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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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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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Baseline Guide Volume 5: Commissioning and Qualification ...
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 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.

Baseline Guide Volume 7: Risk-Based Manufacture of Pharma ...
Existing risk-based approaches to computerized system compliance and

validation as outlined in GAMP® 5International 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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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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ISPE Baseline Guide 12 Draft Verification guide FDA: Quality Systems Approach to Pharmaceutical cGMP Regulations – 2006 EU Annex 20, Quality Risk Management – March 2008 ICH Q8 Pharmaceutical Development - Nov 2005 ICH Q10 – Quality Systems – June 2008

Best Practices Commissioning & Validation
The ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Third Edition) covers engineering aspects of designing new sterile products manufacturing facilities and modifications of existing facilities. The Guide focuses on how to provide cost-effective facilities which make best use of available modern technologies to ensure that products of the highest quality are consistently manufactured.

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Baseline Guide Volume 1: Active Pharmaceutical Ingredients
This second edition of the ISPE Baseline® Guide: Biopharmaceutical Manufacturing Facilities intends to further reinforce the concepts described in the first edition of the Guide, provide examples of how these concepts can be put into practice, and detail the value and benefits of the approach described.

Baseline Guide Volume 6: Biopharmaceutical Manufacturing ...
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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