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Nota di contenuto	Cover; Title page; Copyright page; Contents; Foreword; Preface; Contributors; 1: Introduction to the Study Director; 1.1 Definition of Study Director; 1.2 Regulatory History on the Scope of the Role; 1.2.1 FDA 1976 Proposed Rule (41 FR 1976); 1.2.2 FDA 1978 Final Rule (43 FR 1978); 1.2.3 OECD Consensus Document 1999 (OECD, 1999); 1.3 Guidance on Study Director Qualifications and Training; 1.3.1 OECD on Qualifications of the Study Director; 1.3.2 OECD on Training of Study Directors; 1.4 Study Director Training Courses; 1.5 Summary; References 2: Good Laboratory Practice Regulations: Roles of the Study Director, Management, and Quality Assurance Unit2.1 Introduction and Objectives; 2.2 Regulation Attempts Prior to 1930; 2.3 Critical Events Leading to Regulations; 2.4 Nonclinical Regulation; 2.5 The Purpose of GLP Regulation; 2.6 Industry Benefits of the GLP; 2.7 Requirements of the GLP; 2.8 The Role of Management; 2.9 The Role of the Study Director; 2.10 The Role of the Quality Assurance Unit; 2.11 A Brief Word about the Multi-site GLP Study; 2.12 GLP Interpretation Guidance; 2.13

FDA Concerns and the Future

2.14 Comparing GLP Standards: FDA, EPA, and OECD2.15 Summary; References; 3: International Guidelines and Regulations of Nonclinical Studies; 3.1 General Introduction; 3.2 Scope; 3.3 Legislation, Guidelines, and Regulations; 3.3.1 General; 3.3.2 Globally Acting Organizations; 3.3.3 Region-Specific Regulations; 3.4 Studies; 3.4.1 Screening Information Dataset (SIDS) Dossier; 3.4.2 REACH Data Requirements (Tiers 1-3); 3.4.3 A Discussion on Weight of Evidence and Klimisch Codes; 3.5 Summary; References; 4: Facilities, Operations, Laboratory Animal Care, and Veterinary Services; 4.1 Introduction
4.1.1 Regulatory Oversight and Accreditation Requirements4.1.2 Interaction between GLP and Animal Welfare Regulations; 4.1.3 Control of Study Variables; 4.2 Facilities; 4.2.1 Organization, Personnel, and Management; 4.2.2 Job Descriptions, Training Records, Curriculum Vitae (CV), and Organizational Charts; 4.2.3 Test Facility Design, Construction, and Maintenance; 4.2.4 Formulation Preparation Facilities; 4.2.5 Test and Control Articles; 4.2.6 Specialty Laboratories; 4.2.7 Quality Assurance Unit (QAU): Role and Responsibilities; 4.3 Laboratory Operations
4.3.1 Standard Operating Procedures (SOPs)4.3.2 Reagents and Solutions; 4.3.3 Laboratory Systems and Electronic Records; 4.3.4 Laboratory Instrumentation/Equipment; 4.3.5 Emergency Disaster Plan; 4.4 Laboratory Animal Care and Veterinary Services; 4.4.1 Regulatory Oversight and Accreditation; 4.4.2 Animal Care Facilities; 4.4.3 Animal Health and Veterinary Services Program; 4.4.4 Health Maintenance Program; 4.4.5 Veterinary Services Program; 4.4.6 Veterinary and Animal Care Procedures; 4.5 Other Species; References; 5: Regulatory Inspections; 5.1 Introduction
5.2 Purpose and Types of Regulatory Inspections

Sommario/riassunto

A single-source reference with a broad and holistic overview of nonclinical studies, this book offers critical training material and describes regulations of nonclinical testing through guidelines, models, case studies, practical examples, and worldwide perspectives. The book: Provides a complete overview of nonclinical study organization, conduct, and reporting and describes the roles and responsibilities of a Study Director to manage an effective studyCovers regulatory and scientific concepts, including international testing and Good Laboratory Practice (GLP), complian