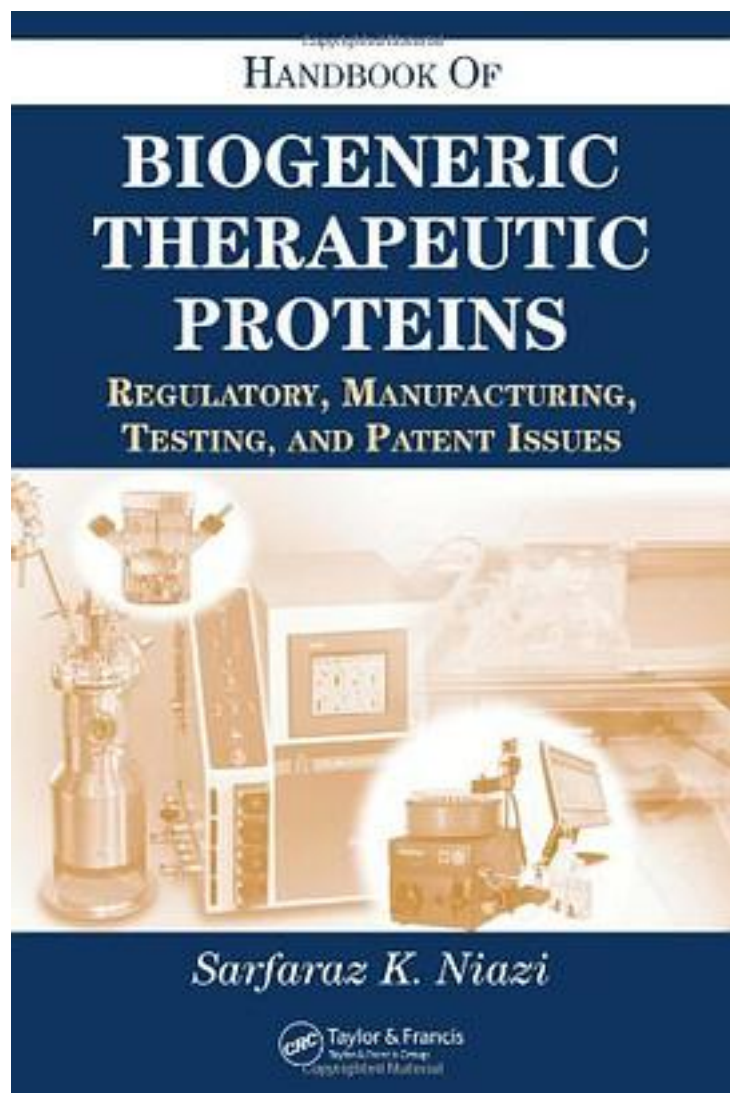


Handbook of Biogeneric Therapeutic Proteins



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More than 20 billion dollars worth of biopharmaceuticals are scheduled to go off-patent by 2006. Given the strong political impetus and the development of technological tools that can answer the questions regulatory authorities may raise, it is inevitable that the FDA and EMEA will allow biogeneric or biosimilar products. Even with all the regulatory wrinkles yet to be ironed out, generic or similar biological products are soon to become a reality. Handbook of Biogeneric Therapeutic Proteins is the first book to review and analyze the status of biotechnology, regulatory environment, manufacturing methodologies, testing requirements and intellectual property issues. The book provides complete and thorough coverage of the regulatory and technological challenges of developing generic therapeutic proteins and how to prepare detailed regulatory and manufacturing plans and policies. The author includes information on establishing a manufacturing system, securing regulatory approval, and setting up facilities to manufacture raw materials and prepare finished products. He also supplies details about the Chemistry, Manufacturing, and Controls (CMC) section of the FDA's New Drug Application for Biological Products. In brief, the book supplies everything a manufacturer would need to plan the development of biogeneric products and complete the process of regulatory filing. Waiting for the FDA to issue guidelines is a mistake. The scramble to catch up could leave your company way behind in the game. Your organization needs to begin developing and characterizing genetically modified cells now and to complete initial GMP production runs through a CRO to get ready for the newer testing the FDA might impose. Packed with tables and figures that provide speedy access to precise, timely data, including full formulation details on all FDA approved biological product, this book contains a broad range of resource materials about suppliers, manufacturers, and testing facilities. These features combined with the author's hands-on, practical approach give you the edge you need.

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