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Nota di contenuto	REGULATED BIOANALYTICAL LABORATORIES: Technical and Regulatory Aspects from Global Perspectives; CONTENTS; PREFACE; ACKNOWLEDGMENT; CONTRIBUTORS AND ADVISORS; 1 INTRODUCTION, OBJECTIVES, AND KEY REQUIREMENTS FOR GLP REGULATIONS; 1.1 INTRODUCTION; 1.1.1 Good Laboratory Practices; 1.1.2 Bioanalytical Laboratories-Bioanalysis; 1.1.3 Good Laboratory Practices Versus Bioanalytical Labs/Bioanalysis; 1.2 OBJECTIVES AND KEY REQUIREMENTS FOR GLP REGULATIONS; 1.3 FUNDAMENTAL UNDERSTANDING OF GLP REGULATIONS AND PRINCIPLES; 1.3.1 Elements of Good Laboratory Practices 1.4 KEY ELEMENTS OF BIOANALYTICAL METHODS VALIDATION 1.4.1 Reference Standards; 1.4.2 Method Development-Chemical/Chromatographic Assay; 1.4.3 Calibration/Standard Curve; 1.4.4 Stability; 1.4.5 Reproducibility; 1.4.6 Robustness or Ruggedness; 1.5 BASIC PRINCIPLES OF BIOANALYTICAL METHOD VALIDATION AND ESTABLISHMENT; 1.5.1 Specific Recommendations for Method Validation; 1.5.2 Acceptance Criteria for Analytical Run; REFERENCES; 2

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2.2 APPLICABILITY AND RELATIONS TO OTHER REGULATIONS/ PRINCIPLES; 2.2.1 GLP, GCP, GMP, and Part 11; 2.2.2 General Terminologies and Definitions of GxPs (GLP, GCP, and cGMP); 2.3 COMPARISON OF FDA GLP, EPA GLP REGULATIONS, AND OECD GLP PRINCIPLES; 2.3.1 US and OECD GLP Similarity and Differences; 2.4 APPLICATIONS OF GLP TO MULTIPLE SITE STUDIES; 2.4.1 Roles and Responsibilities; 2.4.2 Performance of the Studies; 2.4.3 Applications of GLP to In Vitro Studies for Regulatory Submissions; 2.5 21 CFR PART 11 IN RELATION TO GLP PROGRAMS; 2.5.1 A New Risk-Based Approach
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Sommario/riassunto

This book provides useful information for bioanalytical / analytical scientists, analysts, quality assurance managers, and all personnel in bioanalytical laboratories through all aspects of bioanalytical technical and regulatory perspectives within bioanalytical operations and processes. Readers learn how to develop and implement strategies for routine, non-routine, and standard bioanalytical methods and on the entire equipment hardware and software qualification process. The book also gives guidelines on qualification of certified standards and in-house reference material as well as on people
