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a common understanding of the concept and principles of GEP defines and explains the term “Good Engineering Practice”

Good Practice Guide: Good Engineering Practice

Good engineering practice, which includes elements of project

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management and project controls, ensures the following: Systems are specified, designed, and installed and operate in a manner that meets operational, maintenance, safety, health, environmental, ergonomic, industry, statutory, and regulatory requirements—including GxP requirements.

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The ISPE Good Practice Guide on the Management of Engineering Standards aims to provide a common understanding and approach to the management of Engineering Standards. It is based on industry best practices and

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developed with input from several peer organizations. The Guide addresses the knowledge management needs associated with the identification of content, creation, review, and approval of ...

Good Practice Guide: Management of Engineering ... - ISPE

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ISPE has published a new Good Practice Guide: Critical Utilities GMP Compliance—How to Be Compliant and Ready to Prove It. Written and reviewed by a team of experts from around the world, the guide is the first of its kind in the industry. Team co-leads Nik Krpan and Rod Freeman talked with Pharmaceutical Engineering® about the

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importance of critical utilities and the benefits of the new guide.

New ISPE Good Practice Guide on Critical Utilities ...

The ISPE Good Practice Guide: Management of Engineering Standards provides guidance on how to establish and maintain an Engineering Standards

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Program. It covers the entire lifecycle of an Engineering Standard, from chartering to retirement. In addition, it includes a description of the governance process for the Engineering Standards Program.

Good Practice Guide: Management of Engineering Standards

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Single-use technology has grown in both complexity of design and criticality of application in the past twenty years, offering increased flexibility while significantly reducing the risk of contamination in manufacturing equipment. The implementation of single-use technology into a process requires a well-defined plan that

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minimizes surprises during the later stages of implementation.

Good Practice Guide: Single-Use Technology | ISPE ...

Good Practice Guides. The ISPE Good Practice Guide: HVAC and Process Equipment Air Filters aims to be a valuable reference on the selection,

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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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Good Practice Guides | ISPE | International Society for ...

GAMP Good Practice Guides GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems provides pragmatic and practical industry guidance that aims to achieve compliant computerized systems that are fit for

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intended use in an efficient and effective manner, while also enabling innovation and technological advances.

Guidance Documents | ISPE - ISPE | International Society ...

Published. December 2019. The ISPE Good Practice Guide: HVAC and Process Equipment Air Filters aims to be a

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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

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equipment applications.

ISPE - International Society for Pharmaceutical Engineering

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understanding of the concept and principles of GEP defines and explains the term “Good Engineering Practice”

Item Detail - ISPE GPG: Good Engineering Practice (Bound ...

This third edition of the ISPE Good Practice Guide: Technology Transfer, highlights the following: Alignment with

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science and risk-based (Quality by Design (QbD)) principles described in ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, ICH Q10 Pharmaceutical Quality System, and ICH Q11 Development and Manufacture of Drug ...

Good Practice Guide: Technology

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Transfer (Third Edition)

The ISPE Good Practice Guide: Management of Engineering Standards provides guidance on how to establish and maintain an Engineering Standards Program. It covers the entire lifecycle of an Engineering Standard, from chartering to retirement. In addition, it includes a description of the governance

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process for the Engineering Standards Program.

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Effective project progress, monitoring, and control are not regulatory issues, but are necessary for the efficient operation of a company and part of Good Engineering Practice (GEP).

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Entitled ISPE Good Practice Guide: Critical Utilities GMP Compliance—How to Be Compliant and Ready to Prove It, the guide also helps to efficiently show that the critical utility systems established demonstrate good

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manufacturing practice (GMP) compliance to regulatory inspectors and auditors.

ISPE Releases a Good Practice Guide on Critical Utilities ...

Operations Management designs, operates, and improves supply chain systems for getting work done. The ISPE

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Good Practice Guide: Operations Management aims to provide the pharmaceutical industry with a knowledge base to promote the use of best practices and operational excellence within pharmaceutical operations management.

Good Practice Guide: Operations

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Management

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.

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Good Practice Guide: Process Gases - ISPE Publications Home

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

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industries developed the ISPE Good Practice Guide: Cold Chain Management.

Good Practice Guide: Cold Chain Management

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