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Chemical Engineering in the Pharmaceutical Industry Aug 19 2022 A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

Good Design Practices for GMP Pharmaceutical Facilities Sep 20 2022 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.

Baseline Pharmaceutical Engineering Guide Feb 25 2023

The Immunoassay Handbook Jan 20 2020 The fourth edition of The Immunoassay Handbook provides an excellent, thoroughly updated guide to the science, technology and applications of ELISA and other immunoassays, including a wealth of practical advice. It encompasses a wide range of methods and gives an insight into the latest developments and applications in clinical and veterinary practice and in pharmaceutical and life science research. Highly illustrated and clearly written, this award-winning reference work provides an excellent guide to this fast-growing field. Revised and extensively updated, with over 30% new material and 77 chapters, it reveals the underlying common principles and simplifies an abundance of innovation. The Immunoassay Handbook reviews a wide range of topics, now including lateral flow, microsphere multiplex assays, immunohistochemistry, practical ELISA development, assay interferences, pharmaceutical applications, qualitative immunoassays, antibody detection and lab-on-a-chip. This handbook is a must-read for all who use immunoassay as a tool, including clinicians, clinical and veterinary chemists, biochemists, food technologists, environmental scientists, and students and researchers in medicine, immunology and proteomics. It is an essential reference for the immunoassay industry. Provides an excellent revised guide to this commercially highly successful technology in diagnostics and research, from consumer home pregnancy kits to AIDS testing. www.immunoassayhandbook.com is a great resource that we put a lot of effort into. The content is designed to encourage purchases of single chapters or the entire book. David Wild is a healthcare industry veteran, with experience in biotechnology, pharmaceuticals, medical devices and immunodiagnostics, which remains his passion. He worked for Amersham, Eastman-Kodak, Johnson & Johnson, and Bristol-Myers Squibb, and consulted for diagnostics and biotechnology companies. He led research and development programs, design and construction of chemical and biotechnology plants, and integration of acquired companies. Director-level positions included Research and Development, Design Engineering, Operations and Strategy, for billion dollar businesses. He retired from full-time work in 2012 to focus on his role as Editor of The Immunoassay Handbook, and advises on product development, manufacturing and marketing. Provides a unique mix of theory, practical advice and applications, with numerous examples Offers explanations of technologies under development and practical insider tips that are sometimes omitted from scientific papers Includes a comprehensive troubleshooting guide, useful for solving problems and improving assay performancee Provides valuable chapter updates, now available on www.immunoassayhandbook.com

Quality Control Training Manual Mar 22 2020 Written to help companies comply with GMP, GLP, and validation requirements imposed by the FDA and regulatory bodies worldwide, Quality Control Training Manual: Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories presents cost-effective training courses that cover how to apply advances in the life sciences

Guidelines for Safe Handling of Powders and Bulk Solids Apr 22 2020 Powders and bulk solids, handled widely in the chemical, pharmaceutical, agriculture, smelting, and other industries present unique fire, explosion, and toxicity hazards. Indeed, substances which are practically inert in consolidated form may become quite hazardous when converted to powders and granules. The U.S. Chemical Safety and Hazard Investigation Board is currently investigating dust explosions that occured in 2003 at WestPharma, CTA Acoustics, and Hayes-Lemmerz, and is likely to recommend that companies that handle powders or whose operations produce dust pay more attention to understanding the hazards that may exist at their facility. This new CCPS guidelines book will discuss the types of hazards that can occur in a wide range of process equipment and with a wide range of substances, and will present measures to address these hazards.

Pharmaceutical Computer Systems Validation May 16 2022 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 r

Pharmaceutical Process Engineering, Second Edition Jun 17 2022 With step-by-step methods of drug production and knowledge of major unit operations and key concepts of pharmaceutical engineering, this guide will help to improve communication among the varied professionals working in the pharmaceutical industry. Key features: REVISION OF A BESTSELLER - Updates include recent advances in the field to keep pharmaceutical scientists and technologists up-to-date IDEAL INTRODUCTORY TEXT - Covers basic engineering principles, drug production, and development processes, so scientists can easily convert bulk pharmaceutical products into patient-ready dosage forms NEW INFORMATION - on quality principles that include quality by design; mathematical and statistical approaches to experimental design; computer aided design; and PAT (process analytical technology) keeps professionals at the forefront of their field COMPREHENSIVE COVERAGE - Step-by-step methods of drug production, knowledge of major unit operations, and key concepts of pharmaceutical engineering will help to improve communication among the varied professionals working in the pharmaceutical industry

ISPE Good Practice Guide Oct 09 2021

Handbook of Validation in Pharmaceutical Processes, Fourth Edition Dec 19 2019 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

Vaccine Development and Manufacturing Nov 17 2019 Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine - from beginning to end - addressing all classes of vaccines from a processing, production, and regulatory viewpoint. It will provide comprehensive information on the various fields involved in the production of vaccines, from fermentation, purification, formulation, to regulatory filing and facility designs. In recent years, there have been tremendous advances in all aspects of vaccine manufacturing. Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation. Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in-depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues. This book will provide insight to the issues scientists face when producing a vaccine, the steps that are involved, and will serve as a reference tool regarding state-of-the-art vaccine manufacturing technologies and facility set-up. Highlights include: Comprehensive coverage of vaccine production : from a process point of view- fermentation to purification to formulation developments; from a production point of view - from facility design to manufacturing; and from a regulatory point of view - requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines, an area not covered by other books currently on the market

ISPE Good Practice Guide Sep 27 2020

Sterile Processing of Pharmaceutical Products Jan 12 2022 Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.

Pharmaceutical Quality by Design Jun 24 2020 A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Manufacturing of Pharmaceutical Proteins Aug 07 2021 This comprehensive introduction covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues as well as costing procedures. Written by a leading expert at one of the largest pharmaceutical companies worldwide, this practical text is aimed at a wide audience, ranging from libraries, via biotech companies to students and technicians planning to enter biopharmaceutical manufacturing. In addition, it is well suited for academic teaching as well as internal training within larger biotech or pharmaceutical companies.

ISPE Good Practice Guide Jul 18 2022

Quality Control Applications in the Pharmaceutical and Medical Device Manufacturing Industry May 24 2020 Quality control in pharmaceutical products and medical devices is vital for users as failing to comply with national and international regulations can lead to accidents that could easily be avoided. For this reason, manufacturing a quality medical product will support patient safety. Microbiologists working in both the pharmaceutical and medical device industries face considerable challenges in keeping abreast of the myriad microbiological references available to them and the continuously evolving regulatory requirements. Quality Control Applications in the Pharmaceutical and Medical Device Manufacturing Industry presents the importance of quality control in pharmaceutical products and medical devices, which must have very high-quality standards to not cause problems to the health of patients. It reinforces and updates the knowledge of analytical, instrumental, and biological methods to demonstrate the correct quality control and good manufacturing practice for pharmaceutical products and medical devices. Covering topics such as pharmaceutical nano systems, machine learning, and software validation, this book is an essential resource for managers, engineers, supervisors, pharmacists, chemists, academicians, and researchers.

Chemical Engineering in the Pharmaceutical Industry Feb 13 2022 A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: Contains 30new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying Presents updated and expanded example calculations Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industryf ocuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Fermentation and Biochemical Engineering Handbook, 2nd Ed. Mar 14 2022 This is a well-rounded handbook of fermentation and biochemical engineering presenting techniques for the commercial production of chemicals and pharmaceuticals via fermentation. Emphasis is given to unit operations fermentation, separation, purification, and recovery. Principles, process design, and equipment are detailed. Environment aspects are covered. The practical aspects of development, design, and operation are stressed. Theory is included to provide the necessary insight for a particular operation. Problems addressed are the collection of pilot data, choice of scale-up parameters, selection of the right piece of equipment, pinpointing of likely trouble spots, and methods of troubleshooting. The text, written from a practical and operating viewpoint, will assist development, design, engineering and production personnel in the fermentation industry. Contributors were selected based on their industrial background and orientation. The book is illustrated with numerous figures, photographs and schematic diagrams.

Validation of Pharmaceutical Processes Feb 01 2021 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Pharmaceutical Production Jan 24 2023 This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.

Pharmaceutical Manufacturing Handbook Aug 27 2020 This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Chemical Engineering in the Pharmaceutical Industry May 04 2021 This book deals with various unique elements in the drug development process within chemical engineering science and pharmaceutical R&D. The book is intended to be used as a professional reference and potentially as a text book reference in pharmaceutical engineering and pharmaceutical sciences. Many of the experimental methods related to pharmaceutical process development are learned on the job. This book is intended to provide many of those important concepts that R&D Engineers and manufacturing Engineers should know and be familiar if they are going to be successful in the Pharmaceutical Industry. These include basic analytics for quantitation of reaction components– often skipped in ChE Reaction Engineering and kinetics books. In addition Chemical Engineering in the Pharmaceutical Industry introduces contemporary methods of data analysis for kinetic modeling and extends these concepts into Quality by Design strategies for regulatory filings. For the current professionals, in-silico process modeling tools that streamline experimental screening approaches is also new and presented here. Continuous flow processing, although mainstream for ChE, is unique in this context given the range of scales and the complex economics associated with transforming existing batch-plant capacity. The book will be split into four distinct yet related parts. These parts will address the fundamentals of analytical techniques for engineers, thermodynamic modeling, and finally provides an appendix with common engineering tools and examples of their applications.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing Nov 10 2021 Sets forth tested and proven risk management practices indrug manufacturing Risk management is essential for safe and efficientpharmaceutical and biopharmaceutical manufacturing, control, anddistribution. With this book as their guide, readers involved inall facets of drug manufacturing have a single, expertly written,and organized resource to guide them through all facets of riskmanagement and analysis. It sets forth a solid foundation in riskmanagement concepts and then explains how these concepts areapplied to drug manufacturing. Risk Management Applications in Pharmaceutical andBiopharmaceutical Manufacturing features contributions fromleading international experts in risk management and drugmanufacturing. These contributions reflect the latest research,practices, and industry standards as well as the authors' firsthandexperience. Readers can turn to the book for: Basic foundation of risk management principles, practices, andapplications Tested and proven tools and methods for managing risk inpharmaceutical and biopharmaceutical product manufacturingprocesses Recent FDA guidelines, EU regulations, and internationalstandards governing the application of risk management to drugmanufacturing Case studies and detailed examples demonstrating the use andresults of applying risk management principles to drug productmanufacturing Bibliography and extensive references leading to the literatureand helpful resources in the field With its unique focus on the application of risk management tobiopharmaceutical and pharmaceutical manufacturing, this book is anessential resource for pharmaceutical and process engineers as wellas safety and compliance professionals involved in drugmanufacturing.

Fine Chemicals Manufacture Oct 29 2020 The sector of fine chemicals, including pharmaceuticals, agrochemicals, dyes and pigments, fragrances and flavours, intermediates, and performance chemicals is growing fast. For obvious reasons chemistry is a key to the success in developing new processes for fine chemicals. However, as a rule, chemists formulate results of their work as recipes, which usually lack important information for process development. Fine Chemicals Manufacture, Technology and

Engineering is intended to show what is needed to make the recipe more useful for process development purposes and to transform the recipe into an industrial process that will be safe, environmentally friendly, and profitable. The goal of this book is to form a bridge between chemists and specialists of all other branches involved in the scale-up of new processes or modification of existing processes with both a minimum effort and risk and maximum profit when commercializing the process. New techniques for scale-up and optimization of existing processes and improvements in the utilization of process equipment that have been developed in recent years are presented in the book.

GAMP 5 Apr 15 2022 GAMP 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

Automation Applications in Bio-pharmaceuticals Nov 29 2020 A guide for engineers and designers new to the field of bio-pharmaceutical process control. For the experienced automation professional, it outlines the unique design and application issues for the bio-pharmaceutical industry. For those already familiar with this industry, it provides specific advice for automating these processes.

Sterile Manufacturing Facilities Oct 21 2022

Pharmaceutical Dosage Forms - Parenteral Medications Jul 26 2020 This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

ISPE Good Practice Guide Feb 19 2020

ISPE GAMP® Good Practice Guide Dec 31 2020

Quality Apr 03 2021 Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management. This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply

Introductory US Clinical Trial Materials Mar 02 2021

Pharmaceutical Manufacturing Handbook Jun 05 2021 With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Nov 22 2022 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.

Pharmaceutical Preformulation and Formulation Dec 11 2021 Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Pharmaceutical Microbiological Quality Assurance and Control Sep 08 2021 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 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

Downstream Industrial Biotechnology Oct 17 2019 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 Jul 06 2021 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating ventilation and air-conditioning systems (HVAC) ? illustrative part; Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Practical Pharmaceutical Engineering Dec 23 2022 A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise. Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire Addresses topics not covered in university courses but which are crucial to working effectively in the pharma/biotech industry Fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant support design, and project engineering Covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering Practical Pharmaceutical Engineering is an indispensable “tool of the trade” for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.