

1.	Record Nr.	UNISALENTO991002665419707536
	Autore	Aristoteles
	Titolo	Aristoteles und die Paideia / besorgt und übersetzt von Edmund Braun
	Pubbl/distr/stampa	Paderborn : F. Schöningh, 1974
	ISBN	350678367X
	Descrizione fisica	258 p. : ill. ; 22 cm
	Collana	Schöninghs Sammlung pädagogischer Schriften
	Altri autori (Persone)	Braun, Edmundauthor
	Disciplina	185
	Lingua di pubblicazione	Tedesco Molteplice
	Formato	Materiale a stampa
	Livello bibliografico	Monografia
2.	Record Nr.	UNISALENTO991002657359707536
	Autore	Bonomi, Andrea
	Titolo	Esistenza e struttura : saggio su Merleau Ponty / Andrea Bonomi
	Pubbl/distr/stampa	Milano : Il Saggiatore, 1967
	Descrizione fisica	253 p. ; 21 cm
	Collana	La cultura. Biblioteca di filosofia, psicologia e scienze umane
	Disciplina	142.7
	Soggetti	Merleau-Ponty, Maurice
	Lingua di pubblicazione	Italiano
	Formato	Materiale a stampa
	Livello bibliografico	Monografia

3. Record Nr.	UNINA9911019143503321
Autore	Zhou Michael
Titolo	Regulated bioanalytical laboratories : technical and regulatory aspects from global perspectives / / Michael Zhou
Pubbl/distr/stampa	Hoboken, N.J., : Wiley, c2011
ISBN	9786612889059 9780470922804 047092280X 9781282889057 1282889052 9780470920671 047092067X 9780470920664 0470920661
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
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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 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 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