

# Glycosylation Engineering Of Biopharmaceuticals M

**Biopharmaceuticals** Basanta Kumara Behera.2020-12-07 Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in

understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals

Cell Culture Engineering Gyun Min Lee, Helene Fastrup Kildegaard. 2020-01-13 Offers a comprehensive overview of cell culture engineering, providing insight into cell engineering, systems biology approaches and processing technology In Cell Culture Engineering: Recombinant Protein Production, editors Gyun Min Lee and Helene Fastrup Kildegaard assemble top class authors to present expert coverage of topics such as: cell line development for therapeutic protein production; development of a transient gene expression upstream platform; and CHO synthetic biology. They provide readers with everything they need to know about enhancing product and bioprocess attributes using genome-scale models of CHO metabolism; omics data and mammalian systems biotechnology; perfusion culture; and much more. This all-new, up-to-date reference covers all of the important aspects of cell culture engineering, including cell engineering, system biology approaches, and processing technology. It describes the challenges in cell line development and cell engineering, e.g. via gene editing tools like CRISPR/Cas9 and with the aim to engineer glycosylation patterns. Furthermore, it gives an overview about synthetic biology approaches applied to cell culture

engineering and elaborates the use of CHO cells as common cell line for protein production. In addition, the book discusses the most important aspects of production processes, including cell culture media, batch, fed-batch, and perfusion processes as well as process analytical technology, quality by design, and scale down models. -Covers key elements of cell culture engineering applied to the production of recombinant proteins for therapeutic use -Focuses on mammalian and animal cells to help highlight synthetic and systems biology approaches to cell culture engineering, exemplified by the widely used CHO cell line -Part of the renowned Advanced Biotechnology book series Cell Culture Engineering: Recombinant Protein Production will appeal to biotechnologists, bioengineers, life scientists, chemical engineers, and PhD students in the life sciences.

**Biobettters** Amy Rosenberg, Barthélemy Demeule. 2015-08-21 "Biobettters: Protein Engineering to Approach the Curative" discusses the optimization of protein therapeutic products for treatment of human diseases. It is based on the fact that though numerous important therapeutic protein products have been developed for life threatening and chronic diseases that possess acceptable safety and efficacy profiles, these products have generally not been reexamined and modified for an improved clinical performance, with enhancements both to safety and efficacy profiles. Advances in protein engineering, coupled with greatly enhanced understanding of critical product quality attributes for efficacy and safety, make it possible to optimize predecessor products for clinical performance, thereby enhancing patient quality of life and with the potential for great savings in health care costs. Yet despite such knowledge, there is little movement towards such modifications. This book examines engineering protein therapeutic products such that they exhibit an optimal, not just an adequate, clinical performance profile. Two product classes, therapeutic enzymes for lysosomal storage diseases (enzyme replacement therapies, ERT) and monoclonal antibodies (mAbs),

are used as examples of what modifications to such proteins could be made to enhance clinical performance, “closer to a cure” as it were. For ERT, the key to optimizing clinical performance is to ensure the ERT is endowed with moieties that target the protein to the relevant target tissue. Thus, for Gaucher Disease, our best example of how to optimize an ERT to address a disease that manifests in specific target tissues (macrophages and monocytes), the enzyme has been extensively modified to target macrophages. For diseases such as Pompe Disease, largely a disorder of muscle, optimal performance of ERT will depend on endowing the enzyme with the ability to be taken up via the Mannose 6 Phosphate Receptor, and so one of the chapters in the book will discuss such approaches. Moreover, a major failure of biotechnology based products is to gain access to the CNS, a key target tissue in numerous diseases. Thus, a chapter has been devoted to strategies to access the CNS. Additionally, immune responses to therapeutic proteins can be highly problematic, eliminating the efficacy of life saving or highly effective protein therapeutics. This is especially poignant in the case of Pompe Disease wherein great improvement in muscle strength and functionality is lost following development of an immune response to the ERT with consequent patient deterioration and death. Thus, a chapter regarding protein engineering, as well as other non-clinical approaches to diminishing immunogenicity is a valuable part of the book. Monoclonal antibodies (mAbs) can be engineered to bind targets relevant to a wide variety of diseases; binding affinity, however, is only part of the equation and one of the chapters will present a molecular assessment approach that balances affinity with pharmacokinetics and manufacturability. As with other proteins immunogenicity can be problematic, being responsible for loss of efficacy of anti-TNF mAbs, often after prolonged successful treatment. The authors will also share their perspective on the consequences of physico-chemical modifications occurring to mAbs once they reach the

circulation or their target, a research area open to further development from a protein engineering as well as analytical perspective. This book will also discuss novel platforms for protein therapeutics, technologies that exceed mAbs with respect to potency, and hence, potentially efficacy. These platforms consist largely of repeat domain proteins with very high affinity for their target ligands, but while potentially more efficacious, immunogenicity may be a major problem limiting use. The economics surrounding the issue of biobetters is another high-profile issue - this final chapter will explore the incentives and disincentives for developing biobetters and consider incentives that might make their pursuit more rewarding.

*Monoclonal Antibodies* Harleen Kaur, Dietmar Reusch. 2021-08-03 Monoclonal antibodies (mAbs) are naturally occurring complex biomolecules. New engineering methods have turned mAbs into a leading therapeutic modality for addressing immunotherapeutic challenges and led to the rise of mAbs as the dominant class of protein therapeutics. mAbs have already demonstrated a great potential in developing safe and reliable treatments for complex diseases and creating more affordable healthcare alternatives. Developing mAbs into well-characterized antibody therapeutics that meet regulatory expectations, however, is extremely challenging. Obstacles to overcome include the determination and development of physiochemical characteristics such as aggregation, fragmentation, charge variants, identity, carbohydrate structure, and higher-order structure (HOS). This book dives deep into mAbs structure and the array of physiochemical testing and characterization methods that need to be developed and validated to establish a mAb as a therapeutic molecule. The main focus of this book is on physiochemical aspects, including the importance of establishing quality attributes such as glycosylation, primary sequence, purity, and HOS and elucidating the structure of new antibody formats by mass spectrometry. Each of the

aforementioned quality attributes has been discussed in detail; this will help scientists in researching and developing biopharmaceuticals and biosimilars to find practical solutions to physicochemical testing and characterization. Describes the spectrum of analytical tests and characterization methods necessary for developing and releasing mAb batches Details antibody heterogeneity in terms of size, charge, and carbohydrate content Gives special focus to the structural analysis of mAbs, including mass spectrometry analysis Presents the basic structure of mAbs with clarity and rigor Addresses regulatory guidelines - including ICH Q6B - in relation to quality attributes Lays out characterization and development case studies including biosimilars and new antibody formats

*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

**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.

**Microalgal Biotechnology** Eduardo Jacob-Lopes, Leila Queiroz Zepka, Maria Isabel Queiroz. 2018-06-27 Microalgal Biotechnology presents an authoritative and comprehensive overview of the microalgae-based processes and products. Divided into 10 discreet chapters, the book covers topics on applied technology of microalgae. Microalgal Biotechnology provides an insight into future developments in each field and extensive bibliography. It will be an essential resource for researchers and academic and industry professionals in the microalgae biotechnology field.

*Modern Biopharmaceuticals, 4 Volume Set* Jörg Knäblein. 2005-10-28 The biopharmaceutical market has come along way since 1982 when the first biopharmaceutical product, recombinant human insulin, was launched. Over 120 such products are currently being marketed around the world including nine blockbuster drugs. The global market for biopharmaceuticals, which is currently valued at US\$41 billion, has been growing at an impressive compound annual growth rate of 21% over the previous five years. With over one third of all pipe-line products in active development are biopharmaceuticals, this segment is set to continue outperforming the total pharmaceutical market and could easily reach US\$100 billion by the end of this decade.

**Capillary Electrophoresis Mass Spectrometry for Proteomics and Metabolomics** Rawi Ramautar, David D. Y. Chen. 2022-10-11 Capillary Electrophoresis—Mass Spectrometry for Proteomics and Metabolomics A powerful and essential resource for researchers with an interest in CE-MS In Capillary Electrophoresis—Mass Spectrometry for Proteomics and Metabolomics: Principles and Applications, a team of distinguished researchers delivers a comprehensive overview of bioanalytical capillary electrophoresis coupled to mass spectrometry (CE-MS). The book explains foundational principles, technology as well the strategies and techniques used in data analysis for



metabolic and proteomic studies. It also provides a global overview of recent developments and advances for improving CE-MS sensitivity and reproducibility. An essential handbook for everyone performing metabolomic and proteomic analysis, the information provided here will assist researchers in tapping into the full potential of this technique to answer biological and clinical questions. Readers will also find: A thorough introduction to the principles of capillary electrophoresis, including its fundamentals, CE separation modes, capillary coatings, and the fundamentals of mass spectrometry In-depth examinations of technological developments in capillary electrophoresis, including sample preparation, online preconcentration, detection sensitivity, and metabolic coverage Comprehensive discussions of metabolomic studies, including their biomedical and clinical applications Recent advances in proteomics, including top-down and bottom-up approaches Perfect for analytical and clinical chemists, Capillary Electrophoresis—Mass Spectrometry for Proteomics and Metabolomics: Principles and Applications will also earn a place in the libraries of biochemists, molecular biologists, and other molecular life scientists.

Glycosylation Engineering of Biopharmaceuticals Alain Beck.2013 Glyco-engineering is being developed as a method to control the composition of carbohydrates and to enhance the pharmacological properties of monoclonal antibodies (mAbs) and other proteins. In Glycosylation Engineering of Biopharmaceuticals: Methods and Protocols, experts in the field provide readers with production and characterization protocols of glycoproteins and glyco-engineered biopharmaceuticals with a focus on mAbs. The volume is divided in four complementary parts dealing with glyco-engineering of therapeutic proteins, glycoanalytics, glycoprotein complexes characterization, and PK/PD assays for therapeutic antibodies. Written in the highly 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 laboratory protocols, and tips on troubleshooting and avoiding known pitfalls. Authoritative and cutting-edge, *Glycosylation Engineering of Biopharmaceuticals: Methods and Protocols* serves as an ideal guide for scientists striving to push forward the exciting field of engineered biopharmaceuticals.

*Pharmaceutical Biotechnology* Adalberto Pessoa, Michele Vitolo, Paul Frederick Long. 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.

**Plant Glycobiology - a sweet world of lectins, glycoproteins, glycolipids and glycans** Els J. M. Van Damme, Nausicaä Lannoo, Cécile Albenne, Elisabeth Jamet. 2015-02-12 Plants synthesize a wide variety of unique glycan structures which play essential roles during the life cycle of the plant. Being omnipresent throughout the plant kingdom, ranging from simple green algae to modern flowering plants, glycans contribute to many diverse processes. Glycans can function as structural components in the plant cell wall, assist in the folding of nascent proteins, act as signaling molecules in plant defense responses or (ER) stress pathways, or serve within the energy metabolism of a plant. In most cases, glycans are attached to other macromolecules to form so-called glycoconjugates (e.g. glycoproteins, proteoglycans and glycolipids), but they can also be present as free entities residing in the plant cell. Next to the broad, complex set of glycans, plants also evolved an elaborate collection of lectins or proteins with a lectin-like domain, which can recognize and bind to endogenous (plants-own) or exogenous (foreign) glycans. Though still poorly understood in plants, the dynamic interactions between lectins and carbohydrate structures are suggested to be involved in gene transcription, protein folding, protein transport, cell adhesion, signaling as well as defense responses. As such, a complex and largely undetermined glycan-interactome is established inside plant cells, between cells and their surrounding matrix, inside the extracellular matrix, and even

between organisms. Studying the biological roles of plant glycans will enable to better understand plant development and physiology in order to fully exploit plants for food, feed and production of pharmaceutical proteins. In this Research Topic, we want to provide a platform for articles describing the latest research, perspectives and methodologies related to the fascinating world of plant glycobiology, with a focus on following subjects: 1. Identification and characterization of plant glycans, their biosynthetic and degradation enzymes 2. Characterization of plant lectins and glycoproteins 3. Plant glycans in the plant's energy metabolism 4. Role of plant glycans in plant defense signaling 5. Use of plant lectins in pest control 6. Plant lectins as new tools in human medicine 7. Glyco-engineering in plants

**Algae-Based Biopharmaceuticals** Sergio Rosales-Mendoza.2016-05-21 This book constitutes a key reference on the use of algae in the biopharmaceuticals production field; providing an updated outlook on the achievements accomplished thus far and transmitting a prospective view for this biotechnological application. This book provides a detailed description of the technology as well as an updated outlook of the strides achieved thus far in the field of algae-based biopharmaceuticals. Algae constitute attractive expression hosts for the production of recombinant proteins with medical applications. Among the features that make them attractive candidates are: low cost, fast growth, wide biosynthetic capacity, and absence of human pathogens; which constitute substantial advantages with respect to bacterial and mammalian systems. First, the features of algae as convenient hosts for the production of BFs are analyzed in terms of production costs, biosynthetic capacity, and safety (Chapter 1). Second, the genetic engineering tools for algae-species are described. Nuclear and chloroplast-based expression approaches are analyzed and compared in terms of biosynthetic advantages, gene expression complexity, and DNA transfer approaches

(Chapter 2). In the following sections, chapters 3 to 7, the state of the art on producing distinct types of BFs in algae species is presented. Although this book is mainly focused on BFs, considering that the production of compounds with health-promoting properties are achieved using genetically-engineered algae strains, chapter 8 deals with nutraceuticals. In the ninth chapter, the developments reported thus far are placed in perspective and challenges for the field are discussed. Critical future prospects comprise the following: optimizing large-scale production in bioreactors, implementing glycoengineering approaches, optimizing nuclear expression, exploring new approaches for oral delivery, and implementing regulatory frameworks to accomplish technology transfer and regulatory approval of algae-made BFs.

### **Carbohydrate Analysis by Modern Liquid Phase Separation Techniques** Ziad El

Rassi.2021-08-15 Carbohydrate Analysis by Modern Liquid Phase Separation Techniques, Second Edition, presents readers with the various principles of modern liquid phase separation techniques and their contributions to the analysis of complex carbohydrates and glycoconjugates. In a selection of all-new chapters, this fully updated volume covers each technique in detail. The book aims to help analysts solve any of the many practical problems they may face in tackling the analysis of carbohydrates. In addition, it addresses current difficulties that must be resolved in carbohydrate research, thus inspiring further important technological developments to meet these challenges. This is an essential resource for anyone seeking a broad view of the science of carbohydrates and separation techniques. Covers the basic principles of modern liquid phase separation techniques, along with their applications Compiles up-to-date information on the field of carbohydrate analysis, along with updates on separation science Focuses on problems currently faced in carbohydrate analysis and the solutions necessary for further progress

Modern Biopharmaceuticals, 4 Volume Set Jörg Knäblein.2005-10-28 The biopharmaceutical market has come along way since 1982 when the first biopharmaceutical product, recombinant human insulin, was launched. Over 120 such products are currently being marketed around the world including nine blockbuster drugs. The global market for biopharmaceuticals, which is currently valued at US\$41 billion, has been growing at an impressive compound annual growth rate of 21% over the previous five years. With over one third of all pipe-line products in active development are biopharmaceuticals, this segment is set to continue outperforming the total pharmaceutical market and could easily reach US\$100 billion by the end of this decade.

**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.

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.

**Antibody Glycosylation** Marija Pezer.2021-10-22 This book summarizes recent advances in antibody glycosylation research. Covering major topics relevant for immunoglobulin glycosylation - analytical methods, biosynthesis and regulation, modulation of effector functions - it provides new perspectives for research and development in the field of therapeutic antibodies, biomarkers, vaccinations, and immunotherapy. Glycans attached to both variable and constant regions of antibodies are known to affect the antibody conformation, stability, and effector functions. Although it focuses on immunoglobulin G (IgG), the most explored antibody in this context, and unravels the natural phenomena resulting from the mixture of IgG glycovariants present in the human body, the book also discusses other classes of human immunoglobulins, as well as immunoglobulins produced in other species and production systems. Further, it reviews the glycoanalytical methods applied to antibodies and addresses a range of less commonly explored topics, such as automatization and bioinformatics aspects of high-throughput antibody glycosylation analysis. Lastly, the book highlights application areas ranging from the ones already benefitting from antibody glycoengineering (such as monoclonal antibody production), to those still in the research stages (such as exploration of antibody glycosylation as a clinical or biological age biomarker), and the potential use of antibody glycosylation in the optimization of vaccine production and immunization

protocols. Summarizing the current knowledge on the broad topic of antibody glycosylation and its therapeutic and biomarker potential, this book will appeal to a wide biomedical readership in academia and industry alike. Chapter 4 is available open access under a Creative Commons Attribution 4.0 International License via [link.springer.com](http://link.springer.com).

Biopharmaceutical Processing Gunter Jagschies, Eva Lindskog, Karol Lacki, Parrish M.

Gallier. 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

**Trends in Counterfeit Drugs** Kelly M. Elkins. 2023-07-06 Counterfeit drugs continue to infiltrate the drug market in the United States, causing illness and death. This book addresses this issue and examines the recent trends in drug counterfeiting over the past 5-10 years. The text shows perspectives from crime lab and toxicology lab personnel and academic researchers, and includes topics such as a history of cases and issues with counterfeit drugs, trends observed in forensic labs,



instrumental methods and approaches used in detecting counterfeit medicines, and policy approaches for controlling counterfeit drugs. There is a focus on ways to reduce counterfeit drugs in the market, to help improve the health and safety of people all over the world. Features : Focuses on recent (5-10) year trends in counterfeit drugs and analysis. Shows perspectives from crime lab and toxicology lab personnel and academic researchers. Focuses on drugs seized by law enforcement and approaches to reducing counterfeit medicine in the market. Discusses the detection and analysis of counterfeit drugs, and appropriate tools for combating this issue. Emphasizes the global impact of illegal medicines.

**Proceedings of ISPMF 2018 - Plant Molecular Farming** Anneli Ritala, Heiko Rischer, Suvi Tuulikki Häkkinen, Jussi Joonas Joensuu, Kirsi-Marja Oksman-Caldentey. 2020-06-16

Plant Glycobiology - A Sweet World of Glycans, Glycoproteins, Glycolipids, and Carbohydrate-Binding Proteins Els J. M. Van Damme, Georg J. Seifert, Richard Strasser. 2021-10-21

*Basic and Applied Aspects of Biotechnology* Varsha Gupta, Manjistha Sengupta, Jaya Prakash, Baishnab Charan Tripathy. 2016-10-22 This book explores the journey of biotechnology, searching for new avenues and noting the impressive accomplishments to date. It has a harmonious blend of facts, applications and new ideas. Fast-paced biotechnologies are broadly applied and are being continuously explored in areas like the environmental, industrial, agricultural and medical sciences. The sequencing of the human genome has opened new therapeutic opportunities and enriched the field of medical biotechnology while analysis of biomolecules using proteomics and microarray technologies along with the simultaneous discovery and development of new modes of detection are paving the way for ever-faster and more reliable diagnostic methods. Life-saving biopharmaceuticals are being churned out at an amazing rate, and the unraveling of biological

processes has facilitated drug designing and discovery processes. Advances in regenerative medical technologies (stem cell therapy, tissue engineering, and gene therapy) look extremely promising, transcending the limitations of all existing fields and opening new dimensions for characterizing and combating diseases.

**Hydrogen Exchange Mass Spectrometry of Proteins** David D. Weis. 2016-01-12 Hydrogen exchange mass spectrometry is widely recognized for its ability to probe the structure and dynamics of proteins. The application of this technique is becoming widespread due to its versatility for providing structural information about challenging biological macromolecules such as antibodies, flexible proteins and glycoproteins. Although the technique has been around for 25 years, this is the first definitive book devoted entirely to the topic. *Hydrogen Exchange Mass Spectrometry of Proteins: Fundamentals, Methods and Applications* brings into one comprehensive volume the theory, instrumentation and applications of Hydrogen Exchange Mass Spectrometry (HX-MS) - a technique relevant to bioanalytical chemistry, protein science and pharmaceuticals. The book provides a solid foundation in the basics of the technique and data interpretation to inform readers of current research in the method, and provides illustrative examples of its use in bio- and pharmaceutical chemistry and biophysics. In-depth chapters on the fundamental theory of hydrogen exchange, and tutorial chapters on measurement and data analysis provide the essential background for those ready to adopt HX-MS. Expert users may advance their current understanding through chapters on methods including membrane protein analysis, alternative proteases, millisecond hydrogen exchange, top-down mass spectrometry, histidine exchange and method validation. All readers can explore the diversity of HX-MS applications in areas such as ligand binding, membrane proteins, drug discovery, therapeutic protein formulation, biocomparability, and intrinsically

disordered proteins.

Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts Claire Komives, Weichang Zhou. 2018-12-27 Written for industrial and academic researchers and development scientists in the life sciences industry, *Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts* is a guide to the tools, approaches, and useful developments in bioprocessing. This important guide: • Summarizes state-of-the-art bioprocessing methods and reviews applications in life science industries • Includes illustrative case studies that review six milestone bio-products • Discusses a wide selection of host strain types and disruptive bioprocess technologies

*Glycosylation Engineering of Biopharmaceuticals* Alan Beck. 2013-03-09 Glyco-engineering is being developed as a method to control the composition of carbohydrates and to enhance the pharmacological properties of monoclonal antibodies (mAbs) and other proteins. In *Glycosylation Engineering of Biopharmaceuticals: Methods and Protocols*, experts in the field provide readers with production and characterization protocols of glycoproteins and glyco-engineered biopharmaceuticals with a focus on mAbs. The volume is divided in four complementary parts dealing with glyco-engineering of therapeutic proteins, glycoanalytics, glycoprotein complexes characterization, and PK/PD assays for therapeutic antibodies. Written in the highly successful *Methods in Molecular Biology*<sup>TM</sup> series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible laboratory protocols, and tips on troubleshooting and avoiding known pitfalls. Authoritative and cutting-edge, *Glycosylation Engineering of Biopharmaceuticals: Methods and Protocols* serves as an ideal guide for scientists striving to push forward the exciting field of engineered biopharmaceuticals.

Glyco-Engineering Alexandra Castilho.2015-06-17 Conceived with the intention of providing an array of strategies and technologies currently in use for glyco-engineering distinct living organisms, this book contains a wide range of methods being developed to control the composition of carbohydrates and the properties of proteins through manipulations on the production host rather than in the protein itself. The first five sections deal with host-specific glyco-engineering and contain chapters that provide protocols for modifications of the glycosylation pathway in bacteria, yeast, insect, plants and mammalian cells, while the last two sections explore alternative approaches to host glyco-engineering and selected protocols for the analysis of the N-glycans and glyco-profiling by mass spectrometry. Written for the highly successful Methods in Molecular Biology series, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible laboratory protocols and tips on troubleshooting and avoiding known pitfalls. Authoritative and extensive, *Glyco-Engineering: Methods and Protocols* offers vast options to help researchers to choose the expression system and approach that best suits their intended protein research or applications.

*Biosimilars of Monoclonal Antibodies* Cheng Liu,K. John Morrow, Jr..2016-12-12 Addressing a significant need by describing the science and process involved to develop biosimilars of monoclonal antibody (mAb) drugs, this book covers all aspects of biosimilar development: preclinical, clinical, regulatory, manufacturing. • Guides readers through the complex landscape involved with developing biosimilar versions of monoclonal antibody (mAb) drugs • Features flow charts, tables, and figures that clearly illustrate processes and makes the book comprehensible and accessible • Includes a review of FDA-approved mAb drugs as a quick reference to facts and useful information • Examines new technologies and strategies for improving biosimilar mAbs

**Biotechnology and Bioengineering** William G. Flynne.2008 Biotechnology is a popular term for the generic technology of the 21st century. Although it has been utilised for centuries in traditional production processes, modern biotechnology is only 50 years old and in the last decades it has been witnessing tremendous developments. Bioengineering is the science upon which all Biotechnological applications are based. With the development of new approaches and modern techniques, traditional biotechnology industries are also acquiring new horizons enabling them to improve the quality of their products and increase the productivity of their systems. Biological engineering (also biosystems engineering and bioengineering) deals with engineering biological processes in general. It is a broad-based engineering discipline that also may involve product design, sustainability and analysis of biological systems. In other words, Bioengineering is a discipline that applies engineering principles to biological systems for the purpose of developing new technologies of services to improve the living standards of societies. It exploits the new developments in molecular biology, biochemistry, microbiology, cell metabolism and engineering principles and applies them in order to understand living systems and to bring solutions various problems associated with these systems. This book presents leading research in both areas.

Therapeutic Antibody Engineering William R Strohl,Lila M Strohl.2012-10-16 The field of antibody engineering has become a vital and integral part of making new, improved next generation therapeutic monoclonal antibodies, of which there are currently more than 300 in clinical trials across several therapeutic areas. Therapeutic antibody engineering examines all aspects of engineering monoclonal antibodies and analyses the effect that various genetic engineering approaches will have on future candidates. Chapters in the first part of the book provide an introduction to monoclonal antibodies, their discovery and development and the fundamental

technologies used in their production. Following chapters cover a number of specific issues relating to different aspects of antibody engineering, including variable chain engineering, targets and mechanisms of action, classes of antibody and the use of antibody fragments, among many other topics. The last part of the book examines development issues, the interaction of human IgGs with non-human systems, and cell line development, before a conclusion looking at future issues affecting the field of therapeutic antibody engineering. Goes beyond the standard engineering issues covered by most books and delves into structure-function relationships Integration of knowledge across all areas of antibody engineering, development, and marketing Discusses how current and future genetic engineering of cell lines will pave the way for much higher productivity

**Insights in plant biotechnology: 2021** James Lloyd,Jens Kossmann,Peng Zhang,Ralf Alexander Wilhelm,Manoj K. Sharma.2023-03-02

**Post-translational Modification of Protein Biopharmaceuticals** Gary Walsh.2009-08-24 From the leading author in the field, known around the world for his work and his authoritative publications, the contents of this book have been selected so as to reflect their relative importance for biopharmaceuticals. As a result, around half of the book is devoted to protein glycosylation, while the remainder is made up of other modifications, such as carboxylation, hydroxylation, sulfation, amidation and proteolytic processing. A final section addresses the latest trend of engineering the modification pattern to improve a given biopharmaceutical, presenting several recent case studies of successful posttranslational engineering. This first authoritative overview of the topic is an indispensable guide for drug developers and drug manufacturers with an interest in protein pharmaceuticals.

**Perfusion Cell Culture Processes for Biopharmaceuticals** Moritz Wolf,Jean-Marc

Bielser, Massimo Morbidelli. 2020-08-06 Master the design and operation of perfusion cell cultures with this authoritative reference. Discover the current state-of-the-art in the design and operation of continuous bioreactors, with emphasis on mammalian cell cultures for producing therapeutic proteins. Topics include the current market for recombinant therapeutic proteins, current industry challenges and the potential contribution of continuous manufacturing. Provides coverage of every step of process development and reactor operation, including small scale screening to lab-scale and scale-up to manufacturing scale. Illustrated through real-life case studies, this is a perfect resource for groups active in the cell culture field, as well as graduate students in areas such as chemical engineering, biotechnology, chemistry and biology, and to those in the pharmaceutical industry, particularly biopharma, biotechnology and food or agro industry.

**Biopharmaceutical Manufacturing** Ralf Pörtner. 2024-02-11 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/biogenics) 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.

**Pharmaceutical Biotechnology** Gary Walsh.2013-04-25 Pharmaceutical Biotechnology offers students taking Pharmacy and related Medical and Pharmaceutical courses a comprehensive introduction to the fast-moving area of biopharmaceuticals. With a particular focus on the subject taken from a pharmaceutical perspective, initial chapters offer a broad introduction to protein science and recombinant DNA technology- key areas that underpin the whole subject. Subsequent chapters focus upon the development, production and analysis of these substances. Finally the book moves on to explore the science, biotechnology and medical applications of specific biotech products categories. These include not only protein-based substances but also nucleic acid and cell-based products. introduces essential principles underlining modern biotechnology- recombinant DNA technology and protein science an invaluable introduction to this fast-moving subject aimed specifically at pharmacy and medical students includes specific 'product category chapters' focusing on the pharmaceutical, medical and therapeutic properties of numerous biopharmaceutical products. entire chapter devoted to the principles of genetic engineering and how these drugs are developed. includes numerous relevant case studies to enhance student understanding no prior knowledge of protein structure is assumed

**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.

**Essentials of Glycobiology** Ajit Varki, Maarten J. Chrispeels. 1999 Sugar chains (glycans) are often attached to proteins and lipids and have multiple roles in the organization and function of all organisms. *Essentials of Glycobiology* describes their biogenesis and function and offers a useful gateway to the understanding of glycans.

**Advances in Protein Molecular and Structural Biology Methods** Timir Tripathi, Vikash Kumar Dubey. 2022-01-14 *Advances in Protein Molecular and Structural Biology Methods* offers a complete overview of the latest tools and methods applicable to the study of proteins at the molecular and structural level. The book begins with sections exploring tools to optimize recombinant protein expression and biophysical techniques such as fluorescence spectroscopy, NMR, mass spectrometry, cryo-electron microscopy, and X-ray crystallography. It then moves towards computational approaches, considering structural bioinformatics, molecular dynamics simulations, and deep machine learning technologies. The book also covers methods applied to intrinsically disordered

proteins (IDPs) followed by chapters on protein interaction networks, protein function, and protein design and engineering. It provides researchers with an extensive toolkit of methods and techniques to draw from when conducting their own experimental work, taking them from foundational concepts to practical application. Presents a thorough overview of the latest and emerging methods and technologies for protein study Explores biophysical techniques, including nuclear magnetic resonance, X-ray crystallography, and cryo-electron microscopy Includes computational and machine learning methods Features a section dedicated to tools and techniques specific to studying intrinsically disordered proteins

Capillary Gel Electrophoresis Andras Guttman, László Hajba. 2021-12-04 Capillary Gel Electrophoresis and Related Microseparation Techniques covers all theoretical and practical aspects of capillary gel electrophoresis. It also provides an excellent overview of the key application areas of nucleic acid, protein and complex carbohydrate analysis, affinity-based methodologies, micropreparative aspects and related microseparation methods. It not only gives readers a better understanding of how to utilize this technology, but also provides insights into how to determine which method will provide the best technical solutions to particular problems. This book can also serve as a textbook for undergraduate and graduate courses in analytical chemistry, analytical biochemistry, molecular biology and biotechnology courses. Covers all theoretical and practical aspects of capillary gel electrophoresis Excellent overview of the key applications of nucleic acid, protein and complex carbohydrate analysis, affinity-based methodologies, micropreparative aspects and related microseparation methods Teaches readers how to use the technology and select methods that are ideal for fundamental problems Can serve as a textbook for undergraduate and graduate courses in analytical chemistry, analytical biochemistry, molecular biology and

biotechnology courses

Glycobiology and Human Diseases Gherman Wiederschain.2016-02-22 This book discusses glycobiology and various forms of human diseases. Topics covered include immunoglobulins, inflammation and glycosylation, the role and therapeutic significance of natural anti-glycan antibodies in malignancies and in normal and aberrant pregnancy, identifying urinary glycans as a possible method for the diagnosis of lysosomal storage diseases, glycobiology of human milk (biological roles and diseases) and pectins as biological modulators of human physiological reactions. The book includes analysis of comprehensive data and some productive conclusions and perspectives.

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