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**Baseline**  
PHARMACEUTICAL  
ENGINEERING GUIDE

# Pharmaceutical Engineering Guides for New and Renovated Facilities

Volume 2  
**Commissioning  
and Qualification**

2010-2011 Edition

First Edition / March 2011



# Ispe Baseline Pharmaceutical Engineering Volume 5

**International Society for  
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Engineering, International Society of  
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## **Ispe Baseline Pharmaceutical Engineering 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 *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

*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 downstream 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

**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. *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 biopharmaceutical 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. [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. Key Features: Presents insight into the world of pharmaceutical quality systems.

Analyzes regulatory trends and expectations Includes approaches and practices used in the industry to comply with regulatory requirements Discusses recent worldwide supply chain issues Delivers valuable information to a worldwide audience regarding the current GMP practices in the industry

**Rules of Thumb for Chemical Engineers** Stephen Hall, 2017-10-30 Rules of Thumb for Chemical Engineers Sixth Edition is the most complete guide for chemical and process engineers who need reliable and authoritative solutions to on the job problems The text is comprehensively revised and updated with new data and formulas The book helps solve process design problems quickly accurately and safely with hundreds of common sense techniques shortcuts and calculations Its concise sections detail the steps needed to answer critical design questions and challenges The book discusses physical properties for proprietary materials pharmaceutical and biopharmaceutical sector heuristics process design closed loop heat transfer systems heat exchangers packed columns and structured packings This book will help you save time you no longer have to spend on theory or derivations improve accuracy by exploiting well tested and accepted methods culled from industry experts and save money by reducing reliance on consultants The book brings together solutions information and work arounds from engineers in the process industry Includes new chapters on biotechnology and filtration Incorporates additional tables with typical values and new calculations Features supporting data for selecting and specifying heat transfer equipment

**Technical Report Series**, 2011 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* World Health Organization, 2006 This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms The report is complemented by a number of annexes These include a list of available international chemical reference substances and international infrared spectra supplementary guidelines on good manufacturing practices for heating ventilation and air conditioning systems for non sterile pharmaceutical dosage forms updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines supplementary guidelines on good manufacturing practices for validation good distribution practices for pharmaceutical products a model quality assurance system for procurement agencies recommendations for quality assurance systems focusing on prequalification of products and manufacturers purchasing storage and distribution of pharmaceutical products multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release solid oral dosage forms and additional guidance for organizations performing in vivo bioequivalence studies This is an excellent book with a misleading title a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients API and finished pharmaceutical products Annex 5 on Good distribution practices GDP for pharmaceutical products is an excellent Annex that splits the task of GDP into 20 small easy to digest sections that guide the reader through

the process of understanding the complexity of controlling distribution of pharmaceutical products It contains a comprehensive glossary of terms used in GDP a useful reference book for anyone involved in Quality Assurance Manufacturing of marketed products Clinical Manufacturing and Development Industrial Pharmacy **Chemical Engineering** ,2005 **Manual of Industrial Microbiology and Biotechnology** Arnold L. Demain,Julian E. Davies,Ronald M. Atlas,1999 The editors have enlisted a broad range of experts including microbial ecologists physiologists geneticists biochemists molecular biologists and biochemical engineers who offer practical experience not found in texts and journals This comprehensive perspective makes MIMB a valuable how to resource the structure of which resembles the sequence of operation involved in the development of a commercial biological process and product ISPE Baseline Pharmaceutical Engineering Guide for New and Renovated Facilities ,2013 Quality in the Manufacture of Medicines and Other Healthcare Products John Sharp,J. R. Sharp,2000 This overview of quality assurance in pharmaceutical production describes the principles and practice and discusses specific quality issues providing a guide to both national and international regulatory requirements Sterile Product Manufacturing Facilities International Society for Pharmaceutical Engineering,2011 *Topical Conference on Batch Processing* ,2001 **ISPE Baseline® Guide: Volume 7 - Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)** Ispe,2011-04-15 *Risk-based Manufacture of Pharmaceutical Products* International Society for Pharmaceutical Engineering,International Society of Pharmaceutical Engineers,2010 *ISPE Baseline® Guide* Ispe,2016-11-29 *ISPE Baseline® Guide: Volume 1 - Active Pharmaceutical Ingredients* Ispe,2008-04-17

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