

# Ispe Baseline Pharmaceutical Engineering Volume 5

## Technical Report Series 2011

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.

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

**ISPE Baseline® Guide: Volume 5 - Commissioning and Qualification** Ispe 2006-05

**Process Validation in Manufacturing of Biopharmaceuticals** Anurag Singh Rathore 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.

*Chemical Engineering* 2005

*ISPE Baseline® Guide* Ispe 2016-11-29

**Risk-based Manufacture of Pharmaceutical Products** International Society for Pharmaceutical Engineering 2010

*ISPE Baseline® Guide: Volume 7 - Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)* Ispe 2011-04-15

*Manual of Industrial Microbiology and Biotechnology* Arnold L. Demain 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.

**Process Architecture in Biomanufacturing Facility Design** Jeffery Odum 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.

**Quality in the Manufacture of Medicines and Other Healthcare Products** John 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. *Handbook of Validation in Pharmaceutical Processes, Fourth Edition* James Agalloco 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, nanotechnology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture

*ISPE Baseline® Guide* Ispe 2010-03-24 *Sterile Product Manufacturing Facilities* International Society for Pharmaceutical Engineering 2011

**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.

**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  
Topical Conference on Batch Processing 2001  
*ISPE Baseline® Guide: Volume 3 - Sterile Product Manufacturing Facilities* Ispe  
 2011-10-25

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