

Ispe Good Practice Guide Good Engineering Practice

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Good Practice Guides. 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 Conditioning (HVAC), providing detailed information into the subject of air filters in HVAC and process equipment applications.

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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.

Good Practice Guide: Asset Management | ISPE ...

This first edition of the ISPE Good Practice Guide: Good Engineering Practice covers the complete lifecycle of engineering from concept to retirement. The Guide: Aims to promote a common understanding of the concept and principles of GEP defines and explains the term "Good Engineering Practice".

Good Practice Guide: Good Engineering Practice

ISPE - HVAC Good Practice Guide - Heating, Ventilation, and Air Conditioning

(PDF) ISPE - HVAC Good Practice Guide | Tran Thi Thuy Sen ...

The ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC) systems can be critical systems that affect the ability of a pharmaceutical facility to meet its objective of providing safe and effective product to the patient.

Hvac Ispe Good Practice Guide

The ISPE GAMP® RDI Good Practice Guide: Data Integrity - Key Concepts provides detailed practical guidance to support data integrity within a regulated organization. In recent years significant problems with data integrity have been found in the pharmaceutical, biotechnology, and medical

device industries worldwide.

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This first edition of the ISPE Good Practice Guide: Good Engineering Practice covers the complete lifecycle of engineering from concept to retirement.

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The ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC) provides designers and project teams with suggestions to help determine the user requirements and the functional design that define the facility's objectives. It also provides options to be considered in creating a design that has low lifecycle cost and is sustainable.

Good Practice Guide: Heating, Ventilation, & Air ... - ISPE

Covering a wide variety of manufacturing types, the ISPE Good Practice Guide: Practical Implementation of the Lifecycle Approach to Process Validation is a reference of technical and scientific detail to help organizations conduct process validation from scientifically sound development to robust reliable processes.

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Produced by pharmaceutical manufacturing industry professionals, ISPE Guidance Documents provide the practical, "real world" information you need to help your company build on current best practices to meet and exceed regulatory standards.

Pharmaceutical Facility Publications and Guidance ... - ISPE

The ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry provides good practice approaches which promote the successful integration of GxP with relevant project management activities to ensure that compliance risk is managed effectively and proactively.

Good Practice Guide: Project Management for Pharmaceutical ...

It helps to develop, establish, document, implement, maintain and improve industry good practice for product requiring controlled cold conditions. The Guide is intended to provide practical guidance to assist in the specification, design, commissioning and verification of the fixed and passive systems within the cold chain.

Good Practice Guide: Cold Chain Management

Pharmacoepidemiologic studies provide valuable information about the health effects of healthcare products. The ISPE Guidelines for Good Pharmacoepidemiology Practice (GPP) are intended to assist investigators with issues pertaining to the planning, conduct, and interpretation of pharmacoepidemiologic research.

Guidelines for Good Pharmacoepidemiology Practices (GPP ...

The ISPE Good Practice Guide: Single-Use Technology provides information for efficient implementation of single-use technology. This Guide is solely created and owned by ISPE. It is not a regulation, standard or regulatory guideline document.

ISPE Good Practice Guide: Single-Use Technology

The ISPE Good Practice Guide: Maintenance provides practical solutions and tools for ensuring quality and compliance of maintenance operations in

a regulated industry.

Good Practice Guide: Maintenance

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.

Good Practice Guide: Booklet Labels - ISPE Publications Home

The ISPE Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring provides industry good manufacturing practices for the temperature mapping of controlled temperature chambers, along with development of test acceptance criteria and a risk-based approach to practices for periodic review of system performance.

Good Practice Guide: Controlled Temperature Chamber ...

The ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities provides pharmaceutical industry examples, along with checklists, templates, flowcharts and example documents, currently in use in decommissioning of pharmaceutical equipment and facilities in the USA and Europe.

Good Practice Guide: Decommissioning Pharma Equipment ...

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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