

Ispe Baseline Pharmaceutical Engineering Guides

ISPE Baseline Guide: Volume 5 - Commissioning and Qualification
Baseline Pharmaceutical Engineering Guide: Commissioning and qualifications
ISPE Baseline Guide Good Design Practices for GMP Pharmaceutical Facilities
Sterile Product Manufacturing Facilities
ISPE Baseline Guide
ISPE Baseline Guide: Volume 6 - Biopharmaceutical Manufacturing Facilities
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Baseline Pharmaceutical Engineering Guide
Baseline Pharmaceutical Engineering Guide
Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook
Baseline Pharmaceutical Engineering Guide: Water and steam systems
Bulk Pharmaceutical Chemicals
Baseline Pharmaceutical Engineering Guide: Sterile manufacturing facilities
Baseline Pharmaceutical Engineering Guide
Baseline Pharmaceutical Engineering Guide
Manufacturing of Pharmaceutical Proteins
Baseline Pharmaceutical Engineering Guide: Oral solid dosage forms
Downstream Industrial Biotechnology
GMP Compliance, Productivity, and Quality
Ispe Ispe Terry Jacobs International Society for Pharmaceutical Engineering
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this revised publication serves as a handy and current reference for professionals engaged in planning designing building validating and maintaining modern cgm 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 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

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

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 cgm 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

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 co

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