

1. Record Nr.	UNINA9910140133003321
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Titolo	Drug safety evaluation [[electronic resource] /] / Shayne Cox Gad
Pubbl/distr/stampa	Hoboken, NJ, : Wiley, c2009
ISBN	1-282-36841-9 9786612368417 0-470-46415-1 0-470-46409-7
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (1196 p.)
Collana	Pharmaceutical Development Series ; ; v.7
Disciplina	615.19 615/.19
Soggetti	Drugs - Toxicology Drugs - 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	Drug Safety Evaluation; Contents; Preface; Acknowledgment; About the Author; 1. Drug Development Process and Global Pharmaceutical Marketplace; 2. Regulation of Human Pharmaceutical Safety; 3. Prior Art and Its Use in Safety Assessment Process; 4. Screens in Safety and Hazard Assessment; 5. Formulations, Routes, and Dosage Design; 6. Single-Dose (Acute) and Pilot (DRF) Toxicity Testing in Drug Safety Evaluation; 7. Genotoxicity; 8. Repeat-Dose Toxicity Studies; 9. Immunotoxicology in Drug Development; 10. Nonrodent Animal Studies; 11. Developmental and Reproductive Toxicity Testing 12. Carcinogenicity Studies13. Histopathology in Nonclinical Pharmaceutical Safety Assessment; 14. Irritation and Local Tissue Tolerance in Pharmaceutical Safety Assessment; 15. Pharmacokinetics and Toxicokinetics in Drug Safety Evaluation; 16. Safety Pharmacology; 17. Special Concerns for Preclinical Evaluation of Biotechnology Products; 18. Safety Assessment of Inhalant and Dermal Route Drugs; 19. Special-Case Products: Imaging Agents and Oncology Drugs; 20. Occupational Toxicology in Pharmaceutical Industry 21. Strategy and Phasing for Nonclinical Drug Safety Evaluation in Discovery and Development of Pharmaceuticals22. Application of In

Vitro Techniques in Drug Safety Assessment; 23. Evaluation of Human Tolerance and Safety in Clinical Trials: FIM Trials and Beyond; 24. Postmarketing Safety Evaluation: Monitoring, Assessing, and Reporting of Adverse Drug Responses; 25. Statistics in Pharmaceutical Safety Assessment; 26. Combination Products: Drugs and Devices; 27. Qualification of Impurities, Degradants, Residual Solvents, and Leachables in Pharmaceuticals
Appendix A. Selected Regulatory and Toxicological Acronyms
Appendix B. Definition of Terms and Lexicon of Clinical Observations in Nonclinical (Animal) Studies; Appendix C. Notable Regulatory Internet Addresses; Appendix D. Glossary of Terms Used in Clinical Evaluation of Therapeutic Agents; Appendix E. Common Vehicles for Nonclinical Evaluation of Therapeutic Agents; Appendix F. Global Directory of Contract Toxicology Laboratories; Index

Sommario/riassunto

Drug Safety Evaluation Second Edition
Shayne Cox Gad
The updated and expanded safety guide to all aspects of the drug development process
Drug Safety Evaluation, Second Edition presents an all-inclusive, practical guide for those who are responsible for ensuring the safety of drugs and biologics for patients, for health care providers, for those involved in the manufacture of medicinal products, and for all those who need to understand how the safety of these products is evaluated. This Second Edition has been extensively revised and expanded to respond to the many changes
