

BIOSIMILARS AND INTERCHANGEABLE BIOLOGICS

Tactical Elements



Sarfaraz K. Niazi



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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* P. Cornes,A. McBride,2020-01-24 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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