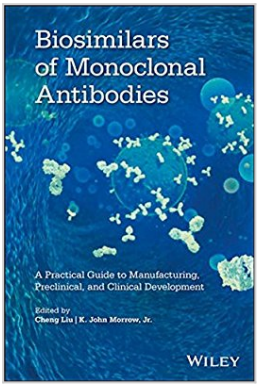

Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical, and Clinical Development

From Wiley-Interscience

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Addressing a significant need by describing the science and process involved to develop biosimilars of monoclonal antibody (mAb) drugs, this book covers all aspects of biosimilar development: preclinical, clinical, regulatory, manufacturing.

• Guides readers through the complex landscape involved with developing biosimilar versions of monoclonal antibody (mAb) drugs
• Features flow charts, tables, and figures that clearly illustrate processes and makes the book comprehensible and accessible
• Includes a review of FDA-approved mAb drugs as a quick reference to facts and useful information
• Examines new technologies and strategies for improving biosimilar mAbs

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Editorial Review

From the Back Cover

As the patents for biopharmaceuticals first marketed in the 1990s begin to expire, there is an opening for generic or non-proprietary versions of these agents to enter the market. The collective revenues of patent-expired biotech industry now total $10 billion annually, yet biosimilar generics have been slow to arise. It is a situation that has drawn much concern from generic and branded drug developers, patient groups, regulatory agencies and lawmakers. The 2012 release of FDA's guidance on biosimilar drug development further stresses the need for a technical yet practical guide to biosimilar drug development.

Arising from this landscape, *Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing and Preclinical and Clinical Development* gives pharmaceutical and biotech scientists and researchers a clear resource to understand the scientific principles and challenges involved in biosimilar drug development.

The book discusses the scientific background including history, classification, and biological activities – including background knowledge unique to monoclonal antibody (mAb) drugs and essential profiling characteristics that regulations require. Contributing authors from the frontlines of biosimilar development address the processes and issues involved with manufacturing biosimilar mAbs, like cell line development, process development, large-scale cell culture of mammalian cells, and final product analysis.

A valuable for all those – from beginners to experts – with an interest in biosimilar drug development of monoclonal antibodies, *Biosimilars of Monoclonal Antibodies*:

• Covers all aspects of biosimilar development: preclinical, clinical, regulatory, manufacturing
• Introduces key topics of bioanalytical development, preclinical and clinical validation of biosimilarity, regulatory issues, and legal considerations concerning approval and commercialization
• Leads readers to think beyond biosimilars by examining new technologies and strategies for improving biosimilar mAbs
• Includes a review of FDA-approved mAb drugs as a quick reference to facts and useful information
• Features flow charts, tables, and figures that clearly illustrate processes and makes the book comprehensible and accessible

About the Author

Cheng Liu, PhD, is founder and CEO of Eureka Therapeutics, a biotech company dedicated to monoclonal antibody drug discovery and development for unmet medical needs. He is an expert on therapeutic antibody and engineering, and a frequent speaker at pharmaceutical conferences. He holds multiple issued US and international patents in the field of therapeutic antibody discovery and engineering and has authored many scientific publications in the field of cancer immunotherapy. Dr. Liu was awarded Special Congressional Recognition for his contributions to improving human health in 2007.

K. John Morrow, Jr., PhD, is President and CEO of Newport Biotechnology Consultants, and has worked in academia and in the private sector. He has published a total of over 280 peer-reviewed articles, reports in biotechnology trade papers, chapters in books, and full length books. He serves as a consultant for Meridian Bioscience, Inc., in Cincinnati, OH and for Point A Consulting in Louisville, KY.

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