Filtration And Purification In The Biopharmaceutical Industry Second Edition Drugs And The Pharmaceutical Sciences

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Parenteral Medications, Fourth Edition - Sandeep Nema 2019-07-19
Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Process Validation in Manufacturing of Biopharmaceuticals - Anurag S. Rathore 2012-05-09
Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in

Animal Cell Biotechnology - Ralf Pörtner 2013-12-04
Animal Cell Biotechnology: Methods and Protocols, Third Edition constitutes a comprehensive manual of state-of-the-art and new techniques for setting up mammalian cell lines for production of biopharmaceuticals, and for optimizing critical parameters for cell culture from lab to final production. The volume is divided into five parts that reflect the processes required for different stages of production. In Part I, basic techniques for establishment of production cell lines are addressed, especially high-throughput synchronization, insect cell lines, transient gene and protein expression, DNA Profiling and Characterisation. Part II addresses tools for process and medium optimization as well as microcarrier technology while Part III covers monitoring of cell growth, viability and apoptosis, metabolic flux estimation, quenching methods as well as NMR-based techniques. Part IV details cultivation techniques, and Part V describes special applications, including vaccine production, baculovirus protein expression, chromatographic techniques for downstream as well as membrane techniques for virus separation. Written in the successful Methods in Molecular Biology series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible protocols, and notes on troubleshooting and avoiding known pitfalls. Animal Cell Biotechnology: Methods and Protocols, Third Edition provides a compendium of techniques for scientists in industrial and research laboratories that use mammalian cells for biotechnology purposes.

Downstream Processing of Proteins - Mohamed A. Desai 2008-02-05
Considerable effort and time is allocated to introducing cell culture and fermentation technology to undergraduate students in academia, generally through a range of courses in industrial biotechnology and related disciplines. Similarly, a large number of textbooks are available to describe the appli- tions of these technologies in industry. However, there has been a general lack of appreciation of the significant developments in downstream processing and isolation technology, the need for which is largely driven by the stringent re- latory requirements for purity and quality of injectable biopharmaceuticals. This is particularly reflected by the general absence of coverage of this s- ject in many biotechnology and related courses in educational institutions. For a considerable while I have felt that there is increasing need for an introductory text to various aspects of downstream processing, particularly with respect to the needs of the biopharmaceutical and biotechnology ind- try. Although there are numerous texts that cover various aspects of protein purification techniques in isolation, there is a need for a work that covers the broad range of isolation technology in an industrial setting. It is anticipated that Downstream Processing of Proteins: Methods and Protocols will play a small part in filling this gap and thus prove a useful contribution to the field. It is also designed to encourage educational strategists to broaden the coverage of these topics in industrial biotechnology courses by including accounts of this important and rapidly developing element of the industrial process.

Current Trends and Future Developments on (Bio-) Membranes - Angelo Basile 2019-10-11
Current Trends and Future Developments on (Bio-) Membranes: Membrane Applications in Artificial Organs and Tissue Engineering reports on membrane applications in the field of biomedical engineering, ranging from artificial organs, to tissue engineering. The book offers a comprehensive review of all the current

scientific developments and various applications of membranes in this area. It is a key reference text for R&D managers in industry who are interested in the development of artificial and bioartificial organs, as well as academic researchers and postgraduate students working in the wider area of artificial organs and tissue engineering. Describes numerous bioartificial organ configurations and their relationships to membranes Includes new innovations and solutions in the development of artificial organs with membrane components Describes various membrane fabrication techniques for tissue engineering

Composite Nonwoven Materials - Dipayan Das 2014-03-14

Composite nonwoven materials are versatile materials with a variety of applications, including hygiene, medicine and filtration. This important book provides a technical resource for professionals and academics in the field. It explores these materials in terms of fiber types used, manufacturing processes, structure, and physical properties. The first part of the book focuses on the use of natural and synthetic fibers in composite nonwovens, discusses their structure in terms of fiber packing and alignment, and their physical properties. Further chapters deal with the practical applications of composite nonwoven materials. Hygiene applications, such as diapers, female sanitary products, incontinence pads, and wipes are covered, as well as composite nonwoven-based medical products and filters. Composite Nonwoven Materials is an ideal reference for R&D managers in the textile industry and academic researchers in textile science. Systematic and comprehensive information on composite nonwovens Critical review of progress in research and development on composite nonwovens Comment on future research direction and ideas for product development

Continuous Biomanufacturing - Ganapathy Subramanian 2017-12-26

This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.

Biopharmaceuticals - Gary Walsh 2013-04-29

The latest edition of this highly acclaimed textbook, provides a comprehensive and up-to-date overview of the science and medical applications of biopharmaceutical products. Biopharmaceuticals refers to pharmaceutical substances derived from biological sources, and increasingly, it is synonymous with 'newer' pharmaceutical substances derived from genetic engineering or hybridoma technology. This superbly written review of the important areas of investigation in the field, covers drug production, plus the biochemical and molecular mechanisms of action together with the biotechnology of major biopharmaceutical types on the market or currently under development. There is also additional material reflecting both the technical advances in the area and detailed information on key topics such as the influence of genomics on drug discovery.

Membrane Processes in Biotechnology and Pharmaceutics - Catherine Charcosset 2012-03-14

Chapter 1: Principles on membrane and membrane processes -- Chapter 2: Ultrafiltration -- Chapter 3: Microfiltration -- Chapter 4: Virus Filtration -- Chapter 5: Membrane chromatography -- Chapter 6: Membranes for the Preparation of Emulsions and Particles -- Chapter 7: Other Membrane Processes -- Chapter 8: Some Perspectives.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals - John Geigert 2012-12-06

"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition - Anurag S. Rathore 2012-05-09

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

Sterile Filtration - Maik W. Jornitz 2020-04-15

This book focuses on sterilizing grade filters in the biopharmaceutical industry, emphasizing practical applications of universal and dependable operational protocols, integrity testing, and troubleshooting to streamline the production and preparation of pharmaceuticals. Addresses the complexities of globalizing redundancy in filtration!

Single-Use Technology in Biopharmaceutical Manufacture - Regine Eibl 2019-07-24
Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.
Approaches to the Purification, Analysis and Characterization of Antibody-Based Therapeutics - Allan Matte 2020-09-07
Approaches to the Purification, Analysis and Characterization of Antibody-Based Therapeutics provides the interested and informed reader with an overview of current approaches, strategies and considerations relating to the purification, analytics and characterization of therapeutic antibodies and related molecules. While there are obviously other books published in and around this subject area, they seem to be either older (c.a. year 2000 publication date) or are more limited in scope. The book will include an extensive bibliography of the published literature in the respective areas covered. It is not, however, intended to be a how-to methods book. Covers the vital new area of R&D on therapeutic antibodies Written by leading scientists and researchers Up-to-date coverage and includes a detailed bibliography
Protein Purification - Jan-Christer Janson 2012-01-03
The authoritative guide on protein purification—now completely updated and revised Since the Second Edition of Protein Purification was published in 1998, the sequencing of the human genome and other developments in bioscience have dramatically changed the landscape of protein research. This new edition addresses these developments, featuring a wealth of new topics and several chapters rewritten from scratch. Leading experts in the field cover all major biochemical separation methods for proteins in use today, providing professionals in biochemistry, organic chemistry, and analytical chemistry with quick access to the latest techniques. Entirely new or thoroughly revised content includes: High-resolution reversed-phase liquid chromatography Electrophoresis in gels Conventional isoelectric focusing in gel slabs and capillaries and immobilized pH gradients Affinity ligands from chemical and biological combinatorial libraries Membrane separations Refolding of inclusion body proteins from E. coli Purification of PEGylated proteins High throughput screening techniques in protein purification The history of protein chromatography
Bioseparations Science and Engineering - Roger G. Harrison 2015-01-27
Designed for undergraduates, graduate students, and industry practitioners, Bioseparations Science and Engineering fills a critical need in the field of bioseparations. Current, comprehensive, and concise, it covers bioseparations unit operations in unprecedented depth. In each of the chapters, the authors use a consistent method of explaining unit operations, starting with a qualitative description noting the significance and general application of the unit operation. They then illustrate the scientific application of the operation, develop the required mathematical theory, and finally, describe the applications of the theory in engineering practice, with an emphasis on design and scaleup. Unique to this text is a chapter dedicated to bioseparations process design and economics, in which a process simular, SuperPro Designer® is used to analyze and evaluate the production of three important biological products. New to this second edition are updated discussions of moment analysis, computer simulation, membrane chromatography, and evaporation, among others, as well as revised problem sets. Unique features include basic information about bioproducts and engineering analysis and a chapter with bioseparations laboratory exercises. Bioseparations Science and Engineering is ideal for students and professionals working in or studying bioseparations, and is the premier text in the field.
Cell Culture Technology for Pharmaceutical and Cell-Based Therapies - Sadettin Ozturk 2005-08-30
Edited by two of the most distinguished pioneers in genetic manipulation and bioprocess technology, this bestselling reference presents a comprehensive overview of current cell culture technology used in the pharmaceutical industry. Contributions from several leading researchers showcase the importance of gene discovery and genomic technology devel
Process Scale Purification of Antibodies - Uwe Gottschalk 2017-04-03
Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing
Pharmaceutical Water Systems - Theodore H. Meltzer 1996-01-01

Continuous Biopharmaceutical Processes - David Pfister 2018-10-11
Provides a coherent and critical view on the potential benefits of various continuous processes in the biopharmaceutical industry.
Aulton's Pharmaceutics E-Book - Kevin M.G. Taylor 2013-07-29
Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or

medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

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.

Biopharmaceutical Manufacturing - Gary Gilleskie 2021-09-07

Biopharmaceuticals, medicines made by or from living organisms (including cells from living organisms), are extremely effective in treating a broad range of diseases. Their importance to human health has grown significantly over the years as more biopharmaceutical products have entered the market, and now the biggest selling drugs in the world are biopharmaceuticals. Biopharmaceutical Manufacturing: Principles, Processes and Practices provides concise, comprehensive, and up-to-date coverage of biopharmaceutical manufacturing. Written in a clear and informal style, the content has been influenced by the authors' substantial industry experience and teaching expertise. That expertise enables the authors to address the many questions posed over the years both by university students and professionals with experience in the field. Consequently, the book will appeal both to undergraduate or graduate students using it as a textbook and specialized industry practitioners seeking to understand the big picture of biopharmaceutical manufacturing. This book:

Filtration and Purification in the Biopharmaceutical Industry - Maik J. Jornitz 2007-11-28

Filtration and Purification in the Biopharmaceutical Industry, First Edition greatly expands its focus with extensive new material on the critical role of purification and the significant advances in filtration science and technology. This new edition provides state-of-the-science information on all aspects of filtration and purification, in

Development of Biopharmaceutical Parenteral Dosage Forms - Cosimo Prantera 1997-07-25

This up-to-the-minute reference delineates-in a systematic fashion-the appropriate, sequential steps for the formulation of safe, effective, stable, and marketable liquid parenteral biopharmaceutical products-covering fundamentals and essential pathways for each phase as well as its purpose, function, and relation to other stages in the product development process. Written by experts currently involved in state-of-the-art advances in the pharmaceutical drug industry, Development of Biopharmaceutical Parenteral Dosage Forms details biopharmaceuticals that are licensed or undergoing clinical development, including genetically engineered cell and engineered vectors in the fermentation process describes purification and characterization techniques for rDNA therapeutics, discussing several types of unit operations for isolation, purification, and characterization considers preformulation and formulation requirements, such as physicochemical properties, drug delivery, stability studies programs, deactivation/denaturation routes, selection of compatible excipients, and regulatory compliance elucidates basics of analytical techniques,

methods development, separation methods using chromatographic and electrophoretic techniques, and bioactivity methods covering bioassays and immunoassays for quantifying the stability of biological activity shows how to select the appropriate filter for maximizing compatibility and minimizing adsorption and inactivation, examining topics from basic filtration theories to future trends reviews the selection process for compatible elastomeric closures, analyzing physical, chemical, toxicological properties, protein adsorption on elastomeric surfaces, strategies to reduce/eliminate adsorption, and specialized containers for biotechnological applications and more! Furnished with helpful references, tables, and drawings, this practical guide is indispensable for pharmaceutical, medicinal, and protein chemists; molecular biologists; process engineers; purification scientists; biopharmaceutical and pharmaceutical formulators and product developers; quality control, quality assurance, and regulatory compliance personnel; and upper-level undergraduate and graduate students in these disciplines.

Continuous Manufacturing for the Modernization of Pharmaceutical Production - National Academies of Sciences, Engineering, and Medicine 2019-04-05

On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical Production. This workshop discussed the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop.

Bioprocess Engineering - Pau Loke Show 2019-06-13

Bioprocess Engineering: Downstream Processing is the first book to present the principles of bioprocess engineering, focusing on downstream bioprocessing. It aims to provide the latest bioprocess technology and explain process analysis from an engineering point of view, using worked examples related to biological systems. This book introduces the commonly used technologies for downstream processing of biobased products. The covered topics include centrifugation, filtration, membrane separation, reverse osmosis, chromatography, biosorption, liquid-liquid separation, and drying. The basic principles and mechanism of separation are covered in each of the topics, wherein the engineering concept and design are emphasized. This book is aimed at bioprocess engineers and professionals who wish to perform downstream processing for their feedstock, as well as students.

Biopharmaceutical Processing - Gunter Jagschies 2018-01-18

Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Filtration and Purification in the Biopharmaceutical Industry, Third Edition - Maik W. Jornitz 2019-06-26

Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing, the third edition of Filtration and Purification in the Biopharmaceutical Industry greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology. It provides state-of-the-science information on all aspects of bioprocessing including the current methods, processes, technologies and equipment. It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. The book is an essential, comprehensive source for all involved in filtration and purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices, as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance, not just from an end-user perspective, but also supplier requirement It discusses the advantages of single-use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compilated by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

Current Trends and Future Developments on (Bio-) Membranes - Angelo Basile 2018-10-16

Current Trends and Future Developments on (Bio-) Membranes: Membrane Processes in the Pharmaceutical and Biotechnological field presents the main membrane techniques along with their basic principles, mode of operations, and applications. It covers well-known techniques such as ultrafiltration and membrane chromatography, while also exploring emerging membrane technologies which are finding their way in pharmaceutical and biotechnology industries, including membrane emulsification, membrane bioreactors, and solvent-resistant nanofiltration. State-of-the-art applications of membrane systems in areas such as drug delivery and virus removal are also investigated by leading experts in the field. Current Trends and Future Developments on (Bio-) Membranes: Membrane Processes in the Pharmaceutical and Biotechnological field is a definitive reference for academics, post-graduates, and researchers in the subjects of biochemical engineering, pharmaceutics, and biotechnology. It is also useful to R&D companies and institutions in these areas, specifically those interested in bioseparations, biopurification, bioproduction, and drug delivery. Offers an overview of classical membrane-based separation techniques such as ultrafiltration, microfiltration and virus filtration Discusses emerging membrane-based separation techniques such as nofiltration in the presence of solvent, membrane emulsification and membrane crystallization Outlines

their applications to bioseparation, biopurification and bioproduction Includes examples in the production of vaccines, antibiotics, biomolecules, drugs, DNA and cells Lists membranes systems for drug delivery like liposomes, nanocapsules and bilayer membranes

Biopharmaceutical Production Technology - Ganapathy Subramanian 2012-05-14

Cost-effective manufacturing of biopharmaceutical products is rapidly gaining in importance, while healthcare systems across the globe are looking to contain costs and improve efficiency. To adapt to these changes, industries need to review and streamline their manufacturing processes. This two volume handbook systematically addresses the key steps and challenges in the production process and provides valuable information for medium to large scale producers of biopharmaceuticals. It is divided into seven major parts: - Upstream Technologies - Protein Recovery - Advances in Process Development - Analytical Technologies - Quality Control - Process Design and Management - Changing Face of Processing With contributions by around 40 experts from academia as well as small and large biopharmaceutical companies, this unique handbook is full of first-hand knowledge on how to produce biopharmaceuticals in a cost-effective and quality-controlled manner.

Clean-In-Place for Biopharmaceutical Processes - Dale A. Seiberling 2007-10-15

An invaluable source instruction on the principles, instrumentation, design, implementation, operation, and maintenance of an effective clean-in-place system (CIP), this guide illustrates best practices and successful applications of CIP in both pharmaceutical and biotechnology facilities. Offering reader-friendly descriptions of the various types of equipment and materials found in typical CIP processes, Clean-In-Place For Biopharmaceutical Processes will take the guess-work out of CIP development, and illustrate all one needs to know for the establishment and optimal functioning of a CIP system.

Applied Biocatalysis - Lutz Hilterhaus 2016-07-27

This reference book originates from the interdisciplinary research cooperation between academia and industry. In three distinct parts, latest results from basic research on stable enzymes are explained and brought into context with possible industrial applications. Downstream processing technology as well as biocatalytic and biotechnological production processes from global players display the enormous potential of biocatalysts. Application of "extreme" reaction conditions (i.e. unconventional, such as high temperature, pressure, and pH value) - biocatalysts are normally used within a well defined process window - leads to novel synthetic effects. Both novel enzyme systems and the synthetic routes in which they can be applied are made accessible to the reader. In addition, the complementary innovative process technology under unconventional conditions is highlighted by latest examples from biotech industry.

Virus filtration - Kurt Brorson 2008

Advanced Membrane Technology and Applications - Norman N Li 2011-09-20

Advanced membranes-from fundamentals and membrane chemistry to manufacturing and applications A hands-on reference for practicing professionals, Advanced Membrane Technology and Applications covers the fundamental principles and theories of separation and purification by membranes, the important membrane processes and systems, and major industrial applications. It goes far beyond the basics to address the formulation and industrial manufacture of membranes and applications. This practical guide: Includes coverage of all the major types of membranes: ultrafiltration; microfiltration; nanofiltration; reverse osmosis (including the recent high-flux and low-pressure membranes and anti-fouling membranes); membranes for gas separations; and membranes for fuel cell uses Addresses six major topics: membranes and applications in water and wastewater; membranes for biotechnology and chemical/biomedical applications; gas separations; membrane contractors and reactors; environmental and energy applications; and membrane materials and characterization Includes discussions of important strategic issues and the future of membrane technology With chapters contributed by leading experts in their specific areas and a practical focus, this is the definitive reference for professionals in industrial manufacturing and separations and research and development; practitioners in the manufacture and applications of membranes; scientists in water treatment, pharmaceutical, food, and fuel cell processing industries; process engineers; and others. It is also an excellent resource for researchers in industry and academia and graduate students taking courses in separations and membranes and related fields.

Biomass, Biofuels, Biochemicals - Ram Sarup Singh 2019-01-31

Biomass, Biofuels and Biochemicals: Advances in Enzyme Technology provides state-of-the-art information on the fundamental aspects and current perspectives in enzyme technology to graduate students, postgraduates and researchers working in industry and academia. The book provides information about the use of enzyme technology as an important tool for biotechnological processes, including food, feed, fuels, textiles, paper, energy and environmental applications. The search for improvements in existing enzyme-catalyzed processes dictates the need to update information on various enzyme technologies. The book gives a snapshot of current practice and research in the area of enzyme technology. Includes current and emerging technologies for the development of novel enzyme catalysis Outlines immobilized enzymes and their implications Refers to enzymes as diagnostic tools Includes metabolic engineering principles for improving industrial enzymes

Pharmaceutical Biotechnology - Adalberto Pessoa 2021-07-16

Pharmaceutical Biotechnology: A Focus on Industrial Application covers the development of new biopharmaceuticals as well as the improvement of those being produced. The main purpose is to provide background and concepts related to pharmaceutical biotechnology, together with an industrial perspective. This is a comprehensive text for undergraduates, graduates and academics in biochemistry, pharmacology and biopharmaceutics, as well as professionals working on the interdisciplinary field of pharmaceutical biotechnology. Written with educators in mind, this book provides teachers with background material to enhance their classes and offers students and other readers an easy-to-read text that examines the step-by-step stages of the development of new biopharmaceuticals. Features: Discusses specific points of great current relevance in relation to new processes as well as traditional processes Addresses the main unitary operations used in the biopharmaceutical industry such as upstream and downstream Includes chapters that allow a broad evaluation of the production process Dr. Adalberto Pessoa Jr. is Full Professor at the School of Pharmaceutical Sciences of the University of São Paulo and Visiting Senior Professor at King’s College London. He has experience in enzyme and fermentation technology and in the purification processes of biotechnological products such as liquid–liquid extraction, cross-flow filtration and chromatography of interest to the pharmaceutical and food industries. Dr. Michele Vitolo is Full Professor at the School of Pharmaceutical Sciences of the University of São Paulo. He has experience in enzyme technology, in immobilization

techniques (aiming the reuse of the biocatalyst) and in the operation of membrane reactors for obtaining biotechnological products of interest to the pharmaceutical, chemical and food industries. Dr. Paul F. Long is Professor of Biotechnology at King's College London and Visiting International Research Professor at the University of São Paulo. He is a microbiologist by training and his research uses a combination of bioinformatics, laboratory and field studies to discover new medicines from nature, particularly from the marine environment.

Biotechnology - Kenneth E. Avis 2020-04-22

Biotechnology: Quality Assurance and Validation provides a practical, detailed discussion of what issues Quality Assurance and Quality Control need to identify for effective control in the preparation of biotechnology products. The book presents a series of topics that define some of the unique challenges facing biotechnology companies in producing biopharmaceutical products. The topics selected address quality and validation issues, starting with the cryopreservation of cell lines through the filling and finishing of the product. It includes a validation guide, a clear presentation of how to use filtration effectively, a synoptic view of cleaning procedures, and much more.

Process Scale Bioseparations for the Biopharmaceutical Industry - Abhinav A. Shukla 2006-07-07

The biopharmaceutical industry has become an increasingly important player in the global economy, and the success of these products depends on the development and implementation of cost-effective, robust and scaleable production processes. Bioseparations-also called downstream processing- can be a key source of competitive advantageto biopharmaceutical developers. Process Scale Bioseparations for the Biopharmaceutical Industry brings together scientific principles, empirical approaches, and practical considerations for designing industrial downstream bioprocesses for various classes of biomolecules. Using clear language along with numerous case studies, examples, tables, flow charts, and schematics, the book presents perspectives from experienced professionals involved in purification processes and industrial downstream unit operations. The authors provide useful experimental design strategies and guidelines for developing application-specific process scale bioseparations. Chapter topics include harvest by centrifugation and filtration, expanded bed chromatography, protein refolding, modes of preparative chromatography, methodologies for resin screening, membrane chromatography, protein crystallization, viral filtration, ultrafiltration/diafiltration, implementing post-approval downstream process changes for an antibody product, and future trends. Ideal for both new and experienced scientists in the biopharmaceutical industry and students, Process Scale Bioseparations for the Biopharmaceutical Industry is a comprehensive resource for all topics relevant to industrial process development.

Aulton's Pharmaceutics - Michael E. Aulton 2013

"Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.