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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 VALIDATION1.4.1 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 HISTORIC PERSPECTIVES OF GLP REGULATIONS, APPLICABILITY, AND RELATION TO OTHER REGULATIONS; 2.1 HISTORIC PERSPECTIVES OF GLP REGULATIONS; 2.1.1 Economic Assessment
2.1.2 Environmental Impact2.2 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
2.5.2 Understanding Predicate Rule Requirements2.5.3 21 CFR Part 11 Best Practices; 2.5.4 Use of Electronic Signatures; 2.6 GLP, cGMP, AND ISO APPLICABILITIES, SIMILARITY, AND DIFFERENCES; 2.6.1 GLPs, cGMPs, ISO 17025:2005: How Do They Differ?; 2.6.2 GLPs Versus GMPs; 2.6.3 GLPs Versus ISO/IEC 17025:2005; 2.6.4 ISO Versus GLPs; 2.7 GOOD CLINICAL PRACTICES AND GOOD CLINICAL LABORATORY PRACTICES; 2.8 GAP AND CURRENT INITIATIVES ON REGULATING LABORATORY ANALYSIS IN SUPPORT OF CLINICAL TRIALS; REFERENCES; 3 GLP QUALITY SYSTEM AND IMPLEMENTATION; 3.1 GLP QUALITY SYSTEM
3.1.1 Regulatory Inspection for GLP Quality System3.1.2 Good Laboratory Practice Inspections; 3.1.3 GLP Quality System Objectives; 3.2 GLOBAL GLP REGULATIONS AND PRINCIPLES; 3.2.1 General; 3.2.2 Responsibilities and Compliance; 3.2.3 Statement of Compliance in the Final Report; 3.2.4 Protocol Approval; 3.2.5 Assignment of Study Director; 3.2.6 Laboratory Qualification/Certification; 3.2.7 Authority Inspections; 3.2.8 Archiving Requirements; 3.3 IMPLEMENTATION OF GLP REGULATIONS AND OECD PRINCIPLES; 3.3.1 Planning (Master Schedule); 3.3.2 Personnel Organization; 3.3.3 Curriculum Vitae
3.3.4 Rules of the Conducts of Studies

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