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The ISPE Baseline® Guide: Commissioning and Qualification (Second Edition) provides practical guidance on the implementation of a science and risk-based approach for the Commissioning and Qualification (C&Q) of pharmaceutical manufacturing facilities, systems, utilities, and equipment to demonstrate that they are suitable for the intended purpose.

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Existing risk-based approaches to computerized system compliance and validation as outlined in GAMP® 5 International Society for Pharmaceutical Engineering. GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems. North Bethesda, MD: International Society for Pharmaceutical...

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This revised Guide builds on the original principles of ISPE's Baseline® Guide Volume 1, Active Pharmaceutical Ingredients, (originally entitled Bulk Pharmaceutical Chemicals). The ISPE API Baseline Guide also incorporates and builds on new regulations and guidance, such as: ICH Q7; ICH Q9; GAMP 4; 21 CFR Part 11

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The ISPE Baseline® Guide: Commissioning and Qualification (Second Edition) provides practical guidance on the implementation of a science and risk-based approach for the Commissioning and Qualification (C&Q) of pharmaceutical manufacturing facilities, systems, utilities, and equipment to demonstrate that they are suitable for the intended purpose.

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Guide supports the application of science and risk management approaches, a focus on product and process ...

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ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Third Edition) aims to offer a consistent interpretation of the latest FDA and EMA guidance, while allowing a flexible and innovative approach to facility design. The Guide is based on key principles such as: the need to understand product and process requirements, use of risk-based approaches, role of barrier and isolator technology, use of consistent terminology for classified environments, categories for processing (open ...

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The International Society for Pharmaceutical Engineering (ISPE) released its newest guide to help pharmaceutical organizations

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achieve and maintain control in their critical utility systems.

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2 PHARMACEUTICAL ENGINEERING July/August 2012 Rouge in Stainless Steel tions material storage conditions, installation environment,, grinding, buffing, passivation state, and treatment, etc.). 3. Process Environment – what process service conditions the system is exposed to (e.g., corrosive process fluids,

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The ISPE Baseline Guide® Water and Steam Systems (Third Edition) aims to assist with the design, construction, operation, and lifecycle management of new and existing water and steam systems. It is intended to help meet Good Manufacturing Practices (GMPs) and comply with regulations and related guidance.

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The ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) Second Edition provides a scientific risk-based approach, based on ICH Q9 Quality Risk Management, for managing the risk of cross-contamination within shared facilities.

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Introduction to ISPE's Risk-MaPP Baseline Guide This fundamental course will help you understand the “why,” what,” and “how to use” the ISPE Baseline® Guide, Risk-Based Manufacturing of Pharmaceutical Products (Risk-MaPP).

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