

VOLUME 5

# Commissioning and Qualification

Second Edition



# Ispe Baseline Pharmaceutical Engineering Guide

## Volume 5

**Anurag Singh Rathore, Hal  
Baseman, Scott Rudge**



## **Ispe Baseline Pharmaceutical Engineering Guide Volume 5:**

ISPE Baseline® Guide: Volume 5 - Commissioning and Qualification Ispe,2006-05      Quality Assurance of Pharmaceuticals World Health Organization,2007 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      **Handbook of Validation in Pharmaceutical Processes, Fourth Edition**

James Agalloco,Phil DeSantis,Anthony Grilli,Anthony Pavell,2021-10-28 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

**Pharmaceutical Microbiological Quality Assurance and Control** David Roesti,Marcel Goverde,2020-01-02 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 Quality assurance of pharmaceuticals: a compendium of guidelines and related materials.

Volume 2. Good manufacturing practices and inspection World Health Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry **Manufacturing of**

**Pharmaceutical Proteins** Stefan Behme,2022-04-18 An expert single volume overview of the core processes and disciplines of biopharmaceutical production In the newly revised Third Edition of Manufacturing of Pharmaceutical Proteins From Technology to Economy renowned chemical engineer Dr Stefan Behme delivers a comprehensive text covering all aspects of biopharmaceutical manufacturing including legal and regulatory considerations production facility design quality assurance supply chain management emerging market regulations and cost control Suitable as both a reference book and a training resource this book extensively explores the impact of digital transformation on pharmaceutical protein manufacturers and includes a brand new chapter dedicated to digitalization The distinguished author provides readers with practical understanding of the terminology and principles driving the various fields involved with biotechnological production including operations legal finance and IT He also offers A thorough introduction to biopharmaceutical production including value creation product types and biological basics Comprehensive explorations of the technology of the manufacturing process and analytics Practical discussions of pharmacology and drug safety quality assurance and pharmaceutical law In depth examinations of pharmaceutical protein production facilities including facility design and the planning construction and commissioning of a manufacturing plant Perfect for biotechnologists working in the pharmaceutical industry Manufacturing of Pharmaceutical Proteins From Technology to Economy will also earn a place in the libraries of pharmaceutical engineers seeking a one stop reference for all aspects of biopharmaceutical production **Process**

**Validation in Manufacturing of Biopharmaceuticals** Anurag Singh Rathore, Hal Baseman, Scott Rudge,2023-12-18 The fourth edition of Process Validation in Manufacturing of Biopharmaceuticals is a practical and comprehensive resource illustrating the different approaches for successful validation of biopharmaceutical processes A pivotal text in its field this new edition provides guidelines and current practices contains industrial case studies and is expanded to include in depth analysis of the new Process Validation PV guidance from the US FDA Key Features Offers readers a thorough understanding of the key concepts that form the basis of a good process validation program for biopharmaceuticals Includes case studies from the various industry leaders that demonstrate application of these concepts Discusses the use of modern tools such as

multivariate analysis for facilitating a process validation exercise Covers process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing including chromatography chemical modification reactions ultrafiltration and microfiltration and practical methods to test raw materials and in process samples Providing a thorough understanding of the key concepts that form the basis of a good process validation program this book will help readers ensure that PV is carried out and exceeds expectations Fully illustrated this is a much needed practical guide for biopharmaceutical manufacturers

Pharmaceutical Quality by Design Walkiria S. Schlindwein, Mark Gibson, 2018-01-11 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

Developing Solid Oral Dosage Forms Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lawrence Yu, Rao V. Mantri, 2016-11-08 Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice Second Edition illustrates how to develop high quality safe and effective pharmaceutical products by discussing the latest techniques tools and scientific advances in preformulation investigation formulation process design characterization scale up and production operations This book covers the essential principles of physical pharmacy biopharmaceutics and industrial pharmacy and their application to the research and development process of oral dosage forms Chapters have been added combined deleted and completely revised as necessary to produce a comprehensive well organized valuable reference for industry professionals and academics engaged in all aspects of the development process New and important topics include spray drying amorphous solid dispersion using hot melt extrusion

modeling and simulation bioequivalence of complex modified released dosage forms biowaivers and much more Written and edited by an international team of leading experts with experience and knowledge across industry academia and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon predictive biopharmaceutics and pharmacokinetics the development of formulations for drug discovery support and much more Presents new case studies throughout and a section completely devoted to regulatory aspects including global product regulation and international perspectives

**Sterile Manufacturing** Sam A. Hout, 2021-07-04 This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements It covers regulations and guidelines instituted by the FDA ISPE EMA MHRA and ICH emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products Additionally this book provides the fundamentals of aseptic techniques quality by design risk assessment and management in support of sterile operations applications It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step by step process to ensure reliability safety and efficacy of healthcare products for human and animal use The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing and how to remain viable with solid strategic planning The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily pharmaceutical and medical device space but can also extend to food and cosmetics that require clean aseptic manufacturing applications It also helps compounding pharmacists and GMP inspectors and auditors

**Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing** Hamid Mollah, Harold Baseman, Mike Long, 2013-02-01 Sets forth tested and proven risk management practices in drug manufacturing Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing control and distribution With this book as their guide readers involved in all facets of drug manufacturing have a single expertly written and organized resource to guide them through all facets of risk management and analysis It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing These contributions reflect the latest research practices and industry standards as well as the authors firsthand experience Readers can turn to the book for Basic foundation of risk management principles practices and applications Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes Recent FDA guidelines EU regulations and international standards governing the application of risk management to drug manufacturing Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing Bibliography and extensive references leading to the literature and

helpful resources in the field With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing

**Process Architecture in Biomanufacturing Facility Design** Jeffery Odum, Michael C. Flickinger, 2018-01-26 Essential information for architects designers engineers equipment suppliers and other professionals who are working in or entering the biopharmaceutical manufacturing field

Biomanufacturing facilities that are designed and built today are radically different than in the past The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature and it s rarely taught in architecture or design schools This is the first book for architects and designers that fills this void Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies use state of the art equipment are energy efficient and sustainable and meet regulatory requirements Relying on their many years of hands on design and operations experience the authors emphasize concepts and practical approaches toward design construction and operation of biomanufacturing facilities including product process facility relationships closed systems and single use equipment aseptic manufacturing considerations design of biocontainment facility and process based laboratory and sustainability considerations as well as an outlook on the facility of the future Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U S A and WHO especially in emerging global markets in India China Latin America and the Asia Pacific regions Focuses on innovative design and equipment to speed construction and time to market increase energy efficiency and reduce footprint construction and operational costs as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines biotechnology and life science industry including architects and designers of industrial facilities construction equipment vendors and mechanical engineers It is also recommended for university instructors advanced undergraduates and graduate students in architecture industrial engineering mechanical engineering industrial design and industrial interior design

**Good Design Practices for GMP Pharmaceutical Facilities** Terry Jacobs, Andrew A. Signore, 2016-08-19 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

*Downstream Industrial Biotechnology* Michael C. Flickinger, 2013-07-17

**DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY** An affordable easily accessible desk reference on biomanufacturing focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology novel materials and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine environmental monitoring and remediation consumer products food production agriculture and forestry and continue to be a major area of research The downstream stage in industrial biotechnology refers to recovery isolation and purification of the microbial products from cell debris processing medium and contaminating biomolecules from the upstream process into a finished product such as biopharmaceuticals and vaccines Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products e g peptides proteins hormones antibiotics and complex antigens dictate different methods for the isolation and purification of these products but contaminating byproducts can also reduce overall process yield and may have serious consequences on clinical safety and efficacy Therefore downstream separation scientists and engineers are continually seeking to eliminate or combine unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity Based on Wiley's Encyclopedia of Industrial Biotechnology Bioprocess Bioseparation and Cell Technology this volume features fifty articles that provide information on down stream recovery of cells and protein capture process development and facility design equipment PAT in downstream processes downstream cGMP operations and regulatory compliance It covers Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification monoclonal and polyclonal Protein aggregation precipitation and crystallization Freeze drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing biochemical engineering biopharmaceutical facility design biochemistry industrial microbiology gene expression technology and cell culture technology Downstream Industrial Biotechnology is also a highly recommended resource for industry professionals and libraries

**Good Manufacturing Practices for Pharmaceuticals, Seventh Edition** Graham P. Bunn, 2019-02-04 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

*Rules of Thumb for Chemical Engineers* Stephen M

Hall, 2012-07-27 Rules of Thumb for Chemical Engineers Fifth Edition provides solutions common sense techniques shortcuts and calculations to help chemical and process engineers deal with practical on the job problems It discusses physical properties for proprietary materials pharmaceutical and biopharmaceutical sector heuristics and process design along with closed loop heat transfer systems heat exchangers packed columns and structured packings Organized into 27 chapters the book begins with an overview of formulae and data for sizing piping systems for incompressible and compressible flow It then moves to a discussion of design recommendations for heat exchangers practical equations for solving fractionation problems along with design of reactive absorption processes It also considers different types of pumps and presents narrative as well as tabular comparisons and application notes for various types of fans blowers and compressors The book also walks the reader through the general rules of thumb for vessels how cooling towers are sized based on parameters such as return temperature and supply temperature and specifications of refrigeration systems Other chapters focus on pneumatic conveying blending and agitation energy conservation and process modeling Online calculation tools Excel workbooks guidelines for hazardous materials and processes and a searchable Rules of Thumb library are included Chemical engineers faced with fluid flow problems will find this book extremely useful Rules of Thumb for Chemical Engineers brings together solutions information and work arounds that engineers in the process industry need to get their job done New material in the Fifth Edition includes physical properties for proprietary materials six new chapters including pharmaceutical biopharmaceutical sector heuristics process design with simulation software and guidelines for hazardous materials and processes Now includes SI units throughout alongside imperial and now accompanied by online calculation tools and a searchable Rules of Thumb library

**WHO Expert Committee on Specifications for Pharmaceutical Preparations**

, 2021-04-26 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      *Technical Report Series* ,2011      **Facility Validation** Graham C. Wrigley,2004-03-29 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 explo      **THE WBF BOOK SERIES-Applying ISA 88 In Discrete and Continuous Manufacturing** The WBF,2010-12-13 THE WBF BOOK SERIES APPLYING ISA 88 In Discrete and Continuous Manufacturing features How to apply ISA 88 batch recipes to continuous and semi continuous manufacturing processes How to use ISA 88 recipes for packaging of consumer packaged goods and defining a Compliant Packaging Environment Examples of applying ISA 88 and 99 to manufacturing and packaging systems integration ISA International Society of Automation standards 88 and 95 are manufacturing standards established in the late 1990s and periodically updated by the governing bodies responsible for them the Instrumentation Society of America and the American National Standards Institute The two standards set up protocols and uniform specifications for batch control systems including types of control equipment design of control systems and interpretation of batch control data In Volume 3 the reader will find innovative applications of ISA batch recipes to continuous and semi continuous manufacturing operations as well as how to integrate with ISA 95 standards for total integrated manufacturing automation The ISA 88 and 95 standards have been around and periodically updated for nearly 20 years now but little really helpful has been published on how to put those standards into use particularly from a pragmatic real life experience point of view The four books in this new series will do exactly that explain to the manufacturing engineer the controls engineers and the industrial planner and manager alike how these standards translate into improved batch and continuous process operations and ultimately how those operations can be integrated and automate into the general business operations accounting inventory customer relations product development of the manufacturing concern

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