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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. The Guide: The Guide: Defines and explains the term “Good Engineering Practice” and aims to promote a common understanding of the concept and principles of GEP

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Good Practice Guide: Good Engineering Practice

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 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 ...

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Good engineering practice, which includes elements of project 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.

Good Engineering Practice in Risk-Based Commissioning

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

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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 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

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

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

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

The ISPE Good Practice Guide: Maintenance provides practical solutions and tools for ensuring quality and compliance of maintenance operations in a regulated industry. Covering current and established practices, this guide helps achieve technical and regulatory accuracy and cost-effective compliance in a new or an existing maintenance program for effective strategy and efficiency.

Good Practice Guide: Maintenance | ISPE | International

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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

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computerized systems that are fit for intended use in an efficient and effective manner, while also enabling innovation and technological advances.

Guidance Documents | ISPE - ISPE | International Society

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December 2019. 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.

ISPE - International Society for Pharmaceutical Engineering

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Good Engineering Practice documentation standards The intent of this revision to the Guide is to help the pharmaceutical industry simplify and improve the C&Q process by bringing the “best of the best” together into one document. This Guide also combines concepts from regulatory guidances (e.g., from EMA, FDA, ISO).

Baseline Guide Volume 5: Commissioning and Qualification ...

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 process for the Engineering Standards Program.

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The ASTM standard (E2500) builds on the concepts of GEPs and has substantial implications for reductions in cost and time for pharmaceutical capital investment projects. This first edition of the ISPE Good Practice Guide: Good Engineering Practice covers the complete lifecycle of engineering from concept to retirement.

ISPE Good Practice Guide: Good Engineering Practice

Entitled ISPE Good Practice Guide: Critical Utilities GMP

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

ISPE Releases a Good Practice Guide on Critical Utilities

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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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