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Reflecting current regulatory expectations and good practices for automated/computerized systems, the GAMP series of Good Practice Guides help to narrow interpretation of regulatory standards for improved compliance and quality, efficiency, and cost reductions. They typically focus on

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the “how”.

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Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved

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in any pharmaceutical production that cannot be eliminated through testing the final product.

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Full Description Good Engineering Practices (GEPs) consist of proven and accepted engineering methods,

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procedures, and practices that provide appropriate, cost-effective, and well-documented solutions to meet user-requirements and compliance with applicable regulations.

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The ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)

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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. The ISPE Good Practice Guide on HVAC provides designers and the project team with suggestions to help determine the user requirements and the functional design that define the facility's

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objectives.

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The ISPE GAMP® RDI Good Practice Guide: Data Integrity - Manufacturing Records provides practical and pragmatic advice on areas such as regulated records, data flows, and risk

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management approaches, with particular focus on process control systems, manufacturing execution systems, and the interfaces and relationship between them.

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Good Engineering Practices (GEPs)

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consist of proven and accepted engineering methods, procedures, and practices that provide appropriate, cost-effective, and well-documented solutions to meet user-requirements and compliance with applicable regulations.

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The ISPE 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.

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Good Engineering Practices (GEPs) consist of proven and accepted engineering methods, procedures, and practices that provide appropriate, cost-effective, and well-documented solutions to meet user-requirements and compliance with applicable regulations.

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ISPE Good Practice Guide: Good Engineering Practice [ISPE] on Amazon.com. *FREE* shipping on qualifying offers. Good Engineering Practices (GEPs) consist of proven and accepted engineering methods, procedures, and practices that provide appropriate

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ISPE 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

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developed with input from several peer organizations.

ISPE - International Society for Pharmaceutical Engineering

Good Engineering Practice Core Concepts Risk Management Risk management is at the core of CEP activity such that there is a balanced

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evaluation of risks against Where practicable efforts should be made to desen out or minimize Identified risks to an I: Identify A regulated company should WentWy significant rigks which may threaten its activRies.

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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 developed with input from several peer organizations.

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Good Practice Guide: Operations Management

International Society for Pharmaceutical Engineering ISPE provides education, training, forums, and technical documents for professionals in pharmaceutical manufacturing. The Society publishes best-practice guides on a wide array of topics, including bulk

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pharmaceutical chemicals, sterile manufacturing facilities, commissioning and qualification, biopharmaceutical manufacturing facilities, and technology transfer.

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

6.6.2 Good Engineering Practice is

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defined as those established engineering methods and standards that are applied throughout the life cycle to deliver appropriate and effective solutions.

6.6.3 Examples of Good Engineering Practices include: 6.6.3.1 Specification, design, and installation activities

Good Practice Guide: Good

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Engineering Practice

ISPE Good Practice Guides Reflecting current regulatory expectations and best practices, Good Practice Guides (GPGs) help to narrow interpretation of regulatory standards for improved compliance and quality, efficiency, and cost reductions. They typically focus on the “how”.

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Good Practice Guide: Management of Engineering Standards

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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