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GAMP Good Practice Guide: Testing GxP Systems (Second Edition)

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The GAMP ® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition)provides guidance in setting up a calibration management system, which will give a structured approach to instrument risk assessment, calibration program management, documentation, and corrective actions, essential to regulatory compliance. The Guide has been updated to address the changing environment, while still satisfying international GxP regulatory expectations.

The ISPE GAMP Good Practice Guide: IT Infrastructure Control and Compliance (Second Edition) is intended to provide comprehensive guidance on meeting regulatory expectations for compliant IT (Information Technology) Infrastructure platforms, both traditional and cloud-based. The increasing prevalence of new technology has presented regulated companies with significant technological advantages, as well as a changed compliance model.

Recently updated to conform with GAMP® 5 concepts and terminology, as well as recent regulatory and industry developments, the ISPE GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems (Second Edition) contains steps that scientists, suppliers and others involved in managing laboratory computerized system acquisition, implementation, and operations can use to verify laboratory systems are fit for their intended use.

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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 management approaches, with particular focus on process control systems, manufacturing execution systems, and the interfaces and relationship between them. Additionally, system-specific examples of topics such as segregation of duties and critical validation activities to support data integrity are discussed.

The ISPE GAMP ® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data (Good eClinical Practice) is intended to provide a risk-based approach to validating diverse computerized GCP systems in compliance with applicable regulations.

This Guide provides a rational and scaleable approach to electronic data archiving through the development of an archiving strategy. The implementation of such a strategy should assist organizations to achieve and maintain regulatory compliance, and to more effectively manage electronic records over the long term.

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GAMP RDI Good Practice Guide: Data Integrity ...

This GAMP Good Practice Guide helps the reader to maximize testing efficiency without compromising the quality of GxP Systems by focusing testing on areas that have the greatest impact and eliminating duplicate testing.

The ISPE GAMP® RDI Good Practice Guide: Data Integrity – Key Concepts provides detailed practical guidance to support data integrity within a regulated organization. In recent years significant problems with data integrity have been found in the pharmaceutical, biotechnology, and medical device industries worldwide.

GAMP Good Practice Guide: Manufacturing Execution Systems Full Title: ISPE GAMP Good Practice Guide: Manufacturing Execution Systems - A Strategic and Program Mgmt Approach . Pages: 144 . Published: 2010-02-25 . Table of Contents pages: 1 2 Preface 2 4; Acknowledgements 3 5;

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It replaces the previous ISPE GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures. This Guide has been developed by the GAMP Community of Practice (CoP) of ISPE; a worldwide community of practitioners and subject matter experts who over twenty-five years have been developing internationally accepted guidance on risk-based approaches to safeguard patient safety, product quality, and data integrity.

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