Good Practice Decommissioning Pharma Ispe

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COOK GINA

ISPE Baseline® Guide Routledge With its coverage of

Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

21 CFR Part 11 Ispe Headquarters

GAMP 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an

automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.
ISPE Baseline® Guide: Volume 5 - Commissioning and Qualification Ispe
The pharmaceutical industry has encountered major shifts in recent years, both within the industry, and in its external environment. The cost of healthcare rising due to an ageing population, the intensification of regulatory requirements and mergers within the industry have led to an increased need for restructuring, cost reduction and culture change projects. Project management is the key to addressing these needs, and also to effective drug development. Given the costs of development and the critical issue of 'time to market', project management techniques - appropriately used - are a key factor in bringing a drug to market. In this book, Laura Brown and Tony Grundy's pharmaceutical expertise and experience offers the reader a guide to the most relevant project management tools and

techniques and how to rigorously apply them in the pharmaceutical industry. The authors cover the technical, strategic and human aspects of project management, including contingency planning, simulation techniques and different project options. Complete with decision-tree diagrams, checklists, exercises and a full glossary, Project Management for the Pharmaceutical Industry provides clinical research, drug development and quality assurance managers or directors with a one-stop reference for successfully managing pharmaceutical projects. The text has been revised for this edition and now includes some additional material on risk management.

Pharmaceutical Manufacturing Handbook John Wiley & Sons

This book helps advance process safety in a key area of interest. Currently, no literature exists which is solely dedicated to process safety for the bioprocessing industry. There are texts, guidelines, and standards on biosafety at the laboratory level and for industrial hygiene, but no guidelines for large-scale production facilities. In fact, biosafety is largely defined as a field that promotes safe laboratory practices, procedures and use of containment equipment and facilities. Additionally, biomedical engineers, biologists, or other

professionals without chemical engineering training or knowledge of inherently safe design are designing many of these facilities.

ISPE Good Practice Guide Springer Science & Business Media

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

ISPE Good Practice Guide: Commissioning and Qualification of Pharmaceutical Water and Steam Systems Academic Press

Today's best practice in environmental mine-waste management requires a thorough understanding of the wastes produced. The knowledge of mine wastes represents a new interdisciplinary science and this book provides an introductory, descriptive and analytic overview of the wastes produced in the mineral industry. It describes the characterization, prediction, monitoring, disposal and treatment

as well as environmental impacts. Intended for undergraduate courses, it systematically builds the reader's understanding and knowledge of the wastes produced, their physical and chemical characteristics, and how to deal responsibly with them on a short and long-term basis. The text employs 22 case studies spanning the world's mineral industry that elucidate best practice and specific challenges in mine-waste management and site rehabilitation.

Pharmaceutical Production John Wiley & Sons

Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews regulations of pharmaceuticals, healthcare products, blood processing, medical devices, clinical systems, and biotechnology. Ensuring that organizations transition smoothly to the new system, this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices. In addition, all 24 case studies from the

previous edition have been revised to reflect the new system. *Good Design Practices for GMP Pharmaceutical Facilities* CRC Press Covering regulatory requirements stipulated by the FDA, this book delineates the organization, planning, verification, and documentation activities and procedural controls required for compliance with worldwide computer systems validation regulations. The author introduces supporting technologies such as encryption and digital signatures and places *ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment* CRC Press The pharmaceutical industry has encountered major shifts in recent years, both within the industry, and in its external environment. The cost of healthcare rising due to an ageing population, the intensification of regulatory requirements and mergers within the industry have led to an increased need for restructuring, cost reduction and culture change projects. Project management is the key to addressing these needs, and also to effective drug development. Given the costs of development and the critical issue of 'time to market', project management techniques - appropriately used - are a key factor in

bringing a drug to market. In this book, Laura Brown and Tony Grundy's pharmaceutical expertise and experience offers the reader a guide to the most relevant project management tools and techniques and how to rigorously apply them in the pharmaceutical industry. The authors cover the technical, strategic and human aspects of project management, including contingency planning, simulation techniques and different project options. Complete with decision-tree diagrams, checklists, exercises and a full glossary, Project Management for the Pharmaceutical Industry provides clinical research, drug development and quality assurance managers or directors with a one-stop reference for successfully managing pharmaceutical projects. The text has been revised for this edition and now includes some additional material on risk management.

ISPE Good Practice Guide John Wiley & Sons

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those

regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

Guidelines for Process Safety in Bioprocess Manufacturing Facilities Ispe Headquarters

This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.

ISPE Good Practice Guide John Wiley & Sons

Equipment Qualification in the Pharmaceutical Industry provides guidance and basic information for the preparation of a quality qualification program. It has been noted that there is a general lack of understanding in the industry, especially for those new to the industry, as to what constitutes a compliant qualification program.

Even experienced professionals have felt a lack of security in reaching a compliant state. This book outlines a guideline for the preparation and execution of qualification protocols including the installation (IQ), operational (OQ), and performance (PQ) protocols. It discusses the importance of related qualification programs (e.g., quality systems, commissioning, computer system, and cleaning) and how to incorporate them into a fully compliant qualification program. Furthermore, it provides matrices of what could be included in each type of protocol for major types of process equipment. While primarily for people entering the pharmaceutical industry, those established in the field will benefit from the multiple examples and matrices as well as integration of related systems. Equipment Qualification in the Pharmaceutical Industry provides students and pharmaceutical scientists a guideline for the preparation and execution of qualification (installation, operational, and performance) protocols. Incorporates good manufacturing processes into a compliant qualification program Provides examples of protocol layout Includes matrices for major process equipment, installation quality, operational quality,

and performance quality requirements

ISPE GAMP® RDI Good Practice Guide CRC Press

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

GAMP Good Practice Guide IChemE

Analytical Method Validation and Instrument Performance Verification Gower Publishing, Ltd.

ISPE Good Practice Guide

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ISPE Baseline® Guide: Volume 7 - Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) ISPE Good Practice Guide