BIOTECHNOLOGY: PHARMACEUTICAL ASPECTS

Current Trends in Monoclonal Antibody Development and Manufacturing

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Current Trends In Monoclonal Antibody Development And Manufacturing Biotechnology Pharmaceutical Aspects

Dimitrios A. Lamprou

Current Trends In Monoclonal Antibody Development And Manufacturing Biotechnology Pharmaceutical Aspects:

Current Trends in Monoclonal Antibody Development and Manufacturing Steven J. Shire,Wayne Gombotz,Karoline Bechtold-Peters,James Andya,2009-11-11 Monoclonal antibodies represent one of the fastest growing areas of new drug development within the pharmaceutical industry Several blockbuster products have been approved over the past several years including Rituxan Remicade Avastin Humira and Herceptin In addition over 300 new drugs are currently in clinical trials With both large established biotechnology companies and small start ups involved in the development of this important class of molecules monoclonal antibodies products will become increasingly prevalent over the next decade Recently the regulatory review of monoclonal antibodies has been moved from Center for Biologics and Research to the Center for Drug Evaluation and Research CDER division of the US Food and Drug Administration It is anticipated that CDER will expect a certain minimal amount of data to be provided as more of these products move through the regulatory pipeline Current Trends in Monoclonal Antibody Development and Manufacturing will provide readers with an understanding of what is currently being done in the industry to develop manufacture and release monoclonal antibody products and what will be required for a successful regulatory submission *Development of Antibody-Based Therapeutics* Mohammad A. Tabrizi,Gadi G. Bornstein,Scott L. Klakamp,2012-04-24 Translational strategies for development of antibody based therapeutics should allow understanding of the relationship between the unit dose and unit effect with respect to both beneficial and deleterious effects from early stages of development The flow of information from later to earlier stages of development should provide opportunities to facilitate selection of more effective novel and next generation drug candidates Selection and evaluation of relevant biomarkers in early preclinical development in relevant animal models should allow for identifying potential risks to humans and establishing safe First In Human FIH dosing strategies Hence integration of knowledge with respect to target antigen properties such as antigen distribution expression profile kinetic properties target pharmacology antigen isoforms and pharmacological redundancy in health and disease as well as antibody design criteria such as antibody isotype affinity PK PD and safety is a critical necessity for the design of effective translational strategies Additionally these factors will further offer critical differentiating characteristics for next generation antibodies and novel technologies prove instrumental in generation of biosuperior antibody candidates for market entry This book will examine many important considerations necessary for the design of effective translational strategies during the development of antibody based therapeutics *Handbook of Therapeutic Antibodies* Stefan Dübel,Janice M. Reichert,2014-08-04 Still the most comprehensive reference source on the development production and therapeutic application of antibodies this second edition is thoroughly updated and now has 30% more content Volume 1 covers selection and engineering strategies for new antibodies while the second volume presents novel therapeutic concepts and antibodies in clinical study as well as their potential Volumes 3 and 4 feature detailed and specific information about each antibody approved for therapeutic purposes

including clinical data This unique handbook concludes with a compendium of marketed monoclonal antibodies and an extensive index Beyond providing current knowledge the authors discuss emerging technologies future developments and intellectual property issues such that this handbook meets the needs of academic researchers decision makers in industry and healthcare professionals in the clinic **Pharmaceutical Stability Testing to Support Global Markets** Kim Huynh-Ba,2009-12-04 The International Conference of Harmonization ICH has worked on har nizing the stability regulations in the US Europe and Japan since the early 1990s Even though the Stability Guidelines Q1A R2 was issued over a decade ago issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations As a result the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements streamlining practices improving processes in order to bring safe and effective medical supplies to the patients around the world In 2007 the American Association of Pharmaceutical Scientists AAPS Stability Focus Group organized two workshops the Stability Workshop and the Degradation Mechanism Workshop These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices Recognizing the importance of documenting these discussions and with the permission of AAPS I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings mainly the Stability Workshop I trust that this book will be beneficial to all of you in providing guidance and up to date information for building quality stability programs v Freedom of our mind is Mother of all inventions

Comprehensive Biotechnology ,2019-07-17 Comprehensive Biotechnology Third Edition Six Volume Set unifies in a single source a huge amount of information in this growing field The book covers scientific fundamentals along with engineering considerations and applications in industry agriculture medicine the environment and socio economics including the related government regulatory overviews This new edition builds on the solid basis provided by previous editions incorporating all recent advances in the field since the second edition was published in 2011 Offers researchers a one stop shop for information on the subject of biotechnology Provides in depth treatment of relevant topics from recognized authorities including the contributions of a Nobel laureate Presents the perspective of researchers in different fields such as biochemistry agriculture engineering biomedicine and environmental science *New Trends in Radiopharmaceutical Synthesis, Quality Assurance, and Regulatory Control* Ali M. Emran,2013-11-09 Marking the 200th National Meeting of the American Chemical Society The Division of Nuclear Chemistry and Technology hosted a group of about 90 scientists from 15 different countries to discuss the new trends in radiopharmaceutical synthesis quality assurance and regulatory control This event took place in Washington D C on August 27 30 1990 When I first suggested the idea for this symposium a group of scientists who pioneered the proposed topics offered their help to organize and run such a big task with me Their names are listed here in appreciation Thomas E Boothe Cyclotron Facility Mt Sinai Medical Center Miami Beach Florida USA Robert F

Dannals Division of Nuclear Medicine The Johns Hopkins Medical Institutions Baltimore Maryland USA Anthony L Feliu Julich Nuclear Research Center Julich Germany Joanna S Fowler Chemistry Department Brookhaven National Laboratory Upton New York USA George W Kabalka Department of Chemistry University of Tennessee Knoxville Tennessee USA Hank F Kung Department of Radiology University of Pennsylvania Philadelphia Pennsylvania USA James F Lamb Imagents Inc Houston Texas USA Harold A O Brien Jr Los Alamos National Laboratory Los Alamos New Mexico USA Joseph R Peterson Dept of Chemistry University of Tennessee Knoxville Tennessee USA Hernan Vera Ruiz International Atomic Energy Agency Vienna Austria Roy S Tilbury University of Texas M D Anderson Cancer Center Houston Texas USA In addition a number of distinguished colleagues have participated in the process of reviewing the manuscripts presented in this volume Their effort is sincerely acknowledged Animal Cell Biotechnology Hansjörg Hauser,Roland Wagner,2014-11-10 This book introduces fundamental principles and practical application of techniques used in the scalable production of biopharmaceuticals with animal cell cultures A broad spectrum of subjects relevant to biologics production and manufacturing are reviewed including the generation of robust cell lines a survey of functional genomics for a better understanding of cell lines and processes as well as advances in regulatory compliant upstream and downstream development The book is an essential reference for all those interested in translational animal cell based pharmaceutical biotechnology **Pharmaceutical Biotechnology** Adalberto Pessoa,Michele Vitolo,Paul Frederick Long,2021-07-15 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 S o 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 S o 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 S o 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 **New and Future Developments in Microbial Biotechnology and Bioengineering** Alexandre Gomes Rodrigues,2020-06-10 New and Future Developments in Microbial Biotechnology and Bioengineering Microbial Biomolecules Properties Relevance and Their Translational Applications presents a concise review on microbial biotechnology along with impacts and recent results from research centers small companies and large enterprises The book brings the most relevant information on how we can use resources in this case from microorganisms and technology to develop solutions in fields like biofuels food cosmetics and medicine It covers case studies of start ups in the field and explains how scientists have moved their ideas into profitable bio based products that are necessary for our current living standards In addition the book describes strategic governmental programs designed to exploit biomass in a sustainable way along with detailed information on research in several high impact worldwide laboratories It gives concrete examples of ongoing research from molecules to methods such as L asparaginase extremophiles new diagnostics tools and the analytical methods that have raised the quality of the data obtained thereby boosting the so called bioeconomy Comprises a unique source of information on the various applications of microbial biomolecules Provides resourceful material for new ideas and strong rational application oriented stories Discusses biotech companies in various areas biofuel food medicine etc who are actively using microbial biomolecules Outlines scientific discoveries and their translation into profitable products Gives an insight perspective of institutional and governmental strategic research programs aiming to preserve explore and generate benefits from microbial biomolecules

Handbook of Biological Therapeutic Proteins Sarfaraz Niazi,2024-04-15 Since 1972 which marks the invention of recombinant engineering more than 500 therapeutic proteins have been approved for clinical use Today biological drugs constitute almost 70% of all new drugs and have a biological origin The first edition of this book dealt with biosimilars and this edition i e the second edition focuses on new drugs yet limits to therapeutic proteins Newer technologies for drug development represent the updated topics in the book and include repur posing AI driven identification of newer designs novel expression systems manufacturing using these systems rapidly changing regulatory pathways and legal hurdles This edition discusses how to identify develop manufacture and take multibillion dollar products to market within the shortest possible time Features Complete and thorough coverage of the regulatory and technological challenges of developing generic therapeutic proteins Comprehensive discovery to market newer technologies regulatory planning and IP hurdles are included that are not found elsewhere Expanded volume that must be in the hands of every company interested in biological drugs including the mRNA based biopharmaceutical companies fast appearing on the market Discusses how to identify develop manufacture and take multibillion dollar products to market in the shortest possible time Renowned author and entrepreneur

in the field of drug discovery and production **Sustainability in the Manufacturing of Pharmaceuticals** Dimitrios A. Lamprou,2025-10-01 Sustainability in Pharmaceutical Manufacturing is a groundbreaking reference for the pharmaceutical industry Currently lagging behind other manufacturing sectors pharmaceutical production requires significant changes in areas such as manufacturing methods waste management packaging and supply chain This book compiles cutting edge research from leading global experts offering scientific insights and innovative strategies to revolutionize sustainability in pharmaceuticals It explores the transformative potential of the circular economy lifecycle management and resource optimization for maximum efficiency and minimal environmental impact The book delves into green chemistry highlighting alternative solvents and methods for drug production It emphasizes novel microfluidic and additive manufacturing techniques utilizing bio based sustainable polymers and materials Chapters on greener drug discovery development and scaling processes provide the most current research at each production stage This invaluable resource enables researchers in academia and industry to make informed choices enhancing their manufacturing practices and shaping the future of sustainability in the pharmaceutical sector Covers the importance of sustainability in the pharmaceutical sector Discusses new manufacturing methods as key elements to make the sector more sustainable Provides a dedicated chapter on regulatory aspects **Recent Trends in Biotechnology** M.K. Rai,N.J. Chikhake,P.V. Thakare,P.A. Wadegaonkar,A.P. Ramteke,2004-09-01 Biotechnology is an emerging field and has been the center of attraction for researchers politicians and common people globally The present proceedings Recent Trends in Biotechnology as the name signify reflects an interdisciplinary approach and status of the technology The book would be useful for readers of diverse disciplines including biotechnologists botanists zoologists pharmacologists bioinformatist and people loving the new technology

Pharmaceutical Biotechnology Daan J. A. Crommelin,Robert D. Sindelar,Bernd Meibohm,2019-04-13 This introductory text explains both the basic science and the applications of biotechnology derived pharmaceuticals with special emphasis on their clinical use It serves as a complete one stop source for undergraduate graduate pharmacists pharmaceutical science students and for those in the pharmaceutical industry The Fifth Edition completely updates the previous edition and also includes additional coverage on the newer approaches such as oligonucleotides siRNA gene therapy and nanotech and enzyme replacement therapy 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 **Industrial Biotechnology** Christoph Wittmann,James C. Liao,2016-11-23 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 Manual of Industrial Microbiology and Biotechnology Richard H. Baltz,Arnold L. Demain,Julian E. Davies,2010-03-25 A rich array of methods and discussions of productive microbial processes Reviews of the newest techniques approaches and options in the use of microorganisms and other cell culture systems for the manufacture of pharmaceuticals industrial enzymes and proteins foods and beverages fuels and fine chemicals and other products Focuses on the latest advances and findings on the current state of the art and science and features a new section on the microbial production of biofuels and fine chemicals as well as a stronger emphasis on mammalian cell culture methods Covers new methods that enhance the capacity of microbes used for a wide range of purposes from winemaking to pharmaceuticals to bioremediation at volumes from micro to industrial scale **Plant Biotechnology: Progress in Genomic Era** S. M. Paul Khurana,Rajarshi Kumar Gaur,2019-11-14 Refinement in sequencing technologies and potential of genomic research resulted in meteoric growth of biological information such as sequences of DNA RNA and protein requiring databases for efficient storage management and retrieval of the biological information Also computational algorithms for analysis of these colossal data became a vital aspect of biological sciences The work aims to show the process of turning bioscience innovation into companies and products covering the basic science the translation of science into technology Due to rapid developments there seems to be no basic difference between the pharmaceutical industry and the biotechnological industry However approved products in the pipeline and renewed public confidence make it one of the most promising areas of economic growth in the near future India offers a huge market for the products as well as cheap manufacturing base for export The book is a sincere work of compilation of new and recent advances in the topic of concern through various innovative researches and scientific opinion therefrom The book is dedicated to the readers who will definitely find it interesting and knowledgeable in carrying out their respective researches in different aspects of applied microbiology and biotechnology

Green Catalysis, Volume 3 ,2014-04-07 The shift towards being as environmentally friendly as possible has resulted in the need for this important volume on the topic of biocatalysis Edited by the father and pioneer of Green Chemistry Professor Paul Anastas and by the renowned chemist Professor Robert Crabtree this volume covers many different aspects from industrial applications to the latest research straight from the laboratory It explains the fundamentals and makes use of everyday examples to elucidate this vitally important field An essential collection for anyone wishing to gain an understanding of the world of green chemistry as well as for chemists environmental agencies and chemical engineers

Biopharmaceutical Processing Gunter Jagschies,Eva Lindskog,Karol Lacki,Parrish M. Galliher,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 Cumulated Index Medicus ,1987

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