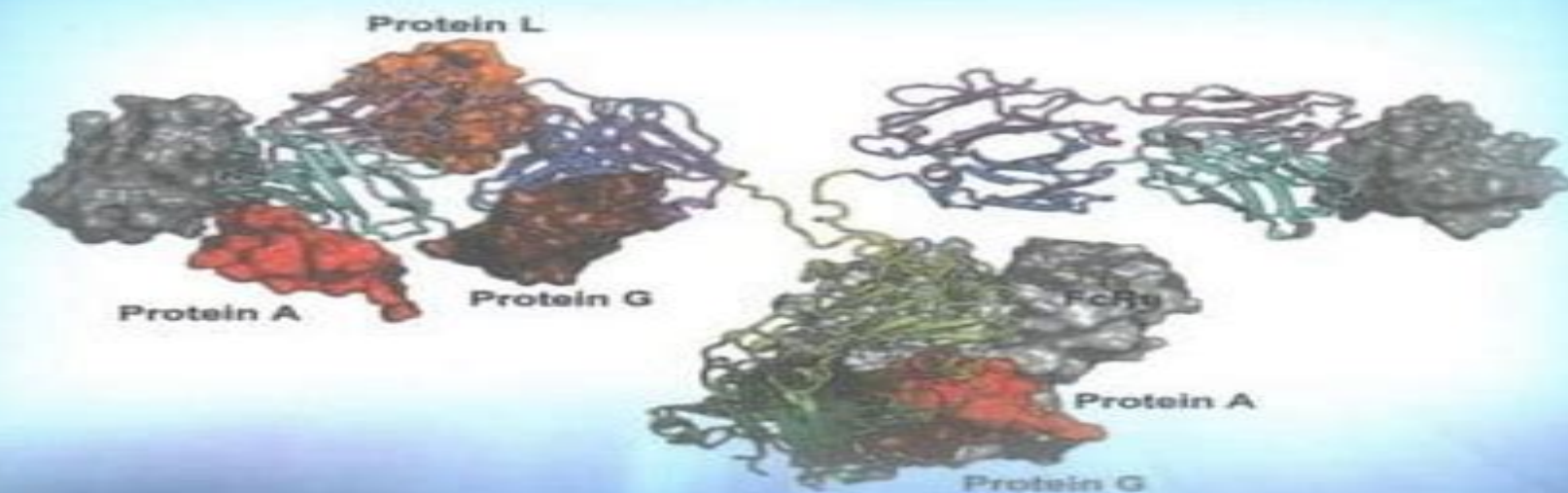


Second Edition

PROCESS SCALE PURIFICATION OF ANTIBODIES



EDITED BY **UWE GOTTSCHALK**

WILEY

Process Scale Purification Of Antibodies

Christoph Wittmann, James C. Liao



Process Scale Purification Of Antibodies:

Process Scale Purification of Antibodies Uwe Gottschalk, 2011-09-20 Traditional column chromatography dominates current purification technology and many of the productivity gains that have been achieved have relied on upscaling such devices. However, this comes with a cost penalty and the pharmaceutical industry has reached the point at which further upscaling becomes economically unsupportable. This book offers a broad-based reassessment of old and new purification methods incorporating an analysis of innovative new trends in purification. The book has wide coverage of different antibody purification strategies and brings together top-tier experts to address problems in process-scale antibody purification.

Process Scale Purification of Antibodies Uwe Gottschalk, 2017-03-07 Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds and strategies for ton-scale manufacturing. Presents new and updated discussions of different purification technologies focusing on how they can address the capacity crunch in antibody purification. Emphasizes antibodies and innovative chromatography methods for processing.

Antibody Expression and Production Mohamed Al-Rubeai, 2011-05-16 Engineered antibodies currently represent over 30% of biopharmaceuticals in clinical trials and their total worldwide sales continue to increase significantly. The importance of antibody applications is reflected in their increasing clinical and industrial applications as well as in the progression of established and emerging production strategies. This volume provides detailed coverage of the generation, optimization, characterization, production and applications of antibody. It provides the necessary theoretical background and description of methods for the expression of antibody in microbial and animal cell cultures and in transgenic animals and plants. There is a strong focus on those issues related to the production of intrabodies, bispecific antibody and antibody fragments and also to novel applications in cancer immunotherapy.

Process Scale Bioseparations for the Biopharmaceutical Industry Abhinav A. Shukla, Mark R. Etzel, Shishir Gadam, 2006-07-07 The biopharmaceutical industry has become an increasingly important player in the global economy and the success of these products depends on the development and implementation of cost-effective, robust and scalable production processes. Bioseparations, also called downstream processing, can be a key source of competitive advantage to biopharmaceutical.

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 Industrial Biotechnology Christoph Wittmann, James C. Liao, 2017-03-06 The latest volume in the Advanced Biotechnology series provides an overview of the main product classes and platform chemicals produced by biotechnological processes today with applications in the food healthcare and fine chemical industries Alongside the production of drugs and flavors as well as amino acids bio based monomers and polymers and biofuels basic insights are also given as to the biotechnological processes yielding such products and how large scale production may be enabled and improved Of interest to biotechnologists bio and chemical engineers as well as those working in the biotechnological chemical and food industries *Continuous Biopharmaceutical Processes* David Pfister, Lucrèce Nicoud, Massimo Morbidelli, 2018-10-11 This innovative reference provides a coherent and critical view on the potential benefits of a transition from batch to continuous processes in the biopharmaceutical industry with the main focus on chromatography It also covers the key topics of protein stability and protein conjugation addressing the chemical reaction and purification aspects together with their integration This book offers a fine balance between theoretical modelling and illustrative case studies between fundamental concepts and applied examples from the academic and industrial literature Scientists interested in the design of biopharmaceutical processes will find useful practical methodologies in particular for single column and multi column chromatographic processes **Biological Drug Products** Wei Wang, Manmohan Singh, 2013-08-29 Tested and proven solutions to the challenges of biological drug product development Biological drug products play a central role in combating human diseases however developing new successful biological drugs presents many challenges including labor intensive production processes tighter regulatory controls and increased market competition This book reviews the current state of the science offering readers a single resource that sets forth the fundamentals as well as tested and proven development strategies for biological drugs Moreover the book prepares readers for the challenges that typically arise during drug development offering straightforward solutions to improve their ability to pass through all the regulatory hurdles and deliver new drug products to the market Biological Drug Products begins with general considerations for the development of any biological drug product and then explores the strategies and challenges involved in the development of specific types of biologics Divided into five parts the book examines Part 1 General Aspects Part 2 Proteins and Peptides Part 3 Vaccines Part 4 Novel Biologics Part 5 Product Administration Delivery Each chapter has been prepared by one or more leading experts in biological drug development Contributions are based on a comprehensive review and analysis of the current literature as well as the authors first hand experience developing and testing new drugs References at the end of each chapter serve as a gateway to original research papers and reviews in the field By incorporating lessons learned and future directions for research Biological Drug Products enables pharmaceutical scientists and students to improve their success rate in developing new biologics to treat a broad range of human diseases **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

Biopharmaceutical Manufacturing Gary Gilleskie, Charles Rutter, Becky McCuen, 2021-09-07 Biopharmaceuticals medicines made by or from living organisms including cells from living organisms are extremely effective in treating a broad range of diseases Their importance to human health has grown significantly over the years as more biopharmaceutical products have entered the market and now the biggest selling drugs in the world are biopharmaceuticals Biopharmaceutical Manufacturing Principles Processes and Practices provides concise comprehensive and up to date coverage of biopharmaceutical manufacturing Written in a clear and informal style the content has been influenced by the authors substantial industry experience and teaching expertise That expertise enables the authors to address the many questions posed over the years both by university students and professionals with experience in the field Consequently the book will appeal both to undergraduate or graduate students using it as a textbook and specialized industry practitioners seeking to understand the big picture of biopharmaceutical manufacturing This book

Therapeutic Fc-Fusion Proteins Steven M. Chamow, Thomas Ryll, Henry B. Lowman, Deborah Farson, 2013-12-18 Edited by three pioneers in the field each with longstanding experience in the biotech industry and a skilled scientific writer this is the first book to cover every step in the development and production of immunoglobulin Fc fusion proteins as therapeutics for human disease from choosing the right molecular design to pre clinical characterization of the purified product through to batch optimization and quality control for large scale cGMP production The whole of the second part is devoted to case studies of Fc fusion proteins that are now commercially successful products In this section the authors several of whom were personally involved in clinical development of the products themselves detail the product s background and give insight into issues that were faced and how these issues were overcome during clinical development This section also includes a chapter on promising new developments for the future An invaluable resource for professionals already working on Fc fusion proteins and an excellent and thorough introduction for physicians researchers and students entering the field

Chemical Engineering in the Pharmaceutical Industry David J. am Ende, 2011-03-10 This book deals with various unique elements in the drug development process within chemical engineering science and pharmaceutical R D The book is intended to be used as a professional reference and potentially as a text book reference in pharmaceutical engineering and pharmaceutical sciences Many of the experimental methods related to pharmaceutical process development are learned on the job This book is intended to provide

many of those important concepts that R D Engineers and manufacturing Engineers should know and be familiar if they are going to be successful in the Pharmaceutical Industry These include basic analytics for quantitation of reaction components often skipped in ChE Reaction Engineering and kinetics books In addition Chemical Engineering in the Pharmaceutical Industry introduces contemporary methods of data analysis for kinetic modeling and extends these concepts into Quality by Design strategies for regulatory filings For the current professionals in silico process modeling tools that streamline experimental screening approaches is also new and presented here Continuous flow processing although mainstream for ChE is unique in this context given the range of scales and the complex economics associated with transforming existing batch plant capacity The book will be split into four distinct yet related parts These parts will address the fundamentals of analytical techniques for engineers thermodynamic modeling and finally provides an appendix with common engineering tools and examples of their applications *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 *Filtration and Purification in the Biopharmaceutical Industry, Third Edition*

Maik W. Jornitz, 2019-06-26 Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing the third edition of *Filtration and Purification in the Biopharmaceutical Industry* greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology It provides state of the science information on all aspects of bioprocessing including the current methods processes technologies and equipment It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries The book is an essential comprehensive source for all involved in filtration and purification

practices training and compliance It describes such technologies as viral retentive filters membrane chromatography downstream processing cell harvesting and sterile filtration Features Addresses recent biotechnology related processes and advanced technologies such as viral retentive filters membrane chromatography downstream processing cell harvesting and sterile filtration of medium buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance not just from an end user perspective but also supplier requirement It discusses the advantages of single use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compiled by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing Each specific topic has been thoroughly examined by a subject matter expert

Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing Ganapathy Subramanian, 2021-12-15 Process Control Intensification and Digitalisation in Continuous Biomanufacturing Explore new trends in continuous biomanufacturing with contributions from leading practitioners in the field With the increasingly widespread acceptance and investment in the technology the last decade has demonstrated the utility of continuous processing in the pharmaceutical industry In Process Control Intensification and Digitalisation in Continuous Biomanufacturing distinguished biotechnologist Dr Ganapathy Subramanian delivers a comprehensive exploration of the potential of the continuous processing of biological products and discussions of future directions in advancing continuous processing to meet new challenges and demands in the manufacture of therapeutic products A stand alone follow up to the editor s Continuous Biomanufacturing Innovative Technologies and Methods published in 2017 this new edited volume focuses on critical aspects of process intensification process control and the digital transformation of biopharmaceutical processes In addition to topics like the use of multivariant data analysis regulatory concerns and automation processes the book also includes Thorough introductions to capacitance sensors to control feeding strategies and the continuous production of viral vaccines Comprehensive explorations of strategies for the continuous upstream processing of induced microbial systems Practical discussions of preparative hydrophobic interaction chromatography and the design of modern protein A resins for continuous biomanufacturing In depth examinations of bioprocess intensification approaches and the benefits of single use for process intensification Perfect for biotechnologists bioengineers pharmaceutical engineers and process engineers Process Control Intensification and Digitalisation in Continuous Biomanufacturing is also an indispensable resource for chemical engineers seeking a one stop reference on continuous biomanufacturing

Antibody Drug Discovery Clive R. Wood, 2012 Monoclonal antibodies have become important treatments for cancer inflammation and a wide range of other diseases representing an increasing share of the most successful pharmaceutical markets The technologies to discover

these drugs have been developed by select centers of excellence in industry and academia and are continually being fine tuned in the race to identify the best antibody based drug candidates and accelerate their paths to patients The objective of this volume is to provide a series of guides to those evaluating and preparing to enter particular areas within the field and to offer specialized perspectives to established researchers The chapters set into context the significance of key developments and important considerations for selecting different approaches such as antibody humanization isotype selection lead candidate selection criteria and protein production All contributors to this work are experts in their fields and many have played pivotal roles in the creation of these technologies

Bioprocess Engineering and Technology Biswanath Bhunia, Navneet Joshi, Muthusivaramapandian Muhuraja, 2025-11-26 This book deals with the practical aspects in bioprocess plant design project engineering process economics IPR and biobusiness prospects related to bioprocess engineering Bioprocess Engineering and Technology Downstream Process and Plant Design also describes how productivity efficiency and safety of process plants hinge on proper equipment functionality The authors explain the various downstream processes that can be employed for separation and purification of desired products The editors provide the protocols for plant design and process design along with the project requirements needed in planning and commissioning a bioprocessing plant The book also emphasizes the importance of biosafety regulations IPR project engineering and bioprocess economics for the development of entrepreneurship within the industry Finally the editors also include various case studies that describe potential biobusiness options within bioprocess engineering The text is wide in scope and highlights the multidimensional approach for developing expertise in bioprocessing and would be a useful resource for students studying bioprocess engineering as well as entrepreneurs and managers in the business

Continuous Processing in Pharmaceutical Manufacturing Ganapathy Subramanian, 2014-12-03 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

Preparative Chromatography for Separation of Proteins Arne Staby, Anurag S. Rathore, Satinder Ahuja, 2017-03-06 Preparative Chromatography for Separation of Proteins addresses a wide range of modeling techniques strategies and case studies of industrial separation of proteins and peptides Covers broad aspects of preparative chromatography with a unique combination of academic and industrial perspectives Presents Combines modeling with compliance using of Quality by Design QbD approaches including modeling Features a variety of chromatographic case studies not readily accessible to the general public Represents an essential reference resource for academic industrial and pharmaceutical researchers

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

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