



GOOD PRACTICE GUIDE: Maintenance

Second Edition



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Ispe Maintenance Baseline Guide

Ying-Ying Zheng



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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.

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 *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 **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 Pharmaceutical Blending and Mixing P. J. Cullen,Rodolfo J. Romañach,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 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 *ASHRAE Handbook* ,1999 *Topical Conference on Batch Processing* ,2001 Consulting-specifying Engineer ,2003 **Technical Report Series** ,2005 Chemical Engineering Progress ,2002 **Genetic Engineering News** ,2006 **Yearbook of International Organizations** ,1967 **Genetic Engineering & Biotechnology News** ,2009 ISPE Good Practice Guide Ispe,2011-11 ISPE GAMP® Good Practice Guide Ispe,2017-02-22 Internet Guide for Maintenance Management Joel Levitt,1998 Guides maintenance professionals through the use of the Internet to solve maintenance problems research maintenance issues and find answers or additional resources Chapters present such topics as search engines and supersites government Internet sites and newsgroups forums and chats Annotat **ISPE GAMP Records and Data Integrity Guide** ,2017 ISPE GAMP® Good Practice Guide Ispe,2010-03-24

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