

1. Record Nr.	UNINA9910829916003321
Autore	Zhou Michael
Titolo	Regulated bioanalytical laboratories : technical and regulatory aspects from global perspectives // Michael Zhou
Pubbl/distr/stampa	Hoboken, New Jersey : , : Wiley, , [2011] ©2011
ISBN	0-470-92280-X 1-282-88905-2 9786612889059 0-470-92067-X 0-470-92066-1
Descrizione fisica	1 online resource (548 p.)
Disciplina	610.28/4
Soggetti	Medical laboratories - Quality control Biological laboratories - Quality control Pharmaceutical technology - Quality control
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
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
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 Impact 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
2.5.2 Understanding Predicate Rule Requirements 2.5.3 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 System 3.1.2 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
