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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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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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~~Cold Chain Management | ISPE | International Society for~~

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~~

In addition to suggestions for effective and compliant booklet label design, the ISPE Good Practice Guide: Booklet Labels includes recommendations and justification for placement of required information and whether it should be included on the label or elsewhere. This Guide is a valuable tool you can use to perform a gap analysis on your ...

~~Good Practice Guide: Booklet Labels | guidance.does.ispe.org~~

The ISPE Good Practice Guide: HVAC and Process Equipment Air Filters aims to be a valuable reference on the selection, application, specification, testing, and operation and maintenance of filters in the pharmaceutical industry. This Guide is intended to be used as supplement to the ISPE Good Practice Guide: Heating, Ventilation, and Air ...

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Good Practice Guide: Cold Chain Management - ISPE Entitled ISPE Good Practice Guide: Critical Utilities GMP Compliance|How to Be Compliant and Ready to Prove It, the guide also helps to efficiently...

~~Ispe Good Practice Guide: Good Engineering Practices~~

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.

~~Item Detail | ISPE GPG: Cold Chain Management (Download) | USP~~

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

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The ISPE Good Practice Guide: Process Gases aims to define current good practices within pharmaceutical manufacturing applications, providing information to allow organizations to benchmark their practices, and improve upon them.

~~Good Practice Guide: Process Gases | ISPE~~

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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The ISPE Good Practice Guide: Asset Management provides practical guidance for establishing an asset management system that enables organizations to realize increased value from their assets, both physical and non-physical. This Guide identifies best practices in strategic asset management as outlined in the ISO 55000 series of standards.

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The ISPE Good Practice Guide: Quality Laboratory Facilities is a comprehensive guide to defining design guidelines for Quality Laboratories supporting GxP-regulated facilities producing pharmaceutical products for human and animal applications. It provides a step-by-step process that guides the reader through all phases of producing a quality ...

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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.