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This ISPE Guide will provide a new approach to meeting regulatory expectations for cleaning and offer a fresh perspective on approaches to cleaning and its validation based on science and risk.

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This second edition of the ISPE Good Practice Guide: Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems, discusses practices and activities associated with the commissioning and qualification (verification) of pharmaceutical water and steam systems. The guide focuses on items which directly affect quality ...

Good Practice Guide: C&Q of Pharma Water & Steam ... - ISPE

The ISPE Good Practice Guide: Quality Laboratory Facilities is a comprehensive guide to defining design guidelines for Quality Laboratories supporting GxP-regulated facilities producing pharmaceutical products for human and animal applications. It provides a step-by-step process that guides the reader through all phases of producing a quality lab and all the factors that must be considered at each phase.

Good Practice Guide: Quality Laboratory Facilities

The guide focuses on items which directly affect quality attributes of water or steam during production, storage, and distribution. Both High Purity Water and Pure (Clean) Steam are considered and information on other types of pharmaceutical water and steam is also provided.

Good Practice Guide: Commissioning & Qualification of ...

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ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP), September, 2010 Fourman, G., and Mullin, M., "Determining Cleaning Validation Acceptance Limits for Pharmaceutical Manufacturing Operations," Pharmaceutical Technology, April 1993 FDA Guidance: Guide to Inspections Validation of Cleaning Processes, July 1993

Current Trends in Cleaning Validation

The ISPE Good Practice Guide: Maintenance provides practical solutions and tools for ensuring quality and compliance of maintenance operations in a regulated industry. Covering current and established practices, this guide helps achieve technical and regulatory accuracy and cost-effective compliance in a new or an existing maintenance program for effective strategy and efficiency.

Good Practice Guide: Maintenance

The ISPE Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring provides industry good manufacturing practices for the temperature mapping of controlled temperature chambers, along with development of test acceptance criteria and a risk-based approach to practices for periodic review of system performance.

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CONFIDENTIAL 4 1.0 FOREWORD This guidance document was updated in 2014 by the APIC Cleaning Validation Task Force on behalf of the Active Pharmaceutical Ingredient Committee (APIC) of CEFIC.

GUIDANCE ON ASPECTS OF CLEANING VALIDATION IN ACTIVE ...

ISPE'S NEW GPG: PHARMA WATER CHAPTER Joe Manfredi GMP Systems, Inc. Connecting Pharmaceutical Knowledge ispe.org
ISPE GOOD PRACTICE GUIDE: SAMPLING FOR PHARMACEUTICAL WATER, PHARMACEUTICAL STEAM, ... hot, hence disposal cannot be overlooked. Sampling in clean environments may be complicated by the lack of accessible drains and other issues. 2 ...

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The ISPE guide states that "Evaluation of the cleaning validation data is the only way to ensure that any residuals after cleaning are as low as possible below the health-based criteria..." [emphasis added] (page 43) It sounds like the guide, while arguing that limits in some cases are more stringent than they need to be, suggests that manufacturers should still clean to residue levels as low as possible.

A Critique of Cleaning Validation Issues in ISPE's RiskMaPP

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