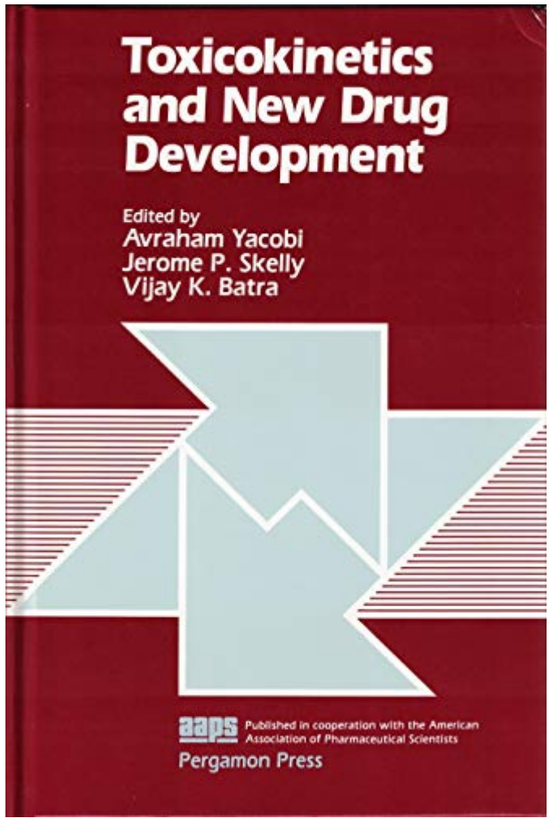

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Toxicokinetics and New Drug Development-Avraham Yacobi 1989

A Comprehensive Guide to Toxicology in Preclinical Drug Development-Ali S. Faqi 2012-11-16 A Comprehensive Guide to Toxicology in Preclinical Drug Development is a resource for toxicologists in industry and regulatory settings, as well as directors working in contract resource organizations, who need a thorough understanding of the drug development process. Incorporating real-life case studies and examples, the book is a practical guide that outlines day-to-day activities and experiences in preclinical toxicology. This multi-contributed reference provides a detailed picture of the complex and highly interrelated activities of preclinical toxicology in both small molecules and biologics. The book discusses discovery toxicology and the international guidelines for safety evaluation, and presents traditional and nontraditional toxicology models. Chapters cover development of vaccines, oncology drugs, botanic drugs, monoclonal antibodies, and more, as well as study development and personnel, the role of imaging in preclinical evaluation, and supporting materials for IND applications. By incorporating the latest research in this area and featuring practical scenarios, this reference is a complete and actionable guide to all aspects of preclinical drug testing. Chapters written by world-renowned contributors who are experts in their fields Includes the latest research in preclinical drug testing and international guidelines Covers preclinical toxicology in small molecules and biologics in one single source

A Comprehensive Guide to Toxicology in Nonclinical Drug Development-Ali S. Faqi 2016-11-03 A Comprehensive Guide to Toxicology in Nonclinical Drug Development, Second Edition, is a valuable reference designed to provide a complete understanding of all aspects of nonclinical toxicology in the development of small molecules and biologics. This updated edition has been reorganized and expanded to include important topics such as stem cells in nonclinical toxicology, inhalation and dermal toxicology, pitfalls in drug development, biomarkers in toxicology, and more. Thoroughly updated to reflect the latest scientific advances and with increased coverage of international regulatory guidelines, this second edition is an essential and practical resource for all toxicologists involved in nonclinical testing in industry, academic, and regulatory settings. Provides unique content that is not always covered together in one comprehensive resource, including chapters on stem cells, abuse liability, biomarkers, inhalation toxicology, biostatistics, and more Updated with the latest international guidelines for nonclinical toxicology in both small and large molecules Incorporates practical examples in order to illustrate day-to-day activities and the expectations associated with working in nonclinical toxicology

Early Drug Development-Mitchell N. Cayen 2011-02-25 The focus of early drug development has been the submission of an Investigational New Drug application to regulatory agencies. Early Drug Development: Strategies and Routes to First-in-Human Trials guides drug development organizations in preparing and submitting an Investigational New Drug (IND) application. By explaining the nuts and bolts of preclinical development activities and their interplay in effectively identifying successful clinical candidates, the book helps pharmaceutical scientists determine what types of discovery and preclinical research studies are needed in order to support a submission to regulatory agencies.

Integration of Pharmacokinetics, Pharmacodynamics, and Toxicokinetics in Rational Drug Development-A. Yacobi 2013-11-11 Proceedings of a conference sponsored by the American Association of Pharmaceutical Scientists, the U.S. Food and Drug Administration, and the American Society for Clinical Pharmacology and Therapeutics, held in Arlington, Virginia, April 24-26, 1991

Toxicokinetics and Risk Assessment-John C. Lipscomb 2016-04-19 Toxicokinetics in Risk Assessment discusses the noncancer risk assessment process and its reliance on uncertainty factors in order to facilitate the continued study and refinement of the scientific basis for health risk assessment. This text clearly demonstrates the application of physiologically-based pharmacokinetic (PBPK) modeling in human healt

Pharmacokinetics and Toxicokinetics-Mehdi Boroujerdi 2015-02-24 Pharmacokinetics and Toxicokinetics provides an overview of pharmacokinetics and toxicokinetics in a comprehensible, interrelated, and applied manner. It integrates the principles held in common by both fields through a logical and systematic approach. The book presents mathematical descriptions of physiological processes employed in different approaches to PK/TK modeling. It focuses on emphasizing general principles and concepts, rather than isolated observations. Above all, the book is an effort to blend the pharmaceutical and toxicological aspects of both fields. The systematic compilation of mathematical concepts and methodologies allows readers to decide on relevant concepts and approaches for their research, scientific or regulatory decisions, or for offering advance courses and seminars. This is an invaluable resource for scientists in the pharmaceutical sciences, clinical sciences, and environmental health sciences, as well as those involved in drug discovery and development.

Pharmacokinetics, Metabolism, and Pharmaceutics of Drugs of Abuse- 1997

New Horizons in Predictive Drug Metabolism and Pharmacokinetics-Alan G. E. Wilson 2015-11-20 This book thoroughly explores the predictive role of drug metabolism and pharmacokinetics in drug discovery and in improving success rates and safety assessments of chemicals.

Pharmacokinetics and Adverse Effects of Drugs-Ntambwe Malangu 2018-05-23 This book is a fruit of a collaborative work from several international scientists. It will be a useful resource for researchers, students, and clinicians. Each individual chapter could serve as a prescribed reading for postgraduate students and clinicians specializing in and practicing clinical pharmacology and toxicology, pharmacotherapy and pharmacotherapeutics, pharmacovigilance, and toxicovigilance, as well as those involved in clinical research, drug discovery, and development. Every chapter in this book discusses and provides illustrations on the theme discussed based on authors' understanding and experience while summarizing existing knowledge. In doing so, each chapter provides a new insight that would benefit a novice as well as a seasoned reader in understanding the pharmacokinetic

mechanisms and risk factors involved in the occurrence of adverse effects of drugs.

Drug Discovery and Evaluation-H. Gerhard Vogel 2006-01-01 This book is a landmark in the continuously changing world of drugs. It is essential reading for scientists and managers in the pharmaceutical industry who are involved in drug finding, drug development and decision making in the development process.

New Drug Development-Mark P. Mathieu 1997

Environmental Toxicology and Chemistry- 2007

Oral Bioavailability Assessment-Ayman F. El-Kattan 2017-06-06 Specifically geared to personnel in the pharmaceutical and biotechnology industries, this book describes the basics and challenges of oral bioavailability – one of the most significant hurdles in drug discovery and development. • Describes approaches to assess pharmacokinetics and how drug efflux and uptake transporters impact oral bioavailability • Helps readers reduce the failure rate of drug candidates when transitioning from the bench to the clinic during development • Explains how preclinical animal models – used in preclinical testing – and in vitro tools translate to humans, which is an underappreciated and complicated area of drug development • Includes chapters about pharmacokinetic modelling, the Biopharmaceutics Drug Disposition Classification System (BDDCS), and the Extended Clearance Classification System (ECCS) • Has tutorials for applying strategies to medicinal chemistry practices of drug discovery/development

Clinical Toxicology-Frank A. Barile 2003-12-17 Concise and authoritative, Clinical Toxicology: Principles and Mechanisms examines the complex interactions associated with clinical toxicological events and chemical exposure or drug administration. The author places special emphasis on signs and symptoms of diseases and pathology caused by toxins and clinical drugs. He covers contemporary issues in clinical toxicology, such as biological and chemical toxins, changes in protocols for managing toxic ingestions, new antidotes, changes in particular treatments, and pharmacology and toxicology of herbal products. After introducing the fundamental principles of toxicology, the book presents the toxicity of therapeutic and non-therapeutic agents in separate sections. Most chapters start with a basic review of the general physiology and pharmacology principles necessary for understanding the underlying mechanisms of toxicity. The book includes numerous drawings, figures, and tables that improve understanding of the mechanisms involved in chemical exposure. It covers widely distributed chemical agents and currently used therapeutic drugs that possess hazardous effects either as principle mechanisms of action or as untoward adverse drug reactions. A reader-friendly exposition of clinical toxicology, Clinical Toxicology: Principles and Mechanisms can be used as a stand-alone text or a professional reference.

Drug Safety Evaluation-Shayne Cox Gad 2003-09-05 Drug Safety Evaluation 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. Individual chapters address specific approaches to evaluating hazards, including problems that are encountered and their solutions. Author Shayne Gad draws upon over twenty years of experience in toxicology, drug development, and risk assessment, explaining the scientific and philosophical bases for evaluating specific concerns (carcinogenicity, development toxicity, etc.) to provide both understanding and guidance for approaching new problems. Containing information specifically relevant to the pharmaceutical and biotechnology industries, Drug Safety Evaluation covers a wide variety of topics, including: Acute toxicity testing in pharmaceutical safety evaluation Genotoxicity Safety assessment of inhalant drugs Immunotoxicology in pharmaceutical development Large animal studies Evaluation of human tolerance and safety in clinical trials Drug Safety Evaluation provides a road map for safety assessment as an integral part of the development of new drugs and therapeutics.

Pediatric Drug Development-Andrew E. Mulberg 2013-05-20 Pediatric Drug Development, Second Edition, encompasses the new regulatory initiatives across EU, US and ROW designed to encourage improved access to safe and effective medicines for children. It includes new developments in biomarkers and surrogate endpoints, developmental pharmacology and other novel aspects of pediatric drug development.

Drug Safety Evaluation-Shayne Cox Gad 2016-11-18 This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics. Helps readers solve scientific, technical, and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns – including local tissue tolerance, target organ toxicity and carcinogenicity, developmental toxicity, immunogenicity, and immunotoxicity Covers the development of new small and large molecules, generics, 505(b)(2) route NDAs, and biosimilars Revises material to reflect new drug products (small synthetic, large proteins and cells, and tissues), harmonized global and national regulations, and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition

Toxicologic Pathology-Pritam S. Sahota 2018-08-31 Following the success of the first edition, this book is designed to provide practical and timely information for toxicologic pathologists working in pharmaceutical drug discovery and development. The majority of the book (Organ Systems) will provide detailed descriptions of histopathological lesions observed in drug development. In addition, it will provide information to assist the pathologist in making determinations of the origin of lesions as well as its relevance to human risk. Toxicologic Pathology: Nonclinical Safety Assessment, Second Edition includes 2 new concept chapters. The first of the new chapters address approaches for the evaluation of unique therapeutic modalities such as cell therapies, gene therapies, and gene expression knockdown therapies. While these still represent new developing therapeutic approaches, there has been significant experience with the therapeutic modalities in the last 5 years. The second new chapter addresses the nonclinical safety assessment of medical devices, a topic of increasing importance that was not addressed in a unique chapter in the first edition. The other concept chapters have been updated and cover important topics including the overview of drug development; principles of nonclinical safety assessment; an introduction to toxicologic pathology; techniques used in toxicologic pathology, clinical pathology, toxicokinetics, and drug development toxicogenomics; and spontaneous lesions. The 13 organ system chapters provide the specifics related to pathologic characteristics, differential diagnosis, and interpretation of toxic responses in each organ system. These chapters are specifically important for the bench pathologist but also for the toxicologist who interacts with pathologists and function as study toxicologists and project team representatives in the drug development arena.

Pharmaceutical Toxicology in Practice-Alberto Lodola 2011-03-31 This book describes, with references to key source materials, the background to, and conduct of, the principal nonclinical studies that are central to drug development. The chapters provide an understanding of the key components of the preclinical phase of drug development with a hands-on description, with core chapters addressing study conduct, types, and reporting. As such, it is a practical guide through toxicology testing and an up-to-date reference on current issues, new developments, and future directions in toxicology. Opening with a practical description of toxicology and its role in the development of pharmaceuticals, the book proceeds to detail international regulations (including the impact of the new REACH standards for chemical safety), interdisciplinary interactions among scientists in drug development, steps in toxicity testing, and risk management. Further, the book covers the methods of genetic toxicology (assays, genomics, in vivo screening) as a complement to “traditional” toxicology in the risk assessment and risk management of pharmaceuticals.

Toxicity Testing in the 21st Century-National Research Council 2007-11-05 Advances in molecular biology and toxicology are paving the way for major improvements in the evaluation of the hazards posed by the large number of chemicals found at low levels in the environment. The National Research Council was asked by the U.S. Environmental Protection Agency to review the state of the science and create a far-reaching vision for the future of toxicity testing. The book finds that developing, improving, and validating new laboratory tools based on recent

scientific advances could significantly improve our ability to understand the hazards and risks posed by chemicals. This new knowledge would lead to much more informed environmental regulations and dramatically reduce the need for animal testing because the new tests would be based on human cells and cell components. Substantial scientific efforts and resources will be required to leverage these new technologies to realize the vision, but the result will be a more efficient, informative and less costly system for assessing the hazards posed by industrial chemicals and pesticides.

Preclinical Development Handbook-Shayne Cox Gad 2008-03-21 A clear, straightforward resource to guide you through preclinical drug development Following 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 in the field. These authors, representing the many disciplines involved in preclinical toxicology screening and testing, give you the tools needed to apply an effective multidisciplinary approach. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. Among the key topics covered are: * In vitro mammalian cytogenetics tests * Phototoxicity * Carcinogenicity studies * The pharmacogenomics of personalized medicine * Bridging studies * Toxicogenomics and toxicoproteomics Each chapter offers a full exploration of problems that may be encountered and their solutions. The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage. This is a hands-on guide for pharmaceutical scientists involved in preclinical testing,enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin.

Pharmacokinetics in Drug Development-Peter L. Bonate 2011-02-21 The topics chosen for this volume were selected because they are some of the current development or technological issues facing drug development project teams. They regard the practical considerations for assessment of selected special development populations. For example, they include characterization of drug disposition in pregnant subjects, for measuring arrhythmic potential, for analysis tumor growth modeling, and for disease progression modeling. Practical considerations for metabolite safety testing, transporter assessments, Phase 0 testing, and development and execution of drug interaction programs reflect current regulatory topics meant to address enhancement of both safety assessment and early decision-making during new candidate selection. Important technologies like whole body autoradiography, digital imaging and dried blood spot sample collection methods are introduced, as both have begun to take a more visible role in pharmacokinetic departments throughout the industry.

Ligand-Binding Assays-Masood N. Khan 2009-10-22 A consolidated and comprehensive reference on ligand-binding assays Ligand-binding assays (LBAs) stand as the cornerstone of support for definition of the pharmaco-kinetics and toxicokinetics of macromolecules, an area of burgeoning interest in the pharmaceutical industry. Yet, outside of the Crystal City Conference proceedings, little guidance has been available for LBA validation, particularly for assays used to support macromolecule drug development. Ligand-Binding Assays: Development, Validation, and Implementation in the Drug Development Arena answers that growing need, serving as a reference text discussing critical aspects of the development, validation, and implementation of ligand-binding assays in the drug development field. Ligand-Binding Assays covers essential topics related to ligand-binding assays, from pharmacokinetic studies, the development of LBAs, assay validation, statistical LBA aspects, and regulatory aspects, to software for LBAs and robotics and other emerging methodologies for LBAs. Highlights include: A general discussion of challenges and proven approaches in the development of ligand-binding assays More detailed examination of characteristics of these assays when applied to support of pharmacokinetic and toxicokinetic studies of compounds at different stages in the discovery or development timeline A concise, but detailed, discussion of validation of ligand-binding assays for macromolecules A practical approach to "fit-for-purpose" validation of assays for biomarkers, those molecules receiving increased attention as potentially demonstrating that the target chosen in discovery is being modulated by the candidate therapeutic, both in nonclinical and clinical studies Written by a team of world-recognized authorities in the field, Ligand-Binding Assays provides key information to a broad range of practitioners, both in the pharmaceutical and allied industries and in related contract research organizations and academic laboratories and, perhaps, even in the field of diagnostics and clinical chemistry.

Evaluation of Drug Candidates for Preclinical Development-Chao Han 2010-01-06 Emphasizes the integration of major areas of drug discovery and their importance in candidate evaluation It is believed that selecting the "right" drug candidate for development is the key to success. In the last decade, pharmaceutical R&D departments have integrated pharmacokinetics and drug metabolism, pharmaceutics, and toxicology into early drug discovery to improve the assessment of potential drug compounds. Now, Evaluation of Drug Candidates for Preclinical Development provides a complete view and understanding of why absorption-distribution-metabolism-excretion-toxicology (ADMET) plays a pivotal role in drug discovery and development. Encompassing the three major interrelated areas in which optimization and evaluation of drug developability is most critical—pharmacokinetics and drug metabolism, pharmaceutics, and safety assessment—this unique resource encourages integrated thinking in drug discovery. The contributors to this volume: Cover drug transporters, cytochrome P-450 and drug-drug interactions, plasma protein binding, stability, drug formulation, preclinical safety assessment, toxicology, and toxicokinetics Address developability issues that challenge pharma companies, moving beyond isolated experimental results Reveal connections between the key scientific areas that are critical for successful drug discovery and development Inspire forward-thinking strategies and decision-making processes in preclinical evaluation to maximize the potential of drug candidates to progress through development efficiently and meet the increasing demands of the marketplace Evaluation of Drug Candidates for Preclinical Development serves as an introductory reference for those new to the pharmaceutical industry and drug discovery in particular. It is especially well suited for scientists and management teams in small- to mid-sized pharmaceutical companies, as well as academic researchers and graduate students concerned with the practical aspects related to the evaluation of drug developability.

Toxicokinetics and Risk Assessment-John C. Lipscomb 2016-04-19 Toxicokinetics in Risk Assessment discusses the noncancer risk assessment process and its reliance on uncertainty factors in order to facilitate the continued study and refinement of the scientific basis for health risk assessment. This text clearly demonstrates the application of physiologically-based pharmacokinetic (PBPK) modeling in human healt

Fundamentals of Toxicology-PK Gupta 2016-08-26 Fundamentals of Toxicology: Essential Concepts and Applications provides a crisp, easy-to-understand overview of the most important concepts, applications, and ideas needed to learn the basics of toxicology. Written by a pre-eminent toxicologist with over five decades of teaching experience, this comprehensive resource offers the hands-on knowledge needed for a strong foundation in the wide field of toxicology. Fundamentals of Toxicology includes a clear structure divided into five units to assist learning and understanding. The first unit provides extensive coverage on the background of toxicology including commonly used definitions and historical perspective, while following units cover: basic concepts; regulatory requirements and good laboratory practices, including types of toxicology testing and evaluation; toxic agents and adverse effects on health; and analytical, forensic, and diagnostic toxicology. This is an essential book for advanced students in toxicology and across the biomedical sciences, life sciences, and environmental sciences who want to learn the concepts of toxicology, as well as early researchers needing to refresh outside of their specialty. Explains the essential concepts of toxicology in a clear fashion Provides in-depth coverage of testing protocols, common drugs, chemicals, and laboratory-based diagnostic and analytical toxicology Explores the history, foundations, and most recent concepts of toxicology Serves as an essential reference for advanced students in toxicology and across the biomedical, life, and environmental sciences who want to learn the concepts of toxicology

Translational Toxicology-Claude L. Hughes 2016-03-23 Bringing together a distinguished interdisciplinary team of contributors, this volume provides a comprehensive exploration of translational toxicology—a systematic approach to developing therapeutic interventions that can protect against, mitigate, or reverse the effects of exposures. In particular, the book addresses modes of action and biomarkers, developmental risks of exposures, and potential translational toxicology therapeutics. The result is a compelling application of developmental toxicology in a new therapeutic discipline that is destined to become part of standard medical practice.

Translational Toxicology: Defining a New Therapeutic Discipline is an essential text for regulatory authorities, scientists, and physicians who are concerned with environmental exposures, public health, nutrition, and pharmaceutical research and development. Basic science, epidemiological, and clinical investigators will also find this book a significant resource.

New Trends in Pharmacokinetics-Aldo Rescigno 2012-12-06 The last decade or so has witnessed tremendous progress in methodology in the field of drug development in general and pharmacokinetics in particular. Clinical pharmacokinetics is using new tools for probing into the "black box" once being ac cessible only partly through experimental techniques and, mostly through mathemati cal and computer means. Development of computerized scanning, positron emission tomography (PET), stereoselectivity and other techniques are now enabling investi gators to have better pictures of the systems they are studying. Mathematical models through computer simulation and statistical estimation, mostly due to easy access be cause of inexpensive yet powerful personal computers, are enabling us to investigate ultrastructures and their functional connectivity in more detail. As a consequence, new hypotheses are being formed and tested in various related fields. In clinical pharmacokinetics, mostly due to mathematical modeling, more accurate interspecies scaling of pharmacokinetic parameters and dosimetry can be done now-a-days. The concept of "a human is a bigger rat" does not necessarily fly as a consequence. Pharmacokinetic concepts are becoming powerful tools in meaningful carcinogenic and toxic risk extrapolation of different chemicals in humans. New dose delivery designs are being formulated using pharmacokinetic techniques for different pharmaceutical compounds. Investigations continue in the academia, research institutions, pharmaceutical, biotechnological, and agricultural industries in developmental and physiological aspects of different chemicals for the benefit of mankind. The idea of a school on "New Trends in Pharmacokinetics", from which the present pUblication was made possible, took shape over almost a year.

Current Catalog-National Library of Medicine (U.S.) 1993 First multi-year cumulation covers six years: 1965-70.

Drug Discovery and Evaluation: Methods in Clinical Pharmacology-H.Gerhard Vogel 2010-12-15 Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

Pharmacokinetics and Toxicokinetics-Mehdi Boroujerdi 2015-02-24 Pharmacokinetics and Toxicokinetics provides an overview of pharmacokinetics and toxicokinetics in a comprehensible, interrelated, and applied manner. It integrates the principles held in common by both fields through a logical and systematic approach. The book presents mathematical descriptions of physiological processes employed in different approaches to PK/TK modeling. It focuses on emphasizing general principles and concepts, rather than isolated observations. Above all, the book is an effort to blend the pharmaceutical and toxicological aspects of both fields. The systematic compilation of mathematical concepts and methodologies allows readers to decide on relevant concepts and approaches for their research, scientific or regulatory decisions, or for offering advance courses and seminars. This is an invaluable resource for scientists in the pharmaceutical sciences, clinical sciences, and environmental health sciences, as well as those involved in drug discovery and development.

Veterinary Toxicology-Ramesh C. Gupta 2011-04-28 Veterinary Toxicology, 2nd edition is a unique single reference that teaches the basic principles of veterinary toxicology and builds upon these principles to offer an essential clinical resource for those practicing in the field. This reference book is thoroughly updated with new chapters and the latest coverage of topics that are essential to research veterinary toxicologists, students, professors, clinicians and environmentalists. Key areas include melamine and cyanuric acid, toxicogenomics, veterinary medical geology, toxic gases, toxicity and safety evaluation of new veterinary pharmaceuticals and much more. The 2nd edition of this popular book represents the collective wisdom of leading contributors worldwide and continues to fill an undeniable need in the literature relating to veterinary toxicology. New chapters covering important and timely topics such as melamine and cyanuric acid, toxicogenomics, toxic gases and veterinary medical geology Expanded look at international topics, such as epidemiology of animal poisonings, regulatory guidelines and poisonous plants in Europe Heavily contributed book with chapters written by qualified and well-experienced authorities across all areas of veterinary toxicology Problem solving strategies are offered for treatment as well as in-depth knowledge of the basic mechanisms of veterinary toxicology

Biopharmaceutics and Pharmacokinetics Considerations- 2021-07-15 Biopharmaceutics and Pharmacokinetics Considerations examines the history of biopharmaceutics and pharmacokinetics. The book provides a biopharmaceutics and pharmacokinetics approach to addressing issues in formulation development and ethical considerations in handling animals. Written by experts in the field, this volume within the Advances in Pharmaceutical Product Development and Research series deepens understanding of biopharmaceutics and pharmacokinetics within drug discovery and drug development. Each chapter delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists, researchers and pharmaceutical industries to study the chemical and physical properties of drugs and the biological effects they produce. Examines the most recent developments in biopharmaceutics and pharmacokinetics for pharmaceutical sciences Covers the principles, methodologies and technologies of biopharmaceutics and pharmacokinetics Focuses on the pharmaceutical sciences, but also encompasses aspects of toxicology, neuroscience, environmental sciences and nanotechnology

Medical Toxicology of Drug Abuse-Donald G. Barceloux 2012-02-03 This book provides a broad reference covering important drugs of abuse including amphetamines, opiates, and steroids. It also covers psychoactive plants such as caffeine, peyote, and psilocybin. It provides chemical structures, analytical methods, clinical features, and treatments of these drugs of abuse, serving as a highly useful, in-depth supplement to a general medical toxicology book. The style allows for the easy application of the contents to searchable databases and other electronic products, making this an essential resource for practitioners in medical toxicology, industrial hygiene, occupational medicine, pharmaceuticals, environmental organizations, pathology, and related fields.

New Horizons in Predictive Toxicology-Alan G E Wilson 2011-11-15 The sophistication of modelling and simulation technologies have improved dramatically over the past decade and their applications in toxicity prediction and risk assessment are of critical importance. The integration of predictive toxicology approaches will become increasingly necessary as industrial chemicals advance and as new pharmaceuticals enter the market. In this comprehensive discussion of predictive toxicology and its applications, leading experts express their views on the technologies currently available and the potential for future developments. The book covers a wide range of topics including in silico, in vitro and in vivo approaches that are being used in the safety assessment of chemical substances. It reflects the growing and urgent need to strengthen and improve our ability to predict the safety and risks posed by industrial and pharmaceutical chemicals in humans. The reader will find extensive information on the use of current animal models used for various toxicities and target mediated toxicities. Also discussed are the recent regulatory initiatives to improve the safety assessment of chemicals. The book provides an expert and comprehensive discussion on the current status and future directions of predictive toxicology and its application. The various chapters in the book also reflect the growing need for improvements in our technologies and abilities to predict toxicities of pharmaceutical and industrial chemicals to ensure product safety and protect public health.

The Illustrated Dictionary of Toxicologic Pathology and Safety Science-Pritam S. Sahota 2019-04-26 There has been a growing interest in toxicologic pathology, especially as related to its impact on the safety assessment of pharmaceuticals and chemicals, and in drug development. Thus, there is a growing need for an Illustrated

Dictionary of Toxicology Pathology and Safety Science (IDTP) that this dictionary aims to fill. The language of toxicologic pathology may be less familiar to a broad range of safety scientists, especially those involved in the safety evaluation of pharmaceuticals and chemicals. The IDTP format provides the brevity and clarity that the user is not likely to receive in a textbook, even if adequately indexed. With the inclusion of descriptions for terms used in toxicology, drug metabolism/pharmacokinetics, and regulatory science, the scope of the IDTP is considerably broadened and decidedly unique in its appeal to all safety scientists. With over 800 photos and illustrations to provide visual context,* an important aim of the IDTP is to present pathological changes as reference examples for terminology, nomenclature, and term descriptions for the entry entry-level as well as seasoned toxicologic pathologist. It will also aid students and non-pathology specialists such as study directors, senior toxicology report reviewers, scientific management of contract research organizations, regulatory agencies, and drug development companies to better understand the biological significance of tissue changes. The IDTP provides a single reference volume for these users to further their understanding and appreciation of biologically significant pathology findings. The IDTP consists of four major areas: 1. A-Z Dictionary of Pathology encompassing all organ systems, together with relevant non-pathology terms supported by references in "For Further Reading" sections. 2. Appendix 1: An Overviews of Drug Development, Nonclinical Safety & Toxicologic Pathology, and Important/Special Topics. 3. Appendix 2: Diagnostic Criteria of for Proliferative Proliferative Lesions in Rodents (Rat and Mouse) and Selected Non-Rodent Laboratory Species containing illustrations with detailed references and links to source material. 4) Appendix 3: Mini-Atlas of Organ System Anatomy and Histology to help re-acquaint the non-pathologist safety scientist with many normal anatomical structures. The editors and contributing scientists (board-certified veterinary pathologists, board-certified toxicologists, allied health safety scientists, health regulatory representatives) have experience from bench-level pathology and toxicology to managing global preclinical safety units in leading pharmaceutical companies. They have considerable experience mentoring pharmaceutical industry project team members, interacting with industry clinicians and representatives of decision-making bodies within the industry, as well as with global health authorities, such as the FDA and EMA. These activities convinced them of the necessity for and usefulness of the IDTP. As experts in their field, they have undertaken the hard work of writing and compiling the information, making the IDTP an exceptional, go-to reference. *Illustrations Editor: Gregory Argentieri

Alternative Toxicological Methods-Harry Salem 2003-03-26 Bringing together the recent and relevant contributions of over 125 scientists from industry, government, and academia in North America and Western Europe, Alternative Toxicological Methods explores the development and validation of replacement, reduction, and refinement alternatives (the 3Rs) to animal testing. Internationally recognized scientist

Drug-Induced Liver Disease-Neil Kaplowitz 2002-10-16 Featuring more than 4100 references, Drug-Induced Liver Disease will be an invaluable reference for gastroenterologists, hepatologists, family physicians, internists, pathologists, pharmacists, pharmacologists, and clinical toxicologists, and graduate and medical school students in these disciplines.

Neurobiology of Huntington’s Disease-Donald C. Lo 2010-07-02 In 1993, the genetic mutation responsible for Huntington’s disease (HD) was identified. Considered a milestone in human genomics, this discovery has led to nearly two decades of remarkable progress that has greatly increased our knowledge of HD, and documented an unexpectedly large and diverse range of biochemical and genetic perturbations that seem to result directly from the expression of the mutant huntingtin gene. Neurobiology of Huntington’s Disease: Applications to Drug Discovery presents a thorough review of the issues surrounding drug discovery and development for the treatment of this paradigmatic neurodegenerative disease. Drawing on the expertise of key researchers in the field, the book discusses the basic neurobiology of Huntington’s disease and how its monogenic nature confers enormous practical advantages for translational research, including the creation of robust experimental tools, models, and assays to facilitate discovery and validation of molecular targets and drug candidates for HD. Written to support future basic research as well as drug development efforts, this volume: Covers the latest research approaches in genetics, genomics, and proteomics, including high-throughput and high-content screening Highlights advances in the discovery and development of new drug therapies for neurodegenerative disorders Examines the practical realities of preclinical testing, clinical testing strategies, and, ultimately, clinical usage While the development of effective drug treatments for Huntington's disease continues to be tremendously challenging, a highly interactive and cooperative community of researchers and clinical investigators now brings us to the threshold of potential breakthroughs in the quest for therapeutic agents. The impressive array of drug discovery resources outlined in the text holds much promise for treating this devastating disease, providing hope to long-suffering Huntington’s disease patients and their families.