Ispe Baseline Pharmaceutical Engineering Volume 5

Volume 3 - Sterile Product Manufacturing Facilities
Quality Assurance of Pharmaceuticals
Calibration Management
ISPE Baseline® Guide
ISPE Baseline® Guide
Quality Standards in the Pharmaceutical and Regulated Industries
Encyclopedia of Pharmaceutical Technology
Pharmaceutical Quality by Design
Biopharmaceutical Manufacturing Facilities
Manufacturing of Pharmaceutical Proteins
A Guide to Managing Risks Associated with Cross-contamination
Pharmaceutical Manufacturing Handbook
ISPE Guide
A Risk-based Approach to Compliant GxP Computerized Systems
ISPE Good Practice Guide
Theory, Practice, and Tools
ISPE Baseline® Guide
Baseline Pharmaceutical Engineering Guide for New and Renovated Facilities: Active pharmaceutical ingredients
Bulk Pharmaceutical Chemicals
GAMP Good Practice Guide
Good Design Practices for GMP Pharmaceutical Facilities, Second Edition
ISPE Baseline Guide
A Practical Approach
From Technology to Economy
Volume 5 - Commissioning and Qualification
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Sterile Product Manufacturing Facilities
Sterile Product Development
Volume 3 - Sterile Manufacturing Facilities
Oral Solid Dosage Forms
Facility Validation
Process Architecture in Biomanufacturing Facility Design
Science and Risk-based Approach for the Delivery of Facilities, Systems, and Equipment
ISPE Baseline® Guide
Good Manufacturing Practices for Pharmaceuticals, Seventh Edition
Rules of Thumb for Chemical Engineers
Formulation, Process, Quality and Regulatory Considerations
fifty-fifth report
Sterile Manufacturing Facilities

ALENA ALEX

Volume 3 - Sterile Product Manufacturing Facilities
Springer Science & Business Media
Relying on practical examples from the authors' experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks

Quality Assurance of Pharmaceuticals Elsevier
A guide for engineers and designers new to the field of bio-pharmaceutical process control. For the experienced automation professional, it outlines the unique design and application issues for the bio-pharmaceutical industry. For those already familiar with this industry, it provides specific advice for automating these

processes.
Calibration Management CRC Press
Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture
ISPE Baseline® Guide CRC Press
Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com
ISPE Baseline® Guide World Health Organization
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.
Quality Standards in the Pharmaceutical and Regulated Industries ISA
This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce
Encyclopedia of Pharmaceutical Technology John Wiley & Sons
Annotation A handbook for chemical and process engineers who need a solution to their practical on-the-job problems. It solves process design problems quickly, accurately and safely, with hundreds of techniques, shortcuts and calculations.
World Health Organization
Completely revised and updated to reflect the significant

advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Pharmaceutical Quality by Design John Wiley & Sons

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations; Points to consider when including Health Based Exposure Limits (HBELs) in cleaning validation; Good manufacturing practices: water for pharmaceutical use; Guideline on data integrity; WHO/United Nations Population Fund recommendations for condom storage and shipping temperatures; WHO/United Nations Population Fund guidance on testing of male latex condoms; WHO/United Nations Population Fund guidance on conducting post-market surveillance of condoms; WHO “Biowaiver List”: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce; Good reliance practices in the regulation of medical products: high-level principles and considerations; and Good regulatory practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.

Biopharmaceutical Manufacturing Facilities John Wiley & Sons

Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

Manufacturing of Pharmaceutical Proteins International Society of Pharmaceutical Engineering (ISPE)

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to

change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

A Guide to Managing Risks Associated with Cross-contamination Ispe Headquarters

Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these requirements in the regulations.

Pharmaceutical Manufacturing Handbook CRC Press

The Pharmaceutical Engineering Series is a comprehensive reference for the pharmaceutical professional covering all aspects from quality, documentation and validation through manufacturing processes to facility design and management. In 'Quality', Dr Kate McCormick provides the reader with comprehensive coverage of this vital subject, including the quality life cycle, management and cost of quality, GMP, auditing and inspections. This book with the others in the series will become a unique source of reference and educational material for the readership. Case studies and examples make the book of direct practical relevance to the professional in the pharmaceutical industry Find the answers you are looking for quickly and easily with clear indexing and referencing Reference to international standards and practice mean this book will be useful wherever you are working

ISPE Guide CRC Press

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product

development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

A Risk-based Approach to Compliant GxP Computerized Systems CRC Press

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

ISPE Good Practice Guide Butterworth-Heinemann

ISPE Baseline Pharmaceutical Engineering Guide for New and Renovated FacilitiesBiopharmaceutical Manufacturing FacilitiesISPE Baseline® GuideVolume 4 - Water and Steam SystemsISPE Baseline® GuideVolume 5 - Commissioning and QualificationSterile Product Manufacturing FacilitiesVol. 3ISPE Baseline® GuideVolume 3 - Sterile Manufacturing FacilitiesISPE Baseline® GuideVolume 2 - Oral Solid Dosage FormsISPE Baseline® GuideVolume 3 - Sterile Product Manufacturing FacilitiesRisk-based Manufacture of Pharmaceutical ProductsA Guide to Managing Risks Associated with Cross-contaminationISPE Baseline GuideWater and Steam SystemsISPE Baseline GuideOral Solid Dosage FormsISPE Good Practice GuideMaintenanceSterile Manufacturing FacilitiesHandbook of Validation in Pharmaceutical Processes, Fourth EditionCRC Press

Theory, Practice, and Tools CRC Press

Sets forth tested and proven risk management practices indrug manufacturing Risk management is essential for safe and efficientpharmaceutical and biopharmaceutical manufacturing, control, anddistribution. With this book as their guide, readers involved inall facets of drug manufacturing have a single, expertly written,and organized resource to guide them through

all facets of riskmanagement and analysis. It sets forth a solid foundation in riskmanagement concepts and then explains how these concepts areapplied to drug manufacturing. Risk Management Applications in Pharmaceutical andBiopharmaceutical Manufacturing features contributions fromleading international experts in risk management and drugmanufacturing. These contributions reflect the latest research,practices, and industry standards as well as the authors' firsthandexperience. Readers can turn to the book for: Basic foundation of risk management principles, practices, andapplications Tested and proven tools and methods for managing risk inpharmaceutical and biopharmaceutical product manufacturingprocesses Recent FDA guidelines, EU regulations, and internationalstandards governing the application of risk management to drugmanufacturing Case studies and detailed examples demonstrating the use andresults of applying risk management principles to drug productmanufacturing Bibliography and extensive references leading to the literatureand helpful resources in the field With its unique focus on the application of risk management tobiopharmaceutical and pharmaceutical manufacturing, this book is anessential resource for pharmaceutical and process engineers as wellas safety and compliance professionals involved in drugmanufacturing.

ISPE Baseline® Guide ISPE Baseline Pharmaceutical Engineering Guide for New and Renovated FacilitiesBiopharmaceutical Manufacturing FacilitiesISPE Baseline® GuideVolume 4 - Water and Steam SystemsISPE Baseline® GuideVolume 5 - Commissioning and QualificationSterile Product Manufacturing FacilitiesVol. 3ISPE Baseline® GuideVolume 3 - Sterile Manufacturing FacilitiesISPE Baseline® GuideVolume 2 - Oral Solid Dosage FormsISPE Baseline® GuideVolume 3 - Sterile Product Manufacturing FacilitiesRisk-based Manufacture of Pharmaceutical ProductsA Guide to Managing Risks Associated with Cross-contaminationISPE Baseline GuideWater and Steam SystemsISPE Baseline GuideOral Solid Dosage FormsISPE Good Practice GuideMaintenanceSterile Manufacturing FacilitiesHandbook of Validation in Pharmaceutical Processes, Fourth Edition

Often considered a necessary evil by the pharmaceutical industry, validation is still understood by many as unrestrained bureaucracy, paperwork, and procedures whose roots and logic are obscure and only serve to slow down progress. Thoroughly defining the philosophy, application, and processes, Facility Validation: Theory, Practice, and Tools explores the validation issues relevant to the start-up of a new or upgraded manufacturing facility. The author describes policies, guidelines, and regulations relating to GMPs in the pharmaceutical industry and explores the relationship between these GMPs and the validation process. He outlines the theory and clarifies the philosophy and key principles of validation such as life-cycle approach and qualification practices. The book includes coverage of common pitfalls and how to avoid them, the difficulties and constraints a validation team has to manage, and the dangers of not adopting and following the recommended best practices. Facility validation has, in fact, become good business. It can be a tool for enhancing reliability, cost, and quality. This book makes the case that design, engineering, commissioning, and validation activities can be integrated and streamlined to accelerate a

pharmaceutical manufacturing plant start-up effort, and demonstrates how to use best practices to achieve the results you desire in your organization.

Baseline Pharmaceutical Engineering Guide for New and Renovated Facilities: Active pharmaceutical ingredients John Wiley & Sons

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.

Bulk Pharmaceutical Chemicals John Wiley & Sons

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.