualification of Pharma Water & Steam Systems (Second Edition)

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||ISPE Good Practice Guide: Cold Chain Management |USP 1079 / 1083 . Cold Chain Components . 1. Stability Data (Technical Documents) |Excursion Budget 2. Shipping System PQ (IQ and / or OQ) |Every shipment |Sample 3. Equipment |Thermometers |Refrigeration units

~~Cold Chain 101 The First Steps - PDA~~

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Organizations need adequate control over cold chain of pharmaceutical and biopharmaceutical distribution systems. ISPE recognized the need for guidance in this area a dedicated team of subject matters experts from across the pharmaceutical and biopharmaceutical industries developed the ISPE Good Practice Guide: Cold Chain Management.

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This Guide aims to provide an example of howthe principles discussed in the ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment, and theISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification may be applied to GMP water and steam systems.

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ISPE Good Practice Guide: Cold Chain Management The industry needs specific guidance on how to attain consistency in the transport of the products requiring specific parameters to maintain safety, efficacy and quality of the medicinal product during transportation from the manufacturer to the consumer.

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This guide serves as a companion to other ISPE guides available, such as ISPE Baseline Pharmaceutical Engineering Guide, Volume 4|Water and Steam Systems. REFERENCE ISPE Releases ISPE Good Practice Guide: Critical Utilities GMP Compliance [news release]. North Bethesda, MD: International Society for Pharmaceutical Engineering; July 16, 2020.