

BIOPHARMACEUTICAL PRODUCTION: INNOVATIONS AND TRENDS



Single-Use Bioprocessing

Single-use bioprocessing systems consist of disposable components, such as bags, tubing, and filters, which are used once and then discarded.



Bioprinting and 3D Biomanufacturing

In the future, biopharmaceutical production may involve printing tissues and organs for transplantation. This innovation has the potential to address the organ shortage crisis and significantly impact healthcare.



Continuous Bioprocessing

Continuous bioprocessing is revolutionizing the industry by enabling the uninterrupted production of biopharmaceuticals.



Personalized Medicine

Personalized medicine takes into account an individual's genetic, environmental, and lifestyle factors to customize treatment plans. It offers the potential for more effective therapies with fewer side effects.



Gene and Cell Therapies

Gene and cell therapies involve the introduction of genetic material or modified cells into a patient's body to treat or prevent disease.



Biosimilars and Biologics

Biosimilars are biologic products that are highly similar to an already approved reference biopharmaceutical. Biologics, on the other hand, are generic versions of biopharmaceuticals, similar to traditional generic drugs.



Artificial Intelligence and Big Data Analytics

AI can optimize bioprocesses, predict potential failures, and analyze vast datasets for research and development.



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Biopharmaceutical Trends & Innovations

Biopharmaceutical In Transition

G. Walsh, B. Murphy



Biopharmaceutical In Transition:

Analytical Techniques for Biopharmaceutical Development Roberto Rodriguez-Diaz, Tim Wehr, Stephen Tuck, 2005-03-29 This reference assists scientists in the selection and application of analytical techniques for biopharmaceutical identification formulation and assessment providing a valuable survey of exploratory methods commonly utilized during the preclinical clinical and commercial phases of development

Lyophilization of Biopharmaceuticals Henry R. Costantino, Michael J. Pikal, 2005-12-05 Humans have been experimenting with lyophilization or freeze drying as a method to preserve biological structures for over a thousand years This comprehensive volume intended for scientists in both academia and industry covers a wide range of topics relevant to the formulation of peptide and protein drugs in the freeze dried state

Production of Recombinant Proteins Gerd Gellissen, 2006-03-06 While the choices of microbial and eukaryotic expression systems for production of recombinant proteins are many most researchers in academic and industrial settings do not have ready access to pertinent biological and technical information since it is normally scattered throughout the scientific literature This book closes the gap by providing information on the general biology of the host organism a description of the expression platform a methodological section with strains genetic elements vectors and special methods where applicable as well as examples of proteins produced with the respective platform The systems thus described are well balanced by the inclusion of three prokaryotes two Gram negatives and one Gram positive four yeasts two filamentous fungi and two higher eukaryotic cell systems mammalian and plant cells Throughout the book provides valuable practical and theoretical information on the criteria and schemes for selecting the appropriate expression platform the possibility and practicality of a universal expression vector and on comparative industrial scale fermentation with the production of a recombinant Hepatitis B vaccine chosen as an industrial example With a foreword by Herbert P Schweizer Colorado State University USA As a whole this book is a valuable and overdue resource for a varied audience It is a practical guide for academic and industrial researchers who are confronted with the design of the most suitable expression platform for their favorite protein for technical or pharmaceutical purposes In addition the book is also a valuable study resource for professors and students in the fields of applied biology and biotechnology

Biopharmaceuticals, an Industrial Perspective G. Walsh, B. Murphy, 2013-03-09 Biopharmaceuticals an Industrial Perspective provides a unique and up to date insight into the biopharmaceutical industry Largely written by industrial authors its scope is multidisciplinary Several chapters overview the production and medical applications of specific biopharmaceuticals Other chapters detail additional relevant issues including the stabilisation of biopharmaceutical products EU biopharmaceutical regulatory affairs and biopharmaceutical patent law A series of four chapters reviews important validation issues as applied to biopharmaceutical manufacturing Additional issues considered include biopharmaceutical information technology as well as viral and non viral gene therapy The book is of particular relevance to scientists and allied professionals already employed in the biopharmaceutical industry or to those seeking

employment within this industry Its scope also renders it an ideal reference source for students undertaking advanced undergraduate or postgraduate courses in biotechnology pharmaceutical science biochemistry or medicine *Approaches to the Conformational Analysis of Biopharmaceuticals* Roger L. Lundblad,2009-12-15 The activity of many biopharmaceutical polymers is dependent on conformation and the next several years will see increased interest in the conformational analysis of these polymers resulting from the development of biosimilar or follow on biological products While a wide variety of approaches to analysis exists finding the most viable ones would *Continuous Processing in Pharmaceutical Manufacturing* Ganapathy Subramanian,2015-02-09 With contributions from biotechnologists and bioengineers this ready reference describes the state of the art in industrial biopharmaceutical production with a strong focus on continuous processes Recent advances in single use technology as well as application guidelines for all types of biopharmaceutical products from vaccines to antibodies and from bacterial to insect to mammalian cells are covered The efficiency robustness and quality control of continuous production processes for biopharmaceuticals are reviewed and compared to traditional batch processes for a range of different production systems *Challenging Transitions in Learning and Work* ,2010-01-01 In the past two decades advanced capitalist countries have seen sustained growth in labour market participation along with a growth in the number of jobs workers tend to have in their working lives Over a slightly longer period we also see that participation in both formal educational attainment and a range of non compulsory learning training has grown However labour market discrimination based on gender age disability and race ethnicity remains a serious issue in virtually all OECD countries *Challenging Transitions in Learning and Work* presents a critical and expansive exploration of learning and work transitions within this context These transitions are challenging for those enmeshed in them and need to be actively challenged through the critical research reported The impetus for this volume its conceptual framing and much of the research emerges from the team of Canadian researchers who together completed case study and survey projects within the Work and Lifelong Learning WALL network The authors include leading scholars with established international reputations as well as emerging researchers with fresh perspectives This volume will appeal to researchers and policy makers internationally with an interest in educational studies and industrial sociology *Mucosal Delivery of Biopharmaceuticals* José das Neves,Bruno Sarmiento,2014-02-03 Biopharmaceutical medicines the newest class of therapeutics are quite heterogeneous and include a range of molecules such as proteins peptides vaccines and nucleic acids with use in virtually all therapeutic fields e g cancer and infectious diseases vaccination metabolic dysfunctions and diagnostics This edited book gives a concise and up to date overview of the biological features justifying the use of different human mucosa as delivery routes for biopharmaceuticals the technological strategies that have been followed so far regarding the optimization of mucosal potentialities as well as the challenges that arise with the advent of new biopharmaceutical drugs and alternative means of administration Following a brief introduction the first section addresses general aspects of the biology of mucosal tissues and their unique aspects

toward beneficial or deleterious interaction with biopharmaceuticals and their delivery systems The second part reviews the different delivery strategies that have recently been investigated for different mucosal sites The third section describes the development and clinical applications of drug delivery systems and products enclosing biopharmaceuticals for mucosal delivery with a focus on the most successful case studies of recent years The last section briefly centers on relevant aspects of the regulatory toxicological and market issues of mucosal delivery of biopharmaceuticals Scientists and researchers in the fields of drug delivery material science biomedical science and bioengineering as well as professionals regulators and policy makers in the pharmaceutical biotechnology and healthcare industries will find in this book an important compendium of fundamental concepts and practical tools for their daily research and activities

Quality by Design for Biopharmaceuticals
Anurag S. Rathore, Rohin Mhatre, 2011-09-20 The concepts applications and practical issues of Quality by Design Quality by Design QbD is a new framework currently being implemented by the FDA as well as EU and Japanese regulatory agencies to ensure better understanding of the process so as to yield a consistent and high quality pharmaceutical product QbD breaks from past approaches in assuming that drug quality cannot be tested into products rather it must be built into every step of the product creation process Quality by Design Perspectives and Case Studies presents the first systematic approach to QbD in the biotech industry A comprehensive resource it combines an in depth explanation of basic concepts with real life case studies that illustrate the practical aspects of QbD implementation In this single source leading authorities from the biotechnology industry and the FDA discuss such topics as The understanding and development of the product s critical quality attributes CQA Development of the design space for a manufacturing process How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology PAT and how it relates to QbD Relevant PAT tools and applications for the pharmaceutical industry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis MVDA to QbD Filled with vivid case studies that illustrate QbD at work in companies today Quality by Design is a core reference for scientists in the biopharmaceutical industry regulatory agencies and students

Freeze-drying of Pharmaceuticals and Biopharmaceuticals
Felix Franks, Tony Auffret, 2008 Freeze drying in the past popular in the food industry has more recently been adopted by the pharmaceutical industry as a standard method for the production of stable solid preparations Freeze drying of Pharmaceuticals and Biopharmaceuticals is the first book to specifically describe this process as related to the pharmaceutical industry The emphasis of this book is on the properties of the materials processed how effective formulations are arrived at and how they are stored and marketed Beginning with a historical overview of the process Freeze drying of Pharmaceuticals and Biopharmaceuticals briefly describes the processes and equipment involved including the physics chemistry and biochemistry associated with freezing aspects of formulation development primary and secondary drying the economics and engineering of scaling up and most importantly attributes of the dried product It also discusses in

detail the science behind freeze drying such as the properties of crystalline and amorphous solids The book concludes with selected case studies and discusses the future of freeze drying advances in alternative drying methods and concludes with an extensive bibliography This book written by a leading expert in the field is aimed primarily at product and process developers in the biopharmaceutical industry and academia Extract from a review this book is a very useful and thorough overview of the processes in operation during freezing and lyophilization and should be read by all those who are interested in freeze drying and pharmaceutical formulation design I certainly will be returning to it as an excellent summary of these important issues CryoLetters c o Royal Veterinary College London UK

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals Feroz Jameel, Susan Hershenson, 2010-08-09 A real world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals there is a need for practical up to date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products This book helps fill the gap in the field examining all areas of biopharmaceuticals manufacturing from development and formulation to production and packaging Written by a group of experts from industry and academia the book focuses on real world methods for maintaining product integrity throughout the commercialization process clearly explaining the fundamentals and essential pathways for all development stages Coverage includes Research and early development phase appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage packaging and shipping methods Case studies relating to therapeutic monoclonal antibodies recombinant proteins and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries for government and regulatory agencies and for anyone with an interest in the latest developments in the field

Biopharmaceutical Manufacturing Ralf Pörtner, 2024-01-10 This volume Cell Engineering 11 Biopharmaceutical Manufacturing Progress Trends and Challenges is a source of the latest innovative research and technical development in biomanufacturing systems It is organised into 2 parts 1 Manufacturing of recombinant therapeutic proteins e g therapeutic antibodies biosimilars biogenerics and 2 Manufacturing aspects of cell and gene therapy Each with selected chapters on the following topics for both up and downstream such as Advanced process strategies especially continuous manufacturing Advanced culture techniques especially single use systems Process transfer scale up scale down models Processing advances Manufacturing productivity efficiency Model assisted process understanding and development Digital Twins Process controls and analytics Quality control Quality by design Facility design and full scale commercial systems manufacturing technology innovation The book comprises contributions of experts from academia and industry active in the field of cell culture development for the production of recombinant proteins cell therapy and gene therapy with consideration of Digital Twin s and facility design The knowledge and expertise of the

authors cover disciplines like cell biology engineering biotechnology and biomedical sciences Inevitably some omissions will occur in the text but the authors have sought to avoid duplications by extensive cross referencing to chapters in other volumes of this series and elsewhere We hope the volume provides a useful compendium of techniques for scientists in industrial and research laboratories active in this field **Plasmid Biopharmaceuticals** Duarte Miguel F.

Prazeres,2011-08-04 The book addresses the basics applications and manufacturing of plasmid biopharmaceuticals The survey of the most relevant characteristics of plasmids provides the basics for designing plasmid products applications and processes manufacturing Key features that the authors include in the book are i consistency and clear line of direction ii an extensive use of cross referencing between the individual chapters iii a rational integration of chapters iv appellative figures tables and schemes and v an updated but selected choice of references with a focus on key papers **Biophysical**

Characterization of Proteins in Developing Biopharmaceuticals Damian J. Houde,Steven A. Berkowitz,2019-11-13

Biophysical Characterization of Proteins in Developing Biopharmaceuticals Second Edition presents the latest on the analysis and characterization of the higher order structure HOS or conformation of protein based drugs Starting from the very basics of protein structure this book explains the best way to achieve this goal using key methods commonly employed in the biopharmaceutical industry This book will help today s industrial scientists plan a career in this industry and successfully implement these biophysical methodologies This updated edition has been fully revised with new chapters focusing on the use of chromatography and electrophoresis and the biophysical characterization of very large biopharmaceuticals In addition best practices of applying statistical analysis to biophysical characterization data is included along with practical issues associated with the concept of a biopharmaceutical s developability and the technical decision making process needed when dealing with biophysical characterization data Presents basic protein characterization methods and tools applicable to biopharmaceutical research and development Highlights the capabilities and limitations of each technique Discusses the underlining science of each tool Empowers industrial biophysical chemists by providing a roadmap for applying biophysical tools Outlines the needs for new characterization and analytical tools in the biopharmaceutical industry **Mass**

Spectrometry in Biopharmaceutical Analysis Igor A. Kaltashov,Shunhai Wang,Guanbo Wang,2021-11-22

Biopharmaceuticals are a unique class of compounds due to their extreme structural complexity The current text puts together a variety of the state of the art approaches that use mass spectrometry to evaluate various aspects of biopharmaceutical products ranging from monitoring stress related structural changes to their quantitation in pharmacokinetic studies *Biopharmaceutical Processing* Gunter Jagschies,Eva Lindskog,Karol Lacki,Parrish M.

Gallihier,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

The Thriving Biopharma Business Alain Eudarc, Jean-Noël Pellegrin, 2025-10-31 In today's fiercely innovative and complex biopharmaceutical industry successfully managing a pharmaceutical or biotech company from concept to patients requires exceptional strategic leadership and managerial abilities This book is a definitive reference that uniquely integrates critical business strategy finance M A regulatory and intellectual property concepts Bringing new therapies to market is both a sought after experience and a distinguished accomplishment A biopharma leadership team that is able to master the critical levers covered in this book will drive unparalleled value creation through tremendous competitive advantage in the industry Chapter by chapter you'll delve into innovation valuation intellectual property strategy financing pitching transactions contracts and regulatory affairs Through numerous case examples and concepts you'll learn practical avenues to avoid pitfalls drive value creation and navigate the intricate world of the biopharma industry This book equips decision makers founders investors and industry professionals with frameworks illustrations and actionable ideas enabling them to tackle the strategic and managerial challenges inherent in the evolution of a biopharma company Elevate your strategic decisions unlock new opportunities and lead your company to success with this indispensable resource

Fusion Protein Technologies for Biopharmaceuticals Stefan R. Schmidt, 2013-01-28 The state of the art in biopharmaceutical FUSION PROTEIN DESIGN Fusion proteins belong to the most lucrative biotech drugs with Enbrel being one of the best selling biologics worldwide Enbrel represents a milestone of modern therapies just as Humulin the first therapeutic recombinant protein for human use approved by the FDA in 1982 and Orthoclone the first monoclonal antibody reaching the market in 1986 These first generation molecules were soon followed by a plethora of recombinant copies of natural human proteins and in 1998 the first de novo designed fusion protein was launched Fusion Protein Technologies for Biopharmaceuticals examines the state of the art in developing fusion proteins for biopharmaceuticals shedding light on the immense potential inherent in fusion protein design and functionality A wide pantheon of international scientists and researchers deliver a comprehensive and complete overview of therapeutic fusion proteins combining the success stories of marketed drugs with the dynamic preclinical and clinical research into novel drugs designed for as yet unmet medical needs The book covers the major types of fusion proteins receptor traps immunotoxins Fc fusions and peptibodies while also detailing the approaches for developing delivering and improving the stability of fusion proteins The main body of the book

contains three large sections that address issues key to this specialty strategies for extending the plasma half life the design of toxic proteins and utilizing fusion proteins for ultra specific targeting The book concludes with novel concepts in this field including examples of highly relevant multifunctional antibodies Detailing the innovative science commercial realities and brilliant potential of fusion protein therapeutics Fusion Protein Technologies for Biopharmaceuticals is a must for pharmaceutical scientists biochemists medicinal chemists molecular biologists pharmacologists and genetic engineers interested in determining the shape of innovation in the world of biopharmaceuticals PAREXEL's Pharmaceutical R & D Statistical Sourcebook ,2005 Biopharmaceutics Modeling and Simulations Kiyohiko Sugano,2012-08-20 A comprehensive introduction to using modeling and simulation programs in drug discovery and development Biopharmaceutical modeling has become integral to the design and development of new drugs Influencing key aspects of the development process including drug substance design formulation design and toxicological exposure assessment biopharmaceutical modeling is now seen as the linchpin to a drug s future success And while there are a number of commercially available software programs for drug modeling there has not been a single resource guiding pharmaceutical professionals to the actual tools and practices needed to design and test safe drugs A guide to the basics of modeling and simulation programs Biopharmaceutics Modeling and Simulations offers pharmaceutical scientists the keys to understanding how they work and are applied in creating drugs with desired medicinal properties Beginning with a focus on the oral absorption of drugs the book discusses The central dogma of oral drug absorption the interplay of dissolution solubility and permeability of a drug which forms the basis of the biopharmaceutical classification system BCS The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used for biopharmaceutical modeling Reliable practices for reporting results With over 200 figures and illustrations and a peerless examination of all the key aspects of drug research including running and interpreting models validation and compound and formulation selection this reference seamlessly brings together the proven practical approaches essential to developing the safe and effective medicines of tomorrow

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Biopharmaceutical In Transition Introduction

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