

1. Record Nr.	UNINA9910787329603321
Autore	Chow Shein-Chung <1955, >
Titolo	Biosimilars : design and analysis of follow-on biologics / / Shein-Chung Chow, Duke University School of Medicine, Durham, North Carolina, USA
Pubbl/distr/stampa	Boca Raton : , : Taylor & Francis, , 2014
ISBN	0-429-07126-4 1-4665-7969-2
Descrizione fisica	1 online resource (424 pages) : illustrations
Collana	Chapman & Hall/CRC biostatistics series ; ; 60
Classificazione	MAT029000MED071000
Disciplina	615.19
Soggetti	Pharmaceutical biotechnology Pharmaceutical biotechnology industry Drugs - Generic substitution Pharmaceutical policy Biological products
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	"A Chapman & Hall book."
Nota di bibliografia	Includes bibliographical references.
Nota di contenuto	Introduction Background Fundamental Differences Regulatory Requirements Biosimilarity Interchangeability of Biological Drug Products Scientific Factors Aim and Scope of the Book Bioequivalence Experience for Small-Molecule Drug Products Background Process for Bioequivalence Assessment Issue of Drug Interchangeability Highly Variable Drugs Practical Issues Frequently Asked Questions Regulatory Requirements for Assessing Follow-On Biologics Background Definitions and Interpretations of Biosimilar Products Regulatory Requirements Review of the FDA Draft Guidances Global Harmonization Criteria for Similarity Introduction Criteria for Bioequivalence Similarity Factor for Dissolution Profile Comparison Measures of Consistency Comparison of Moment-Based and Probability-Based Criteria Alternative Criteria Statistical Methods for Assessing Average Biosimilarity Introduction Classic Methods for Assessing Biosimilarity Bayesian Methods Wilcoxon-Mann-Whitney Two One-Sided Tests Procedure Three-Arm Parallel Design General Approach for Assessing Biosimilarity Background Reproducibility Probability Development of the

Biosimilarity Index Relationship of the Biosimilarity Criterion versus Variability
Biosimilarity Index Based on the Bayesian Approach
Consistency Approach Non-Inferiority versus Equivalence/Similarity
Background Testing for Equality Testing for Noninferiority Testing for Superiority
Testing for Equivalence Relationship among Testing for Noninferiority, Superiority, and Equivalence
Determination of the Noninferiority Margin Sample Size Requirement When There Is a Switch
in Hypothesis Testing Statistical Test for Biosimilarity in Variability
Introduction Pitman-Morgan's Adjusted Test for Comparing Variabilities
F -Type Test under Parallel Design Non-Parametrics Methods Alternative Methods
Sample Size for Comparing Variabilities Introduction Comparing Intra-Subject Variability
Comparing Inter-Subject Variability Comparing Total Variability Comparing Intra-Subject
CVs Impact of Variability on Biosimilarity Limits for Assessing Follow-On
Biologics Introduction Relationship between Variability and Biosimilarity Limits
Scaled Biosimilarity Margins Simulations Discussions Drug Interchangeability
Introduction Population and Individual Bioequivalence Interchangeability for Biosimilar
Products Study Designs for Interchangeability Statistical Methods Issues on Immunogenicity
Studies Introduction Regulatory Requirements Assay Development/Validation Design for
Immunogenicity Studies Sample Size for Immunogenicity Studies CMC Requirements for
Biological Products Introduction CMC Development Product Characterization and
Specification Manufacture and Process Validation Quality Control/Assurance Reference
Standards, Container Closure System, and Stability Test for Comparability in
Manufacturing Process Introduction Biologic Manufacturing Process Consistency Index
Test for Comparability Other Comparability Tests Stability Analysis of Biosimilar
Products Introduction Regulatory Stability Guidelines on Biologicals Stability
Indicating Profile and Expiration Dating Period Stability Designs Statistical Analysis
Assessing Biosimilarity Using Biomarker Data Introduction Assessment of Biosimilarity
Statistical Test for Biosimilarity Using Biomarker Data Numerical Study Current
Issues in Biosimilar Studies Introduction Scientific Factors Current Issues References Index

Sommario/riassunto

This is the first book entirely devoted to the design and analysis for assessment of biosimilarity and drug interchangeability of biosimilars, and test for comparability in manufacturing processes of biologic products. It covers all of the statistical issues that may occur in biosimilar studies under various study designs at various stages of research and development of biologic products--
Biologic drug products are therapeutic moieties that are manufactured using a living system or organism. These are important life-saving drug products for patients with unmet medical needs. They also comprise a growing segment in the pharmaceutical industry. In 2007, for instance, worldwide sales of biological products reached \$94 billion US dollars, accounting for about 15% of the pharmaceutical industry's gross revenue. Meanwhile, many biological products face losing their patents in the next decade--
