Biophysics for the Life Sciences

Linda O. Narhi Editor

Biophysics for Therapeutic Protein Development



Biophysics For Therapeutic Protein Development Biophysics For The Life Sciences

Praveen Kaushik

Biophysics For Therapeutic Protein Development Biophysics For The Life Sciences:

Biophysics for Therapeutic Protein Development Linda O. Narhi, 2013-02-26 This book can be used to provide insight into this important application of biophysics for those who are planning a career in protein therapeutic development and for those outside this area who are interested in understanding it better The initial chapters describe the underlying theory and strengths and weaknesses of the different techniques commonly used during therapeutic development. The majority of the chapters discuss the applications of these techniques including case studies across the product lifecycle from early discovery where the focus is on identifying targets and screening for potential drug product candidates through expression and purification large scale production formulation development lot to lot comparability studies and commercial support including investigations Molecular Biophysics for the Life Sciences Norma Allewell, Linda O. Narhi, Ivan Rayment, 2013-09-28 This volume provides an overview of the development and scope of molecular biophysics and in depth discussions of the major experimental methods that enable biological macromolecules to be studied at atomic resolution It also reviews the physical chemical concepts that are needed to interpret the experimental results and to understand how the structure dynamics and physical properties of biological macromolecules enable them to perform their biological functions Reviews of research on three disparate biomolecular machines DNA helicases ATP synthases and myosin illustrate how the combination of theory and experiment leads to new insights and new questions *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 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 Biophysics: Integrating Physics and Biology Cybellium, in the biopharmaceutical field Biotherapeutics Sandeep Kumar, Satish Kumar Singh, 2015-11-18 Biopharmaceuticals are emerging as frontline medicines to combat several life threatening and chronic diseases However such medicines are expensive to develop and produce on a commercial scale contributing to rising healthcare costs Developability of Biotherapeutics Computational Approaches describes applications of computational and molecular Innovative Physical Chemistry Perspectives Praveen Kaushik, 2025-02-20 Innovative Physical Chemistry Perspectives offers a refreshing take on traditional concepts in physical chemistry presenting them through innovative approaches modern applications and interdisciplinary insights Authored by experts this comprehensive volume explores fundamental principles and cutting edge research topics inviting readers to engage with the dynamic and evolving landscape of physical chemistry Each chapter delves into specific aspects providing in depth discussions theoretical foundations and practical examples From nanochemistry and biomolecular interactions to quantum mechanics and statistical mechanics we cover a wide range of topics highlighting the interconnectedness of various subfields and their relevance to real world phenomena Through clear explanations illustrative examples and thought provoking discussions Innovative Physical Chemistry Perspectives aims to inspire curiosity critical thinking and a deeper appreciation for the complexities of matter and energy at the molecular level Whether you re a student researcher or enthusiast in the field this book serves as a valuable resource for expanding your knowledge and understanding With its emphasis on modern perspectives interdisciplinary approaches and practical applications Innovative Physical Chemistry Perspectives is set to become an essential reference for anyone seeking to explore physical chemistry from new and exciting Biophysics Fouad Sabry, 2025-03-23 Biophysics provides an indepth exploration of molecular biophysics shedding angles light on the vital intersection of biology chemistry and physics As part of the Molecular Biophysics series this book is an essential resource for professionals students and anyone interested in the intricate details of molecular interactions that govern life processes With a strong focus on biophysical principles key figures and cuttingedge research this book will help you understand the mechanisms that power the molecular machinery of living organisms Biophysics Introduces the foundational principles of biophysics and their application in understanding biological systems at the molecular level Mikhail Volkenstein Explores Volkenstein's contributions to molecular biophysics and his theoretical framework for molecular interactions Carlos Bustamante biophysicist Discusses Bustamante s groundbreaking work in the study of molecular motors

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