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

Good Practice Guide: Good Engineering Practice | ISPE ...

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GEP defines and explains the term “ Good Engineering Practice ”

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 Engineering Standards.

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

Good engineering practice, which includes elements of project management and project controls, ensures the following: Systems

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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: 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
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

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benefits of the new guide.

New ISPE Good Practice Guide on Critical Utilities ...

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: Maintenance provides practical solutions and tools for ensuring quality and compliance of maintenance operations in a regulated industry.

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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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Item Detail - ISPE GPG: Good Engineering Practice (Bound ...
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
ISPE announced the release of its latest guide, ISPE Good Practice Guide: Critical Utilities GMP Compliance – How to Be

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Compliant and Ready to Prove It. The Guide was cultivated by leading experts to help pharmaceutical organizations achieve and maintain their critical utility systems in a state of control, and then be able to efficiently demonstrate their systems ' Good Manufacturing ...

ISPE Releases ISPE Good Practice Guide: Critical Utilities ...
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 Publications Home
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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GAMP Good Practice Guides GAMP 5: A Risk-Based Approach to

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Compliant GxP Computerized Systems provides pragmatic and practical industry guidance that aims to achieve compliant 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 ...
Online access to select ISPE Good Practice Guides that will help you learn how to practically implement best practices and principles; Member-only discounts on Guidance Documents, Conferences, and Training; Pharmaceutical Engineering® magazine; Communities of Practice access to pharma professionals in specific topics from around the world; And ...

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Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and

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packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is 'current good manufacturing practice (CGMP)', which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which

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build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

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