
Biopharmaceutical Drug Design and Development

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Yongyut Rojanasakul**

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Jörg Knäblein



Biopharmaceutical Drug Design And Development:

Biopharmaceutical Drug Design and Development Susanna Wu-Pong, Yon Rojanasakul, 2010-01-11 Biopharmaceutical Drug Design and Development Second Edition furthers the widely successful first edition published in 1999. This new expanded edition investigates the dozens of new biopharmaceutical drugs that have become available since that time. Among the drugs discussed are ones in the categories of monoclonal antibodies for in vivo use, cytokines, growth factors, enzymes, immunomodulators, thrombolytics, and immunotherapies including vaccines. Additionally, the volume examines new and emerging technologies such as bioinformatics, DNA microarrays, transgenics, therapeutic gene delivery, stem cells, nucleic acid based therapeutics, and macromolecular drug delivery. Authors also study pharmacogenetics in the clinic and changes in biologic drug approval at the FDA. Biopharmaceutical Drug Design and Development Second Edition is a worthy sequel to a discussion on the dynamic, exciting field of biotechnology. **BIOPHARMACEUTICAL DRUG DESIGN AND**

DEVELOPMENT. WU-PONG., 2010 **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. *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

The Science and Business of Drug Discovery Edward D. Zanders, 2020-11-09 The Science and Business of Drug Discovery is written for those who want to learn about the biopharmaceutical industry and its products whatever their level of technical knowledge Its aim is to demystify the jargon used in drug development but in a way that avoids over simplification and the resulting loss of key information Each of the twenty chapters is illustrated with figures and tables which clarify some of the more technical points being made Also included is a drug discovery case history which draws the relevant material together into a single chapter In recognizing that it is difficult to navigate through the many external resources dealing with drug development the book has been written to guide the reader towards the most appropriate information sources including those listed in the two appendices The following topics are covered Different types of drugs from small molecules to stem cells Background to chemistry of small and large molecules Historical background to drug discovery pharmacology and biotechnology The drug discovery pipeline from target discovery to marketed medicine Commercial aspects of drug discovery Challenges to the

biopharmaceutical industry and its responses Material of specific interest to technology transfer executives recruiters and pharmaceutical translators *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 *Artificial Intelligence and Machine Learning in Drug Design and Development* Abhirup Khanna, May El Barachi, Sapna Jain, Manoj Kumar, Anand Nayyar, 2024-06-21 The book is a comprehensive guide that explores the use of artificial intelligence and machine learning in drug discovery and development covering a range of topics including the use of molecular modeling docking identifying targets selecting compounds and optimizing drugs The intersection of Artificial Intelligence AI and Machine Learning ML within the field of drug design and development represents a pivotal moment in the history of healthcare and pharmaceuticals The remarkable synergy between cutting edge technology and the life sciences has ushered in a new era of possibilities offering unprecedented opportunities formidable challenges and a tantalizing glimpse into the future of medicine AI can be applied to all the key areas of the pharmaceutical industry such as drug discovery and development drug repurposing and improving productivity within a short period Contemporary methods have shown promising results in facilitating the discovery of drugs to target different diseases Moreover AI helps in predicting the efficacy and safety of molecules and gives researchers a much broader chemical pallet for the selection of the best molecules for drug testing and delivery In this context drug repurposing is another important topic where AI can have a substantial impact With the vast amount of clinical and pharmaceutical data available to date AI algorithms find suitable drugs that can be repurposed for alternative use in medicine This book is a comprehensive exploration of this dynamic and rapidly evolving field In an era where precision and efficiency are paramount in drug discovery AI and ML have emerged as transformative tools reshaping the way we identify design and develop pharmaceuticals This book is a testament to the profound impact these technologies have had and will continue to have on the pharmaceutical industry healthcare and ultimately patient well being The editors of this volume have assembled a distinguished group of experts researchers and thought leaders from both the AI ML and pharmaceutical domains Their collective knowledge and insights illuminate the

multifaceted landscape of AI and ML in drug design and development offering a roadmap for navigating its complexities and harnessing its potential In each section readers will find a rich tapestry of knowledge case studies and expert opinions providing a 360 degree view of AI and ML s role in drug design and development Whether you are a researcher scientist industry professional policymaker or simply curious about the future of medicine this book offers 19 state of the art chapters providing valuable insights and a compass to navigate the exciting journey ahead Audience The book is a valuable resource for a wide range of professionals in the pharmaceutical and allied industries including researchers scientists engineers and laboratory workers in the field of drug discovery and development who want to learn about the latest techniques in machine learning and AI as well as information technology professionals who are interested in the application of machine learning and artificial intelligence in drug development

Biopharmaceuticals Basanta 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 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

Modern Biopharmaceuticals Jörg Knäblein,2013-05-07 This collection of high profile contributions provides a unique insight into the development of novel successful biopharmaceuticals Outstanding authors including Nobel laureate Robert Huber as well as prominent company researchers and CEOs present valuable insider knowledge limiting their scope to those procedures and developments with proven potential for the biotechnology industry They cover all relevant aspects from the establishment of biotechnology parks the development of successful compounds and the implementation of efficient manufacturing processes right up to the establishment of advanced delivery routes

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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

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