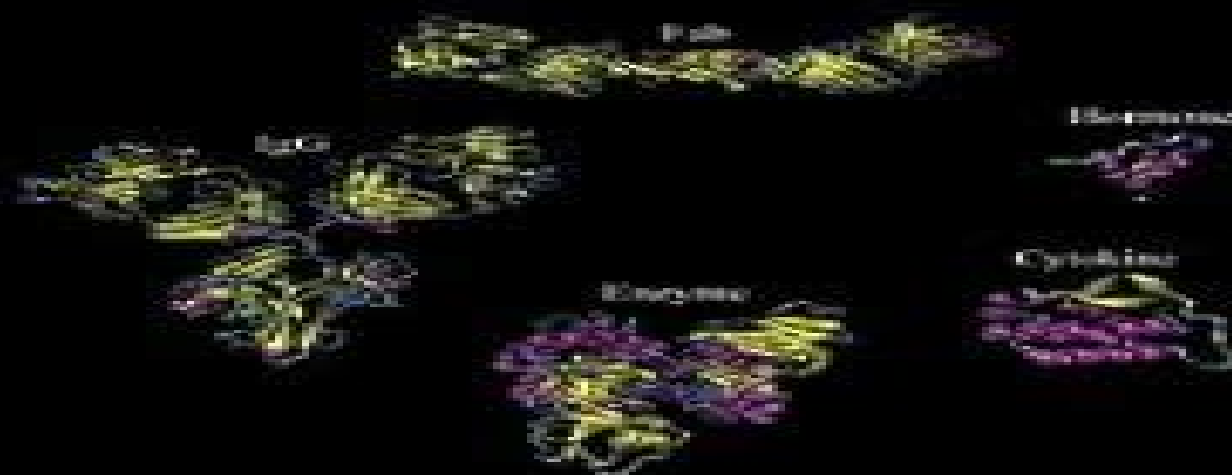


Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals



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FEROZ JAMEEL
SUSAN HERSHENSON

Formulation And Process Development Strategies For Manufacturing Biopharmaceuticals

Feroz Jameel, John W. Skoug, Robert R. Nesbitt



Formulation And Process Development Strategies For Manufacturing Biopharmaceuticals:

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals Feroz Jameel, Susan Hershenson, 2010-07-13 A real world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals there is a need for practical up to date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products This book helps fill the gap in the field examining all areas of biopharmaceuticals manufacturing from development and formulation to production and packaging Written by a group of experts from industry and academia the book focuses on real world methods for maintaining product integrity throughout the commercialization process clearly explaining the fundamentals and essential pathways for all development stages Coverage includes Research and early development phase appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage packaging and shipping methods Case studies relating to therapeutic monoclonal antibodies recombinant proteins and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries for government and regulatory agencies and for anyone with an interest in the latest developments in the field

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Practices of Lyophilization in Product Development and Manufacturing Feroz Jameel, 2023-04-24 The biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates ADCs Bispecific T cell engager BITES Dual Variable Domain DVD Chimeric Antigen Receptor Modified Tcells CART that are currently being used as therapeutic agents for immunology and oncology disease conditions In addition to other pharmaceuticals and biopharmaceuticals all these novel formats are fragile with respect to their stability structure under processing conditions meaning marginal stability in the liquid state and often require lyophilization to enhance their stability and shelf life This book contains chapters topics that will describe every aspect of the lyophilization process and

product development and manufacturing starting from the overview of lyophilization process equipment required characterization of the material design and development of the formulation and lyophilization process various techniques for characterization of the product scale up tech transfer and validation It also describes the application of CFD coupled with mathematical modeling in the lyophilization process and product development scale up and manufacturing Additionally Principles and Practice of Lyophilization Process and Product Development contains an entire dedicated section on Preservation of Biologicals comprised of nine chapters written by experts and including case studies

Development of Biopharmaceutical Drug-Device Products Feroz Jameel, John W. Skoug, Robert R. Nesbitt, 2020-03-13 The biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates ADCs Bispecific T cell engager BITEs Dual Variable Domain DVD antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions Regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of Quality by Design QbD elements demonstrating an in depth understanding of product and process based on sound science Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products A survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies With insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them It also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials Finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design This involves the evolving regulatory framework with perspectives from both the US and EU industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device Finally case studies are provided throughout The typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry

specialists and technology developers working in the biopharmaceutical field **Pharmaceutical Biotechnology** Oliver Kayser, Heribert Warzecha, 2012-05-21 This second edition of a very successful book is thoroughly updated with existing chapters completely rewritten while the content has more than doubled from 16 to 36 chapters As with the first edition the focus is on industrial pharmaceutical research written by a team of industry experts from around the world while quality and safety management drug approval and regulation patenting issues and biotechnology fundamentals are also covered In addition this new edition now not only includes biotech drug development but also the use of biopharmaceuticals in diagnostics and vaccinations With a foreword by Robert Langer Kenneth J Germeshausen Professor of Chemical and Biomedical Engineering at MIT and member of the National Academy of Engineering and the National Academy of Sciences

Challenges in Protein Product Development Nicholas W. Warne, Hanns-Christian Mahler, 2018-06-20 In this volume the authors discuss the many significant challenges currently faced in biotechnology dosage form development providing guidance shared experience and thoughtful reflection on how best to address these potential concerns As the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs Often the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability manufacturing and preclinical or clinical expectations as well as the evolving regulatory expectations and landscape Further there have been new findings that require close assessment as for example those related to excipient quality processing viscosity and device compatibility and administration solubility and opalescence and container closure selection The literature varies widely in its discussion of these critical elements and consensus does not exist This topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally Therefore this book is of interest for business leaders researchers formulation and process development scientists analytical scientists QA and QC officers regulatory staff manufacturing leaders and regulators active in the pharmaceutical and biotech industry and expert reviewers in regulatory agencies *Biophysical Characterization of Proteins in Developing Biopharmaceuticals* Damian J. Houde, Steven A. Berkowitz, 2019-11-13 *Biophysical Characterization of Proteins in Developing Biopharmaceuticals* Second Edition presents the latest on the analysis and characterization of the higher order structure HOS or conformation of protein based drugs Starting from the very basics of protein structure this book explains the best way to achieve this goal using key methods commonly employed in the biopharmaceutical industry This book will help today's industrial scientists plan a career in this industry and successfully implement these biophysical methodologies This updated edition has been fully revised with new chapters focusing on the use of chromatography and electrophoresis and the biophysical characterization of very large biopharmaceuticals In addition best practices of applying statistical analysis to biophysical characterization data is included

along with practical issues associated with the concept of a biopharmaceutical's developability and the technical decision making process needed when dealing with biophysical characterization data Presents basic protein characterization methods and tools applicable to bio pharmaceutical research and development Highlights the capabilities and limitations of each technique Discusses the underlining science of each tool Empowers industrial biophysical chemists by providing a roadmap for applying biophysical tools Outlines the needs for new characterization and analytical tools in the biopharmaceutical industry

Parenteral Medications, Fourth Edition Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements

Development and Manufacture of Protein Pharmaceuticals Steve L. Nail, Michael J. Akers, 2012-12-06 In this era of biotechnology there have been many books covering the fundamentals of recombinant DNA technology and protein chemistry However not many sources are available for the pharmaceutical development scientist and other personnel responsible for the commercialization of the finished dosage forms of these new biopharmaceuticals and other products from biotechnology This text will help to fill this gap Once active biopharmaceutical molecules are candidates for clinical trial investigation and subsequent commercialization a number of other activities must take place while research and development on these molecules continues The active ingredient itself must be formulated into a finished dosage form that can be conveniently used by health care professionals and patients Properties of the biopharmaceutical molecule must be clearly understood so that the appropriate finished product formulation can be developed Finished product formulation development includes not only the chemical formulation but also the packaging system the manufacturing process and appropriate control strategies to assure such good manufacturing practice attributes as safety identity strength purity and

quality **Genetic Engineering News** ,2004 **Genetic Engineering & Biotechnology News** ,2009 **Quality by Design for Biopharmaceutical Drug Product Development** Feroz Jameel,Susan Hershenson,Mansoor A. Khan,Sheryl Martin-Moe,2015-04-01 This volume explores the application of Quality by Design QbD to biopharmaceutical drug product development Twenty eight comprehensive chapters cover dosage forms liquid and lyophilized drug products The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats The next few chapters study the use of small scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing mixing sterile filtration filling lyophilization inspection and shipping and handling Later chapters describe more specialized applications of QbD in the drug product realm This includes the use of QbD in primary containers devices and combination product development The volume also explores QbD applied to vaccine development automation mathematical modeling and monitoring and controlling processes and defining control strategies It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs **High-Throughput Formulation Development of Biopharmaceuticals** Vladimir I. Razinkov,Gerd Kleemann,2016-09-29 High Throughput Formulation Development of Biopharmaceuticals Practical Guide to Methods and Applications provides the latest developments and information on the science of stable and safe drug product formulations presenting a comprehensive review and detailed description of modern methodologies in the field of formulation development a process starting with candidate and pre formulation screening in its early development phase and then progressing to the refinement of robust formulations during commercialization in the later phases of development The title covers topics such as experiment design automation of sample preparation and measurements high throughput analytics stress inducing methods statistical analysis of large amounts of formulation study data emerging technologies and the presentation of several case studies along with a concluding summary Presents applications of high throughput methodologies to accelerate drug formulation development Provides the latest technologies in the field Includes key statistical approaches such as design of experiment and multivariate data analysis Written by highly respected formulation development experts *Perry's Chemical Engineers' Handbook, 9th Edition* Don W. Green,Marylee Z. Southard,2018-07-13 Up to Date Coverage of All Chemical Engineering Topics from the Fundamentals to the State of the Art Now in its 85th Anniversary Edition this industry standard resource has equipped generations of engineers and chemists with vital information data and insights Thoroughly revised to reflect the latest technological

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Development of Biopharmaceutical Drug-device Products, 2020 The biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates ADCs Bispecific T cell engager BITEs Dual Variable Domain DVD antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions Regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of Quality by Design QbD elements demonstrating an in depth understanding of product and process based on sound science Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products A survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies With insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them It also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials Finally the latter half of the book reviews key considerations to ensure the development and approval of a patient

centered delivery system design This involves the evolving regulatory framework with perspectives from both the US and EU industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device Finally case studies are provided throughout The typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field

PAT Applied in Biopharmaceutical Process Development And Manufacturing Cenk Undey,Duncan Low,Jose C. Menezes,Mel Koch,2011-12-07 As with all of pharmaceutical production the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA initiated Quality by Design QbD guidelines and corresponding activities of the International Committee for Harmonization ICH Given the rapid growth in the biopharmaceutical area and the complexity of the molecules the optimum use of which are still being developed there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development Process Analytical Technologies PAT applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm PAT Applied in Biopharmaceutical Process Development and Manufacturing covers technological advances in measurement sciences data acquisition monitoring and control Technical leaders present real life case studies in areas including measuring and monitoring raw materials cell culture purification and cleaning and lyophilization processes via advanced PAT They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis monitoring and control in real time Invaluable for experienced practitioners in PAT in biopharmaceuticals this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area *Business Publication Advertising Source* ,2006

Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation Kenneth E. Avis,Vincent L. Wu,1996-03-31 In this unique book experts describe practices applicable to the large scale processing of biotechnological products Beginning with processing and bulk storage preservation techniques the book provides strategies for improving efficiency of process campaigns of multiple products and manufacturing facilities for such processing techniques Large scale chromatography for the purification of biomolecules in manufacturing and lyophilization of protein pharmaceuticals are discussed Includes a case study on blow fill seal processing technology and a chapter on economic and cost factors for bioprocess engineering [Consultants & Consulting Organizations Directory: Descriptive listings and indexes](#) ,2009

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