

BIOLOGICALS AND INTERCHANGEABLE BIOLOGICS

Tactical Elements



Sarfaraz K. Niazi



Biosimilars Interchangeable Biologics Tactical Elements

Katrin Zwirgmaier



Biosimilars Interchangeable Biologics Tactical Elements:

Biosimilars and Interchangeable Biologics Sarfaraz K. Niazi, 2016-01-05 What's the Deal with Biosimilars Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry The biological drugs are produced by recombinant DNA technology that allows for large scale production and an overall reduction time in costs and development Part of a two volume set th *Biosimilars and Interchangeable Biologics* Sarfaraz K. Niazi, 2018-10-30 What's the Deal with Biosimilars Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry The biological drugs are produced by recombinant DNA technology that allows for large scale production and an overall reduction time in costs and development Part of a two volume set that covers varying aspects of biosimilars *Biosimilars and Interchangeable Biologics Strategic Elements* explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters This includes principal patents and intellectual property regulatory pathways and concerns about affordability on a global scale It addresses the complexity of biosimilar products and it discusses the utilization of biosimilars and related biological drugs in expanding world markets Of specific interest to practitioners researchers and scientists in the biopharmaceutical industry this volume examines the science technology finance legality ethics and politics of biosimilar drugs It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars and it provides detailed descriptions of the legal regulatory and commercial characteristics The book also presents a global strategy on how to build take to market and manage the next generation of biosimilars throughout their life cycle **Handbook of Preformulation** Sarfaraz K. Niazi, 2019-03-22 Preformulation studies are the physical chemical and biological studies needed to characterize a drug substance for enabling the proper design of a drug product whereas the effectiveness of a drug product is determined during the formulation studies phase Though the two disciplines overlap in practice each is a significantly distinct phase of new drug development Entirely focused on preformulation principles this fully revised and updated Handbook of Preformulation Chemical Biological and Botanical Drugs Second Edition provides detailed descriptions of preformulation methodologies gives a state of the art description of each technique and lists the currently available tools useful in providing a comprehensive characterization of a new drug entity Features Addresses the preformulation studies of three different types of new active entities chemical biological and botanical which is the latest established class of active ingredient classified by the FDA Illustrates the activities comprised in preformulation studies and establishes a method of tasking for drug development projects Includes extensive flow charts for characterization decision making Gives extensive theoretical treatment of principles important for testing dissolution solubility stability and solid state characterization Includes over 50% new material *The Future of Pharmaceuticals* Sarfaraz K. Niazi, 2022-02-28 Before now biological systems could only be expressed in terms of linear relationships however as knowledge grows and new

techniques of analysis on biological systems is made available we are realizing the non linearity of these systems The concepts and techniques of nonlinear analysis allow for more realistic and accurate models in science The Future of Pharmaceuticals A Nonlinear Analysis provides an opportunity to understand the non linearity of biological systems and its application in various areas of science primarily pharmaceutical sciences This book will benefit professionals in pharmaceutical industries academia and policy who are interested in an entirely new approach to how we will treat disease in the future Key Features Addresses a new approach of nonlinear analysis Applies a theory of projection to chalk out the future instead of basing on linear evolution Provides an opportunity to better understand the non linearity in biological systems and its applications in various areas of science primarily pharmaceutical sciences Helps change the thought process for those looking for answers to their questions which they do not find in the linear relationship approach Encourages a broader perspective for the creative process of drug development **Biosimilarity** Sarfaraz K. Niazi,2018-10-03 Summary The focus of this book is on how the U S FDA will approve biosimilar drugs as learned from recent approvals by the FDA Understanding the limitations of the statutory limits and non inferiority testing are presented as tools to obviate patient trials and minimize testing of immunogenicity An in depth scientific mathematical and statistical view of the tools required to establish biosimilarity of biological drugs of different complexity a must for every developer of biosimilars Features First comprehensive analysis based on new guidelines and approval packages of several biosimilars Presents the first approach to challenge FDA in reducing or eliminating any testing in patients Provides a comprehensive understanding of the U S statutory requirements vis a vis the regulatory guidelines Provides model CQA and Analytical Similarity testing protocols for cytokines and monoclonal antibodies Allow creation of a fast to market pathway to develop biosimilars Handbook of Pharmaceutical Manufacturing Formulations, Third Edition Sarfaraz K. Niazi,2019-12-06 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume One Compressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this first volume of a six volume set compiles data from FDA new drug applications patent applications and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent GMP Audits in Pharmaceutical and Biotechnology Industries Mustafa Edik,2024-06-28 The fact that good manufacturing practice GMP audits in the pharmaceutical and biotechnology industries have to be evaluated and with very limited resources has created a gap in this field The lack of trained and qualified GMP auditors is on the rise in all organizations that are required to implement FDA EMA MHRA WHO TGA and PIC S regulations This volume is an essential reference source for those organizations operating in the field of health and presents the basic

knowledge needed to perform audits The author also provides useful tips and a selection of samples about GMP audits that are indispensable for professionals and health inspectors working in industry and health authorities Features An essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits Anyone working in the manufacturing sector needs to be aware of GMP be able to identify operational flaws as well as legal violations and have a clear understanding of how to meet GMP standards Assists readers in understanding the importance of GMP and how they can apply each aspect in their working environment Covers a global regulatory landscape Suitable for relevant degree courses including industrial pharmaceuticals and pharmaceutical biotechnology

Biosimilar and Interchangeable Biologics Sarfaraz K. Niazi, 2016-02-15 The field of biosimilar drugs is one of the hottest subjects in the field of new drug development with scores of companies offering seminar and training programs for prospective manufacturers and stakeholders This book is a modern comprehensive overview of the entire biosimilar manufacturing and distribution process covering concepts introduced by the FDA litigation strategies analytical methods pharmacokinetic studies and the future and current status of biosimilar product approvals

Biologics and Biosimilars Xiaodong Feng, Hong-Guang Xie, Ashim Malhotra, Catherine F. Yang, 2022-06-13 Biologics and Biosimilars Drug Discovery and Clinical Applications is a systematic integration and evaluation of all aspects of biologics and biosimilars encompassing research and development clinical use global regulation and more Biosimilars are biological therapeutic agents designed to imitate a reference biologic with high similarities in structure efficacy and safety but also with potential clinical effective and cost efficient options for the manufacturers payers clinicians and patients Most of the top selling prescription drugs in the current market are biologics which have revolutionized the treatment strategies and modalities for life threatening and or rare diseases This book outlines the key processes and challenges in drug development regulations and clinical applications of biologics biosimilars and even interchangeable biosimilars Global experts in the field discuss essential categories and prototype drugs of biologics and biosimilars in clinical practice such as allergenics blood and blood components cell treatment gene therapy recombinant therapeutic proteins or peptides tissues and vaccines Additional features Integrates the latest bench and bedside evidence of drug development and regulations of biologics and biosimilars Contains key study questions for each chapter to guide the readers as well as drug charts for all therapeutic applications of biologics and biosimilars Presents detailed schematic illustrations to explain the drug development clinical trials regulations and clinical applications of biologics and biosimilars This book is an invaluable tool for health care professional students providers and pharmaceutical and health care industries as well as the public providing readers with educational updates about the drug development and clinical affairs of biological medications and their similar drugs

Fast Facts: Biosimilars in Hematology and Oncology Paul Cornes, Ali McBride, 2020-01-23 Biologics have revolutionized and are revolutionizing the treatment of many serious disorders The evidence acquired from more than 10 years of clinical experience with more than 50

biosimilar drugs and more than 700 million patient days exposure in Europe shows that approved biosimilars can be used as safely and effectively as originator biologics Yet concerns persist about biosimilars particularly in curative cancer treatment where they are relatively recent therapeutic options Fast Facts Biosimilars in Hematology and Oncology provides a concise overview of emerging global practice in this fast moving area together with practical information on adding biosimilars to a formulary and switching patients Contents Biologics and the need for biosimilars Why do we need biosimilars How is the quality of biosimilar medicines assured Legal issues Switching interchangeability and extrapolation Safety and pharmacovigilant Global issues Formulary considerations pharmacy issues Formulary considerations supportive care biosimilars Formulary considerations therapeutic anti cancer biosimilars Communication and awareness

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