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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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Special Pricing for Emerging Economies. 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.

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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 Biopharmaceutical Manufacturing Facilities Baseline ® Guide explores products and facilities that house biotechnological processes. More specifically, it applies to process design ties to facility design, controlled processing, preventing contamination, and segregation and flow.

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