1. Record Nr. UNICAMPANIASUN0053870

Autore	International conference on structural mechanics in reactor technology : 9
Titolo	Extreme loading and response of reactor containments / editor Folker H. Wittmann, coordinators Walter J. Ammann, Albrecht Huber, John D. Stevenson
Pubbl/distr/stampa	Rotterdam [etc.] : Balkema, 1987
ISBN	90-619-1770-0
Descrizione fisica	X, 325 p. ; 25 cm.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia

2. Record Nr. UNINA9910784842603321

Titolo	Preclinical development handbook Toxicology [[electronic resource] /] / [edited by] Shayne Cox Gad
Pubbl/distr/stampa	Hoboken, NJ, : Wiley-Interscience, c2008
ISBN	1-281-23742-6 9786611237424 0-470-24905-6 0-470-24904-8
Descrizione fisica	1 online resource (1075 p.)
Collana	Pharmaceutical Development Series ; ; v.4
Altri autori (Persone)	GadShayne C. <1948->
Disciplina	615.7 615.7040724 615.9
Soggetti	Drugs - Toxicology Drugs - Toxicity testing
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	PRECLINICAL DEVELOPMENT HANDBOOK Toxicology; CONTRIBUTORS; CONTENTS; Preface; 1 Preclinical Drug Development Planning; 2 Use of Project Teams in Preclinical Development; 3 Relationship between Animal Models and Clinical Research: Using Mucositis as a Practical Example; 4 Bacterial Mutation Assay; 5 In Vitro Mammalian Cell Mutation Assays; 6 In Vitro Mammalian Cytogenetic Tests; 7 In Vivo Genotoxicity Assays; 8 Repeat Dose Toxicity Studies; 9 Irritation and Local Tissue Tolerance Studies in Pharmacetical Safety Assessment; 10 Safety Assessment Studies: Immunotoxicity 11 Immunotoxicity Testing: ICH Guideline S8 and Related Aspects12 Reproductive and Developmental Toxicology; 13 Carcinogenicity Studies; 14 Toxicokinetics: An Integral Component of Preclinical Toxicity Studies; 15 In Vitro Toxicokinetics and Dynamics: Modeling and Interpretation of Toxicity Data; 16 Toxicologic Pathology; 17 Secondary Pharmacodynamic Studies and In Vitro Pharmacological Profiling; 18 Current Practices in Safety Pharmacology; 19 Safety Assessment of Biotechnology-Derived Therapeutics; 20 Preclinical Development of Protein Pharmaceuticals: An Overview 21 The Pharmacogenomics of Personalized Medicine22 Genomics; 23 Proteomics; 24 Toxicogenomics in Preclinical Development; 25 Toxicoproteomics: Preclinical Studies; 26 Regulatory Considerations; 27 Regulatory Issues in Preclinical Safety Studies (U.S. FDA); 28 Selection and Utilization of CROs for Safety Assessment; 29 Auditing and Inspecting Preclinical Research and Compliance with Good Laboratory Practice (GLP); 30 Drug Impurities and Degradants and Their Safety Qualification; 31 Bridging Studies in Preclinical Pharmaceutical Safety Assessment; Index
Sommario/riassunto	A clear, straightforward resource to guide you through preclinical drug developmentFollowing this book's step-by-step guidance, you can successfully initiate and complete critical phases of preclinical drug development. The book serves as a basic,comprehensive reference to prioritizing and optimizing leads, toxicity, pharmacogenomics, modeling, and regulations. This single definitive, easy-to-use resource discusses all the issues that need consideration and provides detailed instructions for current methods and techniques.Each chapter was written by one or more leading experts