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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

"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"--