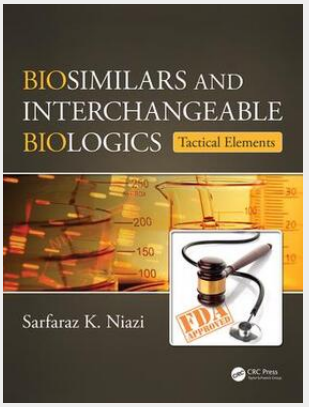
Niazi

Biosimilars and Interchangeable Biologics

Tactical Elements

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: Tactical Elements explores the development and manufacturing of biosimilars and targets challenges surrounding the creation of these products. This includes manufacturing, production costs, and intellectual property barriers, particularly in regulated markets (regulatory agencies are still in the process of developing guidelines). It addresses the complexity of biological drugs, and it discusses specific structural elements vital to the functionality, immunogenicity, and safety of biosimilar products. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume provides an overall understanding of the hurdles, difficulties, and practicalities of developing a strong plan. It introduces a step-by-step approach for creating a strategy that helps develop and manufacture a biosimilar product while reducing overall production costs and meeting the requirements of biosimilarity based on analytical and functional, pharmacokinetic, pharmacodynamic (where applicable), and nonclinical toxicology or toxicokinetic similarity (where appropriate) while remaining competitive in the market.



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