

1.4 AIM AND SCOPE OF THE BOOK

This book is devoted to the development of biosimilar products. It covers the scientific factors and/or practical issues that are commonly encountered at various stages of research and development of biosimilar products. Our goal is to provide a useful desk reference for scientists and researchers engaged in pharmaceutical/clinical research and the development of biosimilar products, and for those in the regulatory agencies who have to make decisions in the review and approval process of biological regulatory submissions. We hope that this book can serve as a bridge among the pharmaceutical/biotechnology industry, government regulatory agencies, and academia.

This book follows the FDA's proposed stepwise approach as well as the approach of the EMA and other regulatory agencies such as China Food and Drug Administration (CFDA) of China for evaluation and approval of the development of biosimilar products. The stepwise approach starts with analytical similarity assessment for functional and structural characterization of critical quality attributes that are relevant to clinical outcomes at various stages of the manufacturing process, pharmacological activities, additional nonclinical studies if needed, and clinical studies for pharmacokinetic and immunogenicity assessment and efficacy confirmation. This book consists of 17 chapters. These chapters cover analytical similarity assessment (Chapters 2 through 4), manufacturing process control (Chapter 5), nonclinical studies (Chapter 6), clinical development (Chapter 7), extrapolation of indications for biosimilars (Chapter 9), design and analysis for assessing biosimilarity and drug interchangeability (Chapters 8, 10, and 11), pharmacovigilance (Chapter 13) and immunogenicity (Chapter 12), patent exclusivities (Chapter 14), and other issues (Chapters 15 through 17).

Discussions of these topics cover a broad range of issues that are important for the development of biosimilar drug products. It is hoped that the explorations will benefit researchers and practitioners involved in such investigations and applications.

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