
Large-Scale Mammalian Cell Culture Technology

edited by Anthony S. Lubinetski

Large Scale Mammalian Cell Culture Technology Biotechnology And Bioprocessing

Warren C. Hyer



Large Scale Mammalian Cell Culture Technology Biotechnology And Bioprocessing:

Large-Scale Mammalian Cell Culture Technology Lubiniecki,2018-05-02 An interdisciplinary approach integrating biochemistry biology genetics and engineering for the effective production of protein pharmaceuticals The volume offers a biological perspective of large scale animal cell culture and examines diverse processing strategies process management regulator

Current Developments in Biotechnology and Bioengineering Christian Larroche,M. Angeles Sanroman,Guocheng Du,Ashok Pandey,2016-09-17 Current Developments in Biotechnology and Bioengineering Bioprocesses Bioreactors and Controls provides extensive coverage of new developments state of the art technologies and potential future trends reviewing industrial biotechnology and bioengineering practices that facilitate and enhance the transition of processes from lab to plant scale which is becoming increasingly important as such transitions continue to grow in frequency Focusing on industrial bioprocesses bioreactors for bioprocesses and controls for bioprocesses this title reviews industrial practice to identify bottlenecks and propose solutions highlighting that the optimal control of a bioprocess involves not only maximization of product yield but also taking into account parameters such as quality assurance and environmental aspects Describes industrial bioprocesses based on the reaction media Lists the type of bioreactors used for a specific bioprocess application Outlines the principles of control systems in various bioprocesses

Commercial biotechnology : an international analysis. , Industrial Biotechnology Christoph Wittmann,James C. Liao,2017-03-06 The latest volume in the Advanced Biotechnology series provides an overview of the main product classes and platform chemicals produced by biotechnological processes today with applications in the food healthcare and fine chemical industries Alongside the production of drugs and flavors as well as amino acids bio based monomers and polymers and biofuels basic insights are also given as to the biotechnological processes yielding such products and how large scale production may be enabled and improved Of interest to biotechnologists bio and chemical engineers as well as those working in the biotechnological chemical and food industries

Cell Culture Engineering and Technology Ralf Pörtner,2022-02-20 This contributed volume is dedicated towards the progress achieved within the last years in all areas of Cell Culture Engineering and Technology It comprises contributions of active researchers in the field of cell culture development for the production of recombinant proteins cell line development cell therapy and gene therapy with consideration of media development process scale up reactor design monitoring and control and model assisted strategies for process design The knowledge and expertise of the authors cover disciplines like cell biology engineering biotechnology and biomedical sciences This book is conceived for graduate students postdoctoral fellows and researchers interested in the latest developments in Cell Engineering

Cell Culture Technology for Pharmaceutical and Cell-Based Therapies Sadettin Ozturk,Wei-Shou Hu,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 development

Biotransformations and Bioprocesses Mukesh Doble, Anil Kumar Kruthiventi, Vilas Ganjanan Gaikar, 2004-03-24 From the laboratory to full scale commercial production this reference provides a clear and in depth analysis of bioreactor design and operation and encompasses critical aspects of the biocatalytic manufacturing process It clarifies principles in reaction and biochemical engineering synthetic and biotransformation chemistry and biocell and enzyme

Bioprocess Technology Mr. Rohit Manglik, 2024-01-12 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels

Process Validation in Manufacturing of Biopharmaceuticals Anurag Singh Rathore, Hal Baseman, Scott Rudge, 2023-12-18 The fourth edition of Process Validation in Manufacturing of Biopharmaceuticals is a practical and comprehensive resource illustrating the different approaches for successful validation of biopharmaceutical processes A pivotal text in its field this new edition provides guidelines and current practices contains industrial case studies and is expanded to include in depth analysis of the new Process Validation PV guidance from the US FDA Key Features Offers readers a thorough understanding of the key concepts that form the basis of a good process validation program for biopharmaceuticals Includes case studies from the various industry leaders that demonstrate application of these concepts Discusses the use of modern tools such as multivariate analysis for facilitating a process validation exercise Covers process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing including chromatography chemical modification reactions ultrafiltration and microfiltration and practical methods to test raw materials and in process samples Providing a thorough understanding of the key concepts that form the basis of a good process validation program this book will help readers ensure that PV is carried out and exceeds expectations Fully illustrated this is a much needed practical guide for biopharmaceutical manufacturers

Process Architecture in Biomanufacturing Facility Design Jeffery Odum, Michael C. Flickinger, 2018-01-26 Essential information for architects designers engineers equipment suppliers and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities that are designed and built today are radically different than in the past The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature and it is rarely taught in architecture or design schools This is the first book for architects and designers that fills this void Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies use state of the art equipment are energy efficient and sustainable and meet regulatory requirements Relying on their many years of hands on design and operations experience the authors emphasize concepts and practical approaches toward design

construction and operation of biomanufacturing facilities including product process facility relationships closed systems and single use equipment aseptic manufacturing considerations design of biocontainment facility and process based laboratory and sustainability considerations as well as an outlook on the facility of the future Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U S A and WHO especially in emerging global markets in India China Latin America and the Asia Pacific regions Focuses on innovative design and equipment to speed construction and time to market increase energy efficiency and reduce footprint construction and operational costs as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines biotechnology and life science industry including architects and designers of industrial facilities construction equipment vendors and mechanical engineers It is also recommended for university instructors advanced undergraduates and graduate students in architecture industrial engineering mechanical engineering industrial design and industrial interior design

A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry Nuala Calnan, Martin J Lipa, Paige E. Kane, Jose C. Menezes, 2017-06-26 This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical medical devices and medical diagnostics industries In particular it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients The book also provides good practice examples of how the effective use of an organisation s knowledge assets can provide a path towards business excellence

PAT Applied in Biopharmaceutical Process Development And Manufacturing Cenk Undey, Duncan Low, Jose C. Menezes, Mel Koch, 2011-12-07 As with all of pharmaceutical production the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA initiated Quality by Design QbD guidelines and corresponding activities of the International Committee for Harmonization ICH Given the rapid growth in the biopharmaceutical area and the comp

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition Anurag S. Rathore, Gail Sofer, 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 **Bioprocessing Safety** Warren C. Hyer,1990

Comprehensive Biotechnology,2011-08-26 The second edition of Comprehensive Biotechnology Six Volume Set continues the tradition of the first inclusive work on this dynamic field with up to date and essential entries on the principles and practice of biotechnology The integration of the latest relevant science and industry practice with fundamental biotechnology concepts is presented with entries from internationally recognized world leaders in their given fields With two volumes covering basic fundamentals and four volumes of applications from environmental biotechnology and safety to medical biotechnology and healthcare this work serves the needs of newcomers as well as established experts combining the latest relevant science and industry practice in a manageable format It is a multi authored work written by experts and vetted by a prestigious advisory board and group of volume editors who are biotechnology innovators and educators with international influence All six volumes are published at the same time not as a series this is not a conventional encyclopedia but a symbiotic integration of brief articles on established topics and longer chapters on new emerging areas Hyperlinks provide sources of extensive additional related information material authored and edited by world renown experts in all aspects of the broad multidisciplinary field of biotechnology Scope and nature of the work are vetted by a prestigious International Advisory Board including three Nobel laureates Each article carries a glossary and a professional summary of the authors indicating their appropriate credentials An extensive index for the entire publication gives a complete list of the many topics treated in the increasingly expanding field [Mammalian Cell Cultures for Biologics Manufacturing](#) Weichang Zhou,Anne Kantardjieff,2014-01-15 Volumes are organized topically and provide a comprehensive discussion of developments in the respective field over the past 3 5 years The series also discusses new discoveries and applications Special volumes are dedicated to selected topics which focus on new biotechnological products and new processes for their synthesis and purification In general special volumes are edited by well known guest editors The series editor and publisher will however always be pleased to receive suggestions and supplementary information Manuscripts are accepted in English *Protein Therapeutics* Zuben E. Sauna,Chava Kimchi-Sarfaty,2017-07-19 Medicinal chemistry is both science and art The science of medicinal chemistry offers mankind one of its best hopes for improving the quality of life The art of medicinal chemistry continues to challenge its practitioners with the need for both intuition and experience to discover new drugs Hence sharing the experience of drug research is uniquely beneficial to the field of medicinal chemistry Drug research requires interdisciplinary team work at the interface between chemistry biology and medicine Therefore the topic related series

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Applied Bioengineering Toshiomi Yoshida, 2017-01-12 A comprehensive overview of the topic highlighting recent developments ongoing research trends and future directions Experts from Europe Asia and the US cover five core areas of imminent importance to the food feed pharmaceutical and water treatment industries in terms of sustainable and innovative processing and production In the field of enzyme engineering they summarize historic developments and provide an overview of molecular enzyme engineering while also discussing key principles of microbial process engineering including chapters on process development and control Further sections deal with animal and plant cell culture engineering The final section of the book deals with environmental topics and highlights the application of bioengineering principles in waste treatment and the recovery of valuable resources With its cutting edge visions extensive discussions and unique perspectives this is a ready reference for biotechnologists bioengineers bioengineers biotechnological institutes and environmental chemists

Putting Biotechnology to Work National Research Council, Division on Earth and Life Studies, Commission on Life Sciences, Committee on Bioprocess Engineering, 1992-02-01 The ability of the United States to sustain a dominant global position in biotechnology lies in maintaining its primacy in basic life science research and developing a strong resource base for bioprocess engineering and bioproduct manufacturing This book examines the status of bioprocessing and biotechnology in the United States current bioprocess technology products and opportunities and challenges of the future and what must be done to meet those challenges It gives recommendations for action to provide suitable incentives to establish a national program in bioprocess engineering research development education and technology transfer

Continuous Manufacturing of Pharmaceuticals Peter Kleinebudde, Johannes Khinast, Jukka Rantanen, 2024-10-28 A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes Continuous process manufacturing provides a proven solution Among its many benefits are minimized waste energy consumption and raw material use the accelerated introduction of new drugs the use of smaller production facilities with lower building and capital costs the ability to monitor drug quality on a continuous basis and enhanced process reliability and flexibility Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency This book covers key aspects of the continuous manufacturing of pharmaceuticals The first part provides an

overview of key chemical engineering principles and the current regulatory environment The second covers existing technologies for manufacturing both small molecule based products and protein peptide products The following section is devoted to process analytical tools for continuously operating manufacturing environments The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state of art approaches for innovative new manufacturing principles Brings together the essential know how for anyone working in drug manufacturing as well as chemical food and pharmaceutical scientists working on continuous processing Covers chemical engineering principles regulatory aspects primary and secondary manufacturing process analytical technology and quality by design Contains contributions from researchers in leading pharmaceutical companies the FDA and academic institutions Offers an extremely well informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely comprehensive and authoritative Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing

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