

# Commissioning and Qualification

Second Edition



# Ispe Maintenance Baseline Guide

**Steven Ostrove**



## **Ispe Maintenance Baseline Guide:**

### **Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook** Jordi Botet,2015-09-28

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing materials, purchase, procurement, production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is current good manufacturing practice (CGMP) which is applied within the frame of a pharmaceutical quality system (PQS). This implementation however requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence pharmaceutical manufacturing is a complex subject in terms of regulation given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements such as risk management, quality hazards, and management systems, documentation, clean environments, personnel training, and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains, as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

**GMP Compliance, Productivity, and Quality** Vinay Bhatt,1998-06-30. Written by twenty eight experts filled with recommendations that can immediately be put into action, this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost effective regulatory compliance. Drawn from name brand and generic companies and regulatory and contract organizations across the globe, the contributing authors bring readers a combined 450 years of hands on experience. They offer thought provoking questions to help readers diagnose their company's challenges, needs, and available options, all with the single purpose of achieving their ultimate goals: quality, high productivity, and profitability.

**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 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

**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

Pharmaceutical Blending and Mixing P. J. Cullen, Rodolfo J. Románach, Nicolas Abatzoglou, Chris D. Rielly, 2015-05-11 Written in four parts this book provides a dedicated and in depth reference for blending within the pharmaceutical manufacturing industry It links the science of blending with regulatory requirements associated with pharmaceutical manufacture The contributors are a combination of leading academic and industrial experts who provide an informed and industrially relevant perspective of the topic This is an essential book for the pharmaceutical manufacturing industry and related academic researchers in pharmaceutical science and chemical and mechanical engineering

**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

**Manufacturing of Quality Oral Drug Products** Sam A. Hout, 2022-06-27 This book provides an understanding of what is required to engineer and manufacture drug products It bridges established concepts and provides for a new outlook by concentrating and creating new linkages in the implementation of manufacturing quality assurance and business practices related to drug manufacturing and healthcare products This book fills a gap by providing a connection between drug production and regulated applications It focuses on drug manufacturing quality techniques in oral solid dosage and capsule filling including equipment and critical systems to control production and the finished products The book offers a correlation between design strategies and a step by step process to ensure the reliability safety and efficacy of healthcare products Fundamentals of techniques quality by design risk assessment and management are covered along with a scientific method approach to continuous improvement in the usage of computerized manufacturing and dependence on information technology and control operations through data and metrics Manufacturing and Quality Assurance of Oral Pharmaceutical Products Processing and Safe Handling of Active Pharmaceutical Ingredients API is of interest to professionals and engineers in the fields of manufacturing engineering quality assurance reliability business management process and continuous improvement life cycle management healthcare products manufacturing pharmaceutical processing and computerized manufacturing

**Principles of Parenteral Solution Validation** Igor Gorsky, Harold S. Baseman, 2019-11-27 Principles of Parenteral Solution Validation A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product By using a lifecycle approach this book discusses the latest technology compliance developments and regulatory considerations and trends from process design to divesting As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin this book incorporates numerous case studies and real world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area

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 *20th ISPE International Conference on Concurrent Engineering* C. Bil, J. Mo, J. Stjepandić, 2013-09-12 As a concept Concurrent Engineering CE initiates processes with the goal of improving product quality production efficiency and overall customer satisfaction Services are becoming increasingly important to the economy with more than 60% of the GDP in Japan the USA Germany and Russia deriving from service based activities The definition of a product has evolved from the manufacturing and supplying of goods only to providing goods with added value to eventually promoting a complete service business solution with support from introduction into service and from operations to decommissioning This book presents the proceedings of the 20th ISPE International Conference on Concurrent Engineering held in Melbourne Australia in September 2013 The conference had as its theme Product and Service Engineering in a Dynamic World and the papers explore research results new concepts and insights covering a number of topics including service engineering cloud computing and digital manufacturing knowledge based engineering and sustainability in concurrent engineering 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 Handbook of Near-Infrared Analysis Donald A. Burns, Emil W. Ciurczak, 2007-09-07 Fast inexpensive and easy to use near infrared NIR spectroscopy can be used to analyze small samples of virtually any composition The Handbook of Near Infrared Analysis Third Edition explains how to perform accurate as well as time and cost effective analyses across a growing spectrum of disciplines Presenting nearly 50% new and re *Process Validation & cGMP (Part - 1)* Mr. Rohit Manglik, 2024-03-24 Covers fundamentals of process validation documentation regulatory guidelines and GMP principles in pharmaceutical manufacturing **Equipment Qualification in the Pharmaceutical Industry** Steven Ostrove, 2019-06-13 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 *Comprehensive Membrane Science and Engineering* Enrico Drioli, Lidietta Giorno, 2010-07-09 *Comprehensive Membrane Science and Engineering* Four Volume Set covers all aspects of membrane science and technology from basic phenomena to the most advanced applications and future perspectives Modern membrane engineering is critical to the development of process intensification strategies and to the stimulation of industrial growth The work presents researchers and industrial managers with an indispensable tool toward achieving these aims Covers membrane science theory and economics as well as applications ranging from chemical purification and natural gas enrichment to potable water Includes contributions and case studies from internationally recognized experts and from up and coming researchers working in this multi billion dollar field Takes a unique multidisciplinary approach that stimulates research in hybrid technologies for current and future life saving applications artificial organs drug delivery

Pharmaceutical Computer Systems Validation Guy Wingate, 2016-04-19 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 **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

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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