Physiologically Based Pharmacokinetic Pbpk Modeling And Simulations Principles Methods And Applications In The Pharmaceutical Industry

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Biopharmaceutics Modeling and Simulations - Kiyohiko Sugano 2012-08-20
A comprehensive introduction to using modeling and simulation programs in drug discovery and development Biopharmaceutical modeling has become integral to the design and development of new drugs. Influencing key aspects of the development process, including drug substance design, formulation design, and toxicological exposure assessment, biopharmaceutical modeling is now seen as the linchpin to a drug's future success. And while there are a number of commercially available software programs for drug modeling, there has not been a single resource guiding pharmaceutical professionals to the actual tools and practices needed to design and test safe drugs. A guide to the basics of modeling and simulation programs, Biopharmaceutics Modeling and Simulations offers pharmaceutical scientists the keys to understanding how they work and are applied in creating drugs with desired medicinal properties. Beginning with a focus on the oral absorption of drugs, the book discusses: The central dogma of oral drug absorption (the interplay of dissolution, solubility, and permeability of a drug), which forms the basis of the biopharmaceutical classification system (BCS) The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used for biopharmaceutical modeling Reliable practices for reporting results With over 200 figures

and illustrations and a peerless examination of all the key aspects of drug research—including running and interpreting models, validation, and compound and formulation selection—this reference seamlessly brings together the proven practical approaches essential to developing the safe and effective medicines of tomorrow.

The Use of Drugs in Food Animals - National Research Council 1999-02-12

The use of drugs in food animal production has resulted in benefits throughout the food industry; however, their use has also raised public health safety concerns. The Use of Drugs in Food Animals provides an overview of why and how drugs are used in the major food-producing animal industriesâ€"poultry, dairy, beef, swine, and aquaculture. The volume discusses the prevalence of human pathogens in foods of animal origin. It also addresses the transfer of resistance in animal microbes to human pathogens and the resulting risk of human disease. The committee offers analysis and insight into these areas: Monitoring of drug residues. The book provides a brief overview of how the FDA and USDA monitor drug residues in foods of animal origin and describes quality assurance programs initiated by the poultry, dairy, beef, and swine industries. Antibiotic resistance. The committee reports what is known about this controversial problem and its potential effect on human health. The volume also looks at how drug use may be minimized with new approaches in genetics, nutrition, and animal management.

Biopharmaceutics Applications in Drug Development - Rajesh Krishna 2007-09-20

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications, Third Edition - Johan Gabrielsson 2001-11-30

This is a revised and very expanded version of the previous second edition of the book. "Pharmacokinetic and Pharmacodynamic Data Analysis" provides an introduction into pharmacokinetic and pharmacodynamic concepts using simple illustrations and reasoning. It describes ways in which pharmacodynamic and pharmacodynamic theory may be used to give insight into modeling questions and how these questions can in turn lead to new knowledge. This book differentiates itself from other texts in this area in that it bridges the gap between relevant theory and the actual application of the theory to real life situations. The book is divided into two parts; the first introduces fundamental principles of PK and PD concepts, and principles of mathematical modeling, while the second provides case studies obtained from drug industry and academia. Topics included in the first part include a discussion of the statistical principles of model fitting, including how to assess the adequacy of the fit of a model, as well as strategies for selection of time points to be included in the design of a study. The first part also introduces basic pharmacokinetic and pharmacodynamic concepts, including an excellent discussion of effect compartment (link) models as well as indirect response models. The second part of the text includes over 70 modeling case studies. These include a discussion of the selection of the model, derivation of initial parameter estimates and interpretation of the corresponding output. Finally, the authors discuss a number of pharmacodynamic modeling situations including receptor binding models, synergy, and tolerance models (feedback and precursor models). This book will be of interest to researchers, to graduate students and advanced undergraduate students in the PK/PD area who wish to learn how to analyze biological data and build models and to become familiar with new areas of application. In addition, the text will be of interest to toxicologists interested in learning about determinants of exposure and performing toxicokinetic modeling. The inclusion of the numerous exercises and models makes it an excellent primary or adjutant text for traditional PK courses taught in pharmacy and medical schools. A diskette is included with the text that includes all of the exercises and solutions using WinNonlin.

Basic Pharmacokinetics and Pharmacodynamics - Sara E. Rosenbaum 2016-11-22

Updated with new chapters and topics, this book provides a comprehensive description of all essential topics in contemporary pharmacokinetics and pharmacodynamics. It also features interactive computer simulations for students to experiment and observe PK/PD models in action. • Presents the essentials of pharmacokinetics and pharmacodynamics in a clear and progressive manner • Helps students better appreciate important concepts and gain a greater understanding of the mechanism of action of drugs by reinforcing practical applications in both the book and the computer modules • Features interactive computer simulations, available online through a companion website at: https://web.uri.edu/pharmacy/research/rosenbaum/sims/ • Adds new chapters on physiologically based pharmacokinetic models, predicting drug-drug interactions, and pharmacogenetics while also strengthening original chapters to better prepare students for more advanced applications • Reviews of the 1st edition: “This is an ideal textbook for those starting out … and also for use as a reference book …." (International Society for the Study of Xenobiotics) and “I could recommend Rosenbaum’s book for pharmacology students because it is written from a perspective of drug action . . . Overall, this is a well-written introduction to PK/PD …. “ (British Toxicology Society Newsletter)

Inhaled Medicines - Stavros Kassinos 2021-02-05

Inhaled medicines are widely used to treat pulmonary and systemic diseases. The efficacy and safety of these medicines can be influenced by the deposited fraction, the regional deposition pattern within the lungs and by post-depositional events such as drug dissolution, absorption and clearance from the lungs. Optimizing performance of treatments thus requires that we understand and are able to quantify these product and drug attributes. Inhaled Medicines: Optimizing Development through Integration of In Silico, In Vitro and In Vivo Approaches explores the current state of the art with respect to inhalation drug delivery, technologies available to assess product performance, and novel in silico methods now available to link in vitro product performance to clinical performance. Recent developments in the latter field, especially the prospect of integration of three-dimensional Computational Fluid Particle Methods (3D-CFPD) with physiologically based pharmacokinetic (PBPK models), unlocks the potential for in silico population studies that can help inform and optimize treatment and product development strategies. In this highly multidisciplinary field, where progress occurs at the intersection of several disciplines of engineering and science, this work aims to integrate current knowledge and understanding and to articulate a clear vision for future developments. ? Considers the healthcare needs driving the field, and where inhaled drugs could have the maximum impact ? Gives a concise account of the state of the art in key areas and technologies such as device and formulation technologies, clinically relevant in vitro performance assessment, medical imaging, as well as in silico modelling and simulation ? Articulates how the combination of in vitro product performance data, medical imaging and simulations technologies in the framework of large scale in silico pre-clinical trials could revolutionize the field ? Provides systematic and thorough referencing to sources offering a more-in-depth analysis of technical issues

Basic Pharmacokinetics and Pharmacodynamics - Sara E. Rosenbaum 2016-11-28

Updated with new chapters and topics, this book provides a comprehensive description of all essential topics in contemporary pharmacokinetics and pharmacodynamics. It also features interactive computer simulations for students to experiment and observe PK/PD models in action. • Presents the essentials of pharmacokinetics and pharmacodynamics in a clear and progressive manner • Helps students better appreciate important concepts and gain a greater understanding of the mechanism of action of drugs by reinforcing practical applications in both the book and the computer modules • Features interactive computer simulations, available online through a companion website at: https://web.uri.edu/pharmacy/research/rosenbaum/sims/ • Adds new chapters on physiologically based pharmacokinetic models, predicting

drug-drug interactions, and pharmacogenetics while also strengthening original chapters to better prepare students for more advanced applications • Reviews of the 1st edition: “This is an ideal textbook for those starting out ... and also for use as a reference book ...." (International Society for the Study of Xenobiotics) and “I could recommend Rosenbaum’s book for pharmacology students because it is written from a perspective of drug action . . . Overall, this is a well-written introduction to PK/PD .... “ (British Toxicology Society Newsletter)

Chemical Mixtures and Combined Chemical and Nonchemical Stressors - Cynthia V. Rider 2018-02-16

In this book, both basic and advanced concepts are discussed for considering mixtures from initial exposure characterization through evaluation of risk associated with combined exposures. This book will provide an introduction to key issues and multiple options for evaluating both the toxicity of mixtures as well as the risk associated with exposure to mixtures. Additionally, promising tools adapted from other disciplines will be discussed in the context of mixtures toxicology and risk assessment. Finally, the discussion will move beyond chemical mixtures to address incorporating non-chemical stressors into toxicity studies and cumulative risk assessments. Although exposure to multiple chemical and non-chemical stressors is the rule, not the exception, consideration of mixtures in toxicology and risk assessment continues to be a significant challenge. This book will be an essential resource for researchers and professionals in the fields of toxicology, epidemiology, exposure science, risk assessment, and statistics.

Dynamic Systems Biology Modeling and Simulation - Joseph DiStefano III 2015-01-10

Dynamic Systems Biology Modeling and Simuation consolidates and unifies classical and contemporary multiscale methodologies for mathematical modeling and computer simulation of dynamic biological systems – from molecular/cellular, organ-system, on up to population levels. The book pedagogy is developed as a well-annotated, systematic tutorial – with clearly spelled-out and unified nomenclature – derived from the author’s own modeling efforts, publications and teaching over half a century. Ambiguities in some concepts and tools are clarified and others are rendered more accessible and practical. The latter include novel qualitative theory and methodologies for recognizing dynamical signatures in data using structural (multicompartmental and network) models and graph theory; and analyzing structural and measurement (data) models for quantification feasibility. The level is basic-to-intermediate, with much emphasis on biomodeling from real biodata, for use in real applications. Introductory coverage of core mathematical concepts such as linear and nonlinear differential and difference equations, Laplace transforms, linear algebra, probability, statistics and stochastics topics; PLUS ..... The pertinent biology, biochemistry, biophysics or pharmacology for modeling are provided, to support understanding the amalgam of “math modeling” with life sciences. Strong emphasis on quantifying as well as building and analyzing biomodels: includes methodology and computational tools for parameter identifiability and sensitivity analysis; parameter estimation from real data; model distinguishability and simplification; and practical bioexperiment design and optimization. Companion website provides solutions and program code for examples and exercises using Matlab, Simulink, VisSim, SimBiology, SAAMII, AMIGO, Copasi and SBML-coded models. A full set of PowerPoint slides are available from the author for teaching from his textbook. He uses them to teach a 10 week quarter upper division course at UCLA, which meets twice a week, so there are 20 lectures. They can easily be augmented or stretched for a 15 week semester course. Importantly, the slides are editable, so they can be readily adapted to a lecturer’s personal style and course content needs. The lectures are based on excerpts from 12 of the first 13 chapters of DSBMS. They are designed to highlight the key course material, as a study guide and structure for students following the full text content. The complete PowerPoint slide package (~25 MB) can be obtained by instructors (or prospective instructors) by emailing the author directly, at: joed@cs.ucla.edu

Physiologically Based Pharmacokinetic (PBPK) Modeling - Jeffrey W.

Fisher 2020-05-20
Physiologically Based Pharmacokinetic (PBPK) Modeling: Methods and Applications in Toxicology and Risk Assessment presents foundational principles, advanced techniques and applications of PBPK modeling. Contributions from experts in PBPK modeling cover topics such as pharmacokinetic principles, classical physiological models, the application of physiological models for dose-response and risk assessment, the use of in vitro information, and in silico methods. With end-of-chapter exercises that allow readers to practice and learn the skills associated with PBPK modeling, dose-response, and its applications to safety and risk assessments, this book is a foundational resource that provides practical coverage of PBPK modeling for graduate students, academics, researchers, and more. Provides end-of-chapter exercises to teach hands-on computational tools used in toxicology Supplies computer code and explanations and includes examples of applied models used in regulatory toxicology and research Authored by expert editors and contributors who are among the best PBPK modelers in the world

Textbook of Aging Skin - Miranda A. Farage 2009-12-02
This comprehensive 'Major Reference Book' compiles all current and latest information on aging skin in a two-volume set. Highly structured with a reader-friendly format, it covers a wide range of areas such as basic sciences, the different diseases and conditions which occur with aging (from malignant to non-malignant), the latest techniques and methods being used such as bioengineering methods and biometrics as well as toxicological and safety considerations for the elderly population. It also illustrates the global consumers' sociological and psychological implications, ethnicity and gender differences and includes marketing considerations for this elderly group. This unique and comprehensive guide will become the main reference textbook on this topic.

Guidance for National Tuberculosis Programmes on the Management of Tuberculosis in Children - Who Global Tb Programme 2015-02-05
It is estimated that one third of the world's population is infected with Mycobacterium tuberculosis (the bacterium that causes tuberculosis (TB)), and that each year, about 9 million people develop TB, of whom about 2 million die. Of the 9 million annual TB cases, about 1 million (11%) occur in children (under 15 years of age). Of these childhood cases, 75% occur annually in 22 high-burden countries that together account for 80% of the world's estimated incident cases. In countries worldwide, the reported percentage of all TB cases occurring in children varies from 3% to more than 25%. The Stop TB Strategy, which builds on the DOTS strategy developed by the World Health Organization (WHO) and the International Union Against TB and Lung Disease, has a critical role in reducing the worldwide burden of disease and thus in protecting children from infection and disease. The management of children with TB should be in line with the Stop TB Strategy, taking into consideration the particular epidemiology and clinical presentation of TB in children. These consensus guidelines were produced to help the National Tuberculosis Programmes on the management of tuberculosis in children.

Systems Pharmacology and Pharmacodynamics - Donald E. Mager 2016-11-29
While systems biology and pharmacodynamics have evolved in parallel, there are significant interrelationships that can enhance drug discovery and enable optimized therapy for each patient. Systems pharmacology is the relatively new discipline that is the interface between these two methods. This book is the first to cover the expertise from systems biology and pharmacodynamics researchers, describing how systems pharmacology may be developed and refined further to show practical applications in drug development. There is a growing awareness that pharmaceutical companies should reduce the high attrition in the pipeline due to insufficient efficacy or toxicity found in proof-of-concept and/or Phase II studies. Systems Pharmacology and Pharmacodynamics discusses the framework for integrating information obtained from understanding physiological/pathological pathways (normal body function system vs. perturbed system due to disease) and pharmacological targets in order to predict clinical efficacy and adverse events through iterations between mathematical modeling and experimentation.

Toxicological Profile for Methylene Chloride - 1998

Ecotoxicology Modeling - James Devillers 2009-08-07
Ecotoxicology Modeling is a comprehensive and well-documented text providing a collection of computational methods to the ecotoxicologists primarily interested in the study of the adverse effects of chemicals, their mechanisms of action and/or their environmental fate and behavior. Avoiding mathematical jargon, the book presents numerous case studies to enable the reader to understand the interest but also the limitations of linear and nonlinear models in ecotoxicology. Written by an international team of scientists, Ecotoxicology Modeling is of primary interest to those whose research or professional activity is directly concerned with the development and application of models in ecotoxicology. It is also intended to provide the graduate and post-graduate students with a clear and accessible text covering the main types of modeling approaches used in environmental sciences.

Drug-Drug Interactions - A. David Rodrigues 2019-01-03
Authored by renowned leaders in the field, this comprehensive volume covers all aspects of drug-drug interactions, including preclinical, clinical, toxicological, and regulatory perspectives.Thoroughly updated, this second edition reflects the significant advances and includes extensive new material on:key interplay between transporters and enzymes

Cardiac Output and Regional Flow in Health and Disease - A-M. Salmasi 1993
Cardiac output has always been a subject of interest to both clinicians and researchers in different branches of medicine and surgery. In the last decade more attention has also been paid to its application in pediatrics, neonatology, fetal medicine and pregnancy. Better understanding of the peripheral circulation has provided more insight into the pathophysiology of different diseases. Many cardiac and non-cardiac disorders affect cardiac outputs. Monitoring of the changes in cardiac output is also important in the acutely ill patient. There are several methods to measure cardiac output, each with advantages and pitfalls. This book deals with all relevant aspects of cardiac output in eight parts: part one describes the methods of measuring cardiac output and a comparison between the catheterisation based and the noninvasive techniques, while part two describes the changes in cardiac output due to physiological causes. Part three describes cardiac output in cardiac diseases and systemic hypertension. Cardiac output in acutely ill patients is discussed in part four. Effect of cardiac medications, temporary atrial pacing, permanent pacing, pharmacologic stress testing and anesthesia are covered in detail in part six, while changes in cardiac output in noncardiac diseases are described in part seven. Finally great attention has been paid in part eight to the regional circulation including cerebral, coronary, skeletal and splanchnic circulations. A separate chapter discusses in detail the dynamics of blood flow. This book will be useful both to the cardiologists as well as to physicians in other fields of surgery and medicine and to their trainees. Readers will find this book an interesting and a useful reference on the topic of cardiac output.

Monte Carlo Simulation for the Pharmaceutical Industry - Mark Chang 2010-09-29
Helping you become a creative, logical thinker and skillful "simulator," Monte Carlo Simulation for the Pharmaceutical Industry: Concepts, Algorithms, and Case Studies provides broad coverage of the entire drug development process, from drug discovery to preclinical and clinical trial aspects to commercialization. It presents the theories and methods needed to carry out computer simulations efficiently, covers both descriptive and pseudocode algorithms that provide the basis for implementation of the simulation methods, and illustrates real-world problems through case studies. The text first emphasizes the importance of analogy and simulation using examples from a variety of areas, before introducing general sampling methods and the different stages of drug development. It then focuses on simulation approaches based on game theory and the Markov decision process, simulations in classical and adaptive trials, and various challenges in clinical trial management and execution. The author goes on to cover prescription drug marketing strategies and brand planning, molecular design and simulation, computational systems biology and biological pathway simulation with Petri nets, and physiologically based pharmacokinetic modeling and

pharmacodynamic models. The final chapter explores Monte Carlo computing techniques for statistical inference. This book offers a systematic treatment of computer simulation in drug development. It not only deals with the principles and methods of Monte Carlo simulation, but also the applications in drug development, such as statistical trial monitoring, prescription drug marketing, and molecular docking.

Pharmacokinetic-Pharmacodynamic Modeling and Simulation - Peter L. Bonate 2011-07-01

This is a second edition to the original published by Springer in 2006. The comprehensive volume takes a textbook approach systematically developing the field by starting from linear models and then moving up to generalized linear and non-linear mixed effects models. Since the first edition was published the field has grown considerably in terms of maturity and technicality. The second edition of the book therefore considerably expands with the addition of three new chapters relating to Bayesian models, Generalized linear and nonlinear mixed effects models, and Principles of simulation. In addition, many of the other chapters have been expanded and updated.

In Vitro-In Vivo Correlations - David B. Young 2013-03-08

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

Introduction to Population Pharmacokinetic / Pharmacodynamic Analysis with Nonlinear Mixed Effects Models - Joel S. Owen 2014-06-19

This book provides a user-friendly, hands-on introduction to theNonlinear Mixed Effects Modeling (NONMEM) system, the most powerfultool for pharmacokinetic / pharmacodynamic analysis. • Introduces requisite background to using NonlinearMixed Effects Modeling (NONMEM), covering data requirements, modelbuilding and evaluation, and quality control aspects • Provides examples of nonlinear modeling concepts andestimation basics with discussion on the model buildingprocess and applications of empirical Bayesian estimates in thedrug development environment • Includes detailed chapters on data set structure,developing control streams for modeling and simulation, modelapplications, interpretation of NONMEM output and results, andquality control • Has datasets, programming code, and practice exerciseswith solutions, available on a supplementary website

Oral Drug Absorption - Jennifer B. Dressman 2016-04-19

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

Comparative Pharmacokinetics - Jim E. Riviere 2011-01-14

Now in a revised edition, Comparative Pharmacokinetics: Principles, Techniques, and Applications presents the principles and techniques of comparative and veterinary pharmacokinetics in a detailed yet practical

manner. Developed as a tool for ensuring that pharmacokinetics studies are properly designed and correctly interpreted, the book provides complete coverage of the conceptual basis of pharmacokinetics as used for quantifying biological processes from the perspectives of physiology and medicine. New chapters have been added on quantitative structure permeability relationships and bioequivalence, and a number of existing chapters have been significantly revised and expanded to provide a current resource for veterinary and comparative pharmacokinetics.

Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations - Sheila Annie Peters 2021-09-30

Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations The first book dedicated to the emerging field of physiologically based pharmacokinetic modeling (PBPK) Now in its second edition, Physiologically Based Pharmacokinetic (PBPK) Modelling and Simulations: Principles, Methods, and Applications in the Pharma Industry remains the premier reference book throughout the rapidly growing PBPK user community. Using clear and concise language, author Sheila Annie Peters connects theory with practice as she explores the vast potential of PBPK modeling for improving drug discovery and development. This fully updated new edition covers key developments in the field of PBPK modelling and simulations that have emerged in recent years. A brand-new section provides case studies in different application areas of PBPK modelling, including drug-drug interaction, genetic polymorphism, renal impairment, and pediatric extrapolation. Additional chapters address topics such as model-informed drug development (MIDD) and expose readers to a wide range of current applications in the field. Throughout the book, substantially revised chapters simplify complex topics and offer a balanced view of both the opportunities and challenges of PBPK modelling. Providing timely and comprehensive coverage of one of the most exciting new areas of pharmaceutical science, this book: Describes the principles behind physiological modeling of pharmacokinetic processes, inter-individual variability, and drug interactions for small molecule drugs and biologics Features a wealth of new figures and case studies of the applications of PBPK modelling along the value chain in drug discovery and development Reflects the latest regulatory guidelines on the reporting of PBPK modelling analysis Includes access to a new companion website containing code, datasets, explanations of case examples in the text, and discussion of key developments in the field Contains a brief overview of the field, end-of-chapter keywords for easy reference, and an extensive bibliography Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industry, Second Edition is an indispensable single-volume resource for beginning and intermediate practitioners across the pharmaceutical sciences in both industry and academia.

Clinical Challenges in Therapeutic Drug Monitoring - William Clarke 2016-07-21

Clinical Challenges in Therapeutic Drug Monitoring: Special Populations, Physiological Conditions and Pharmacogenomics focuses on critical issues in therapeutic drug monitoring including special requirements of therapeutic drug monitoring important to special populations (infants and children, pregnant women, elderly patients, and obese patients). The book also covers issues of free drug monitoring and common interferences in using immunoassays for therapeutic drug monitoring. This book is essential reading for any clinician, fellow, or trainee who wants to gain greater insight into the process of therapeutic drug monitoring for individual dosage adjustment and avoiding drug toxicity for certain drugs within a narrow therapeutic window. The book is written specifically for busy clinicians, fellows, and trainees who order therapeutic drug monitoring and need to get more familiar with testing methodologies, issues of interferences, and interpretation of results in certain patient populations. Offers busy clinicians, pathologists, and trainees a concise resource on the key aspects and critical issues in therapeutic drug monitoring Focuses on patient populations such as infants and children, pregnant women, elderly patients, and obese patients, who have special requirements in therapeutic drug monitoring Explores special topics in therapeutic drug monitoring including free drug monitoring and common immunoassay interference Explains how

individual dosage adjustments can prevent drug toxicity for certain drugs within a narrow therapeutic window

Physiologically Based Pharmacokinetic Modeling - Micaela Reddy 2005-06-14

A definitive, single source of information on PBPK modeling Physiologically-based pharmacokinetic (PBPK) modeling is becomingincreasingly important in human health risk assessments and insupporting pharmacodynamic modeling for toxic responses. Organizedby classes of compounds and modeling purposes so users can quicklyaccess information, this is the first comprehensive reference ofits kind. This book presents an overview of the underlying principles of PBPKmodel development. Then it provides a compendium of PBPK modelinginformation, including historical development, specific modelingchallenges, and current practices for: * Halogenated Alkanes * Halogenated Alkenes * Alkene and Aromatic Compounds * Reactive Vapors in the Nasal Cavity * Alkanes, Oxyhydrocarbons, and Related Compounds * Pesticides and Persistent Organic Pollutants * Dioxin and Related Compounds * Metals and Inorganic Compounds * Drugs * Antineoplastic Agents * Perinatal Transfer * Mixtures * Dermal Exposure Models In addition to pinpointing specific information, readers canexplore diverse modeling techniques and applications. Anauthoritative reference for toxicologists, ecotoxicologists, riskassessors, regulators, pharmacologists, pharmacists, and graduatestudents in pharmacokinetics and toxicology, Physiologically-BasedPharmacokinetic Modeling compiles information from leaders in thefield and discusses future directions for PBPK modeling.

Pharmacokinetics of Drugs - Peter G. Welling 2012-12-06

A compilation of researchers' experience in the areas of bioanalysis, pharmacokinetics, and drug metabolism, to present an up-to-date and comprehensive treatise on the application of these and related technologies in drug discovery, development, and clinical use. Contents cover descriptions of analytical methods, in vitro metabolism technology and membrane transport, reappraisal of classical pharmacokinetic problems, and the time course of drug action. The book concludes with a description of PET and imaging methods in pharmacokinetics and an appendix containing a critical appraisal of computer methods and pharmacokinetic software available for PCs.

Transporters and Drug-Metabolizing Enzymes in Drug Toxicity - Albert P. Li 2021-07-27

TRANSPORTERS AND DRUG-METABOLIZING ENZYMES IN DRUG TOXICITY Explore up-to-date coverage on the interaction between drug metabolism enzymes, transporters, and drug toxicity with this leading resources Transporters and Drug-Metabolizing Enzymes in Drug Toxicity delivers a comprehensive and updated review of the relationship between drug metabolism, transporters, and toxicity, providing insights into a major challenge in drug development – accurate assessment of human drug toxicity. Combining two disciplines frequently considered independently of one another, the book combines drug metabolism and toxicology with a focus on the role of biotransformation on drug toxicity and as a major factor for species and individual differences. Mechanism and species differences in drug metabolizing enzymes and transporters are discussed, as are the methods used to investigate the role of drug metabolizing enzymes and transporters in drug toxicity. Finally, the distinguished authors describe promising new experimental approaches to accurately assessing human drug toxicity via the consideration of human-specific drug metabolism in toxicity assays. In addition to topics as diverse as extended clearance models, experimental approaches for the estimation of DILI potential of drug candidates and roles of transporters in renal drug toxicity, readers will also enjoy the inclusion of such subjects as: A thorough overview of and introduction to drug metabolism and transporters and drug toxicity An exploration of drug metabolism enzymes and transporter activities as risk factors of marketed drugs associated with drug-induced fatalities A discussion of human-based in vitro experimental models for the evaluation of metabolism-dependent drug toxicity A treatment of mechanism-based experimental models for the evaluation of BSEP inhibition and DILI An examination of transporters and cochlea toxicity Perfect for scientists, students, and practitioners with interests in metabolism, toxicology, and

drug development in the pharmaceutical industry, Transporters and Drug-Metabolizing Enzymes in Drug Toxicity will also earn a place in the libraries of medicinal chemists, pharmacologists, biochemists, toxicologists, and regulators in the pharmaceutical and health industries.

Assessing the Human Health Risks of Trichloroethylene - National Research Council 2007-01-08

Trichloroethylene is a chlorinated solvent widely used as a degreasing agent in industrial and manufacturing settings. It is also used as a chemical intermediate in making other chemicals and is a component of products such as typewriter correction fluid, paint removers, adhesives, and spot removers. In 2001, EPA issued a draft health risk assessment and proposed exposure standards for trichloroethylene. PA's Scientific Advisory Board (SAB) reviewed the draft and it was issued for public comment. A number of scientific issues were raised during the course of these reviews. Assessing the Human Health Risks of Trichloroethylene identifies and assesses the key scientific issues relevant to analyzing the human health risks of trichloroethylene, considering pertinent toxicologic, epidemiologic, population susceptibility, and other available information, including relevant published scientific literature, EPA's 2001 draft health risk assessment of trichloroethylene, scientific and technical comments received by EPA from public and private sources, and additional relevant information to be provided by the sponsoring agencies. This report highlights issues critical to the development of an objective, realistic, and scientifically balanced trichloroethylene health risk assessment. Guidance for hazard characterization of trichloroethylene is presented in Chapters 2 through 10. Chapter 2 provides guidance for evaluating large sets of epidemiologic data. In Chapter 3, the committee applies this guidance as an example in its evaluation of the epidemiologic data on trichloroethylene and kidney cancer, and this example should help guide evaluations of other cancer risks. Chapter 3 also assesses new information on the kidney toxicity of trichloroethylene and its metabolites and potential modes of action. Chapters 4, 5, 6, 7, and 8 evaluate the key issues regarding liver toxicity and cancer, reproductive and developmental toxicity, neurotoxicity, respiratory tract toxicity and cancer, and immunotoxicity, respectively. However, the committee's review focused on mode-of-action information to understand how trichloroethylene might affect certain processes differently in different species. Chapter 9 discusses susceptibility to trichloroethylene and its metabolites, and Chapter 10 describes important factors in considering trichloroethylene in mixtures. Physiologically based pharmacokinetic models are evaluated in Chapter 11, and guidance is provided on future directions for model development. Finally, Chapter 12 considers issues related to dose-response assessment and quantitative assessment of risk.

Principles of Characterizing and Applying Human Exposure Models - International Program on Chemical Safety 2005

The objective of this manual is to provide guidance to risk assessors on the use of quantitative toxicokinetic and toxicodynamic data to address interspecies and interindividual differences in dose and concentration-response assessment. Section 1 focuses on the relevance of this guidance in the context of the broader risk assessment paradigm and other initiatives of the International Program on Chemical Safety (IPCS) project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals. Technical background material is presented in section 2, followed by generic guidance for the development of chemical-specific adjustment factors in section 3 and accompanying summary figures. Illustrative case-studies are included in an Appendix, and a glossary of terms is also provided.--Publisher's description.

New Insights into Toxicity and Drug Testing - Sivakumar Joghi Thatha Gowder 2013-01-23

This book "New Insights into Toxicity and Drug Testing" covers all emerging technologies (profiling technologies, 3D cultures, next generation sequencing etc.), available methods and models to evaluate candidate drugs and medicinal plants with reference to toxicity, drug testing and development. This book is an original contribution of experts from different parts of the globe and the in-depth information will be a significant resource for scientists and physicians who are directly dealing with drugs / medicines and human life.

Drug Transporters - Martin F. Fromm 2010-11-19
It is increasingly recognized that various transporter proteins are expressed throughout the body and determine absorption, tissue distribution, biliary and renal elimination of endogenous compounds and drugs and drug effects. This book will give an overview on the transporter families which are most important for drug therapy. Most chapters will focus on one transporter family highlighting tissue expression, substrates, inhibitors, knock-out mouse models and clinical studies.
Drug Delivery with Targeted Nanoparticles - Yılmaz Çapan 2021-11-30
Nanotechnology has the potential to change every part of our lives. Today, nanotechnology-based products are used in many areas, and one of the most important areas is drug delivery. Nanoparticulate drug delivery systems not only provide controlled delivery of drugs and improved drug solubility but also improve drug efficiency and reduce side effects via targeting mechanisms. However, compared with conventional drug delivery systems, few nanoparticle-based products are on the market and almost all are nontargeted or only passively targeted systems. In addition, obtaining targeted nanoparticle systems is quite complex and requires several evaluation mechanisms. This book discusses the production, characterization, regulation, and currently marketed targeted nanoparticle systems in a broad framework. It provides an overview of targeted nanoparticles' (i) in vitro characterization, such as particle size, stability, ligand density, and type; (ii) in vivo behavior for different targeting areas, such as tumor, brain, and vagina; and (iii) current advances in this field, including clinical trials and regulation processes.
HIV and Aging - M. Brennan-Ing 2016-11-22
Despite decades of attention on building a global HIV research and programming agenda, HIV in older populations has generally been neglected until recently. This new book focuses on HIV and aging in the context of ageism with regard to prevention, treatment guidelines, funding, and the engagement of communities and health and social service organizations. The lack of perceived HIV risk in late adulthood among older people themselves, as well on the part of providers and society in general, has led to a lack of investment in education, testing, and programmatic responses. Ageism perpetuates the invisibility of older adults and, in turn, renders current medical and social service systems unprepared to respond to patients' needs. While ageism may lead to some advantages – discounts for services, for example – it is the negative aspects that must be addressed when determining the appropriate community-level response to the epidemic.
Human Biomonitoring for Environmental Chemicals - National Research Council 2006-10-30
Biomonitoring—a method for measuring amounts of toxic chemicals in human tissues—is a valuable tool for studying potentially harmful environmental chemicals. Biomonitoring data have been used to confirm exposures to chemicals and validate public health policies. For example, population biomonitoring data showing high blood lead concentrations resulted in the U.S. Environmental Protection Agency's (EPA's) regulatory reduction of lead in gasoline; biomonitoring data confirmed a resultant drop in blood lead concentrations. Despite recent advances, the science needed to understand the implications of the biomonitoring data for human health is still in its nascent stages. Use of the data also raises communication and ethical challenges. In response to a congressional request, EPA asked the National Research Council to address those challenges in an independent study. Human Biomonitoring for Environmental Chemicals provides a framework for improving the use of biomonitoring data including developing and using biomarkers (measures of exposure), research to improve the interpretation of data, ways to communicate findings to the public, and a review of ethical issues.
Personalized Anaesthesia - Pedro L. Gambús 2020-02-06
Presents a modern vision of anaesthesia, integrating technology and knowledge, to change how anaesthesia is taught and practised.
Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations - Sheila Annie Peters 2012-02-17
The only book dedicated to physiologically-based

pharmacokineticmodeling in pharmaceutical science Physiologically-based pharmacokinetic (PBPK) modeling has becomeincreasingly widespread within the pharmaceutical industry over thelast decade, but without one dedicated book that provides theinformation researchers need to learn these new techniques, itsapplications are severely limited. Describing the principles,methods, and applications of PBPK modeling as used inpharmaceutics, Physiologically-Based Pharmacokinetic (PBPK)Modeling and Simulations fills this void. Connecting theory with practice, the book explores theincredible potential of PBPK modeling for improving drug discoveryand development. Comprised of two parts, the book first provides adetailed and systematic treatment of the principles behindphysiological modeling of pharmacokinetic processes,inter-individual variability, and drug interactions for smallmolecule drugs and biologics. The second part looks in greaterdetail at the powerful applications of PBPK to drug research. Designed for a wide audience encompassing readers looking for abrief overview of the field as well as those who need more detail,the book includes a range of important learning aids. Featuringend-of-chapter keywords for easy reference—a valuable assetfor general or novice readers without a PBPK background—alongwith an extensive bibliography for those looking for furtherinformation, Physiologically- Based Pharmacokinetic (PBPK) Modelingand Simulations is the essential single-volume text on one of thehottest topics in the pharmaceutical sciences today.

Biopharmaceutics - Hannah Batchelor 2021-12-13

Explore the latest research in biopharmaceutics from leading contributors in the field In Biopharmaceutics - From Fundamentals to Industrial Practice, distinguished Scientists from the UK's Academy of Pharmaceutical Sciences Biopharmaceutica Focus Group deliver a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development. This edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves. Beginning with an expansive introduction to the basics of biopharmaceutics and the context that underpins the field, the included resources go on to discuss how biopharmaceutics are integrated into product development within the pharmaceutical industry. Explorations of how the regulatory aspects of biopharmaceutics function, as well as the impact of physiology and anatomy on the rate and extent of drug absorption, follow. Readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations. The book goes on to discuss: Thorough introductions to biopharmaceutics, basic pharmacokinetics, and biopharmaceutics measures Comprehensive explorations of solubility, permeability, and dissolution Practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization, as well as biopharmaceutics tools for rational formulation design In-depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics, as well as regulatory biopharmaceutics and the impact of anatomy and physiology Perfect for professionals working in the pharmaceutical and biopharmaceutical industries, Biopharmaceutics - From Fundamentals to Industrial Practice is an incisive and up-to-date resource on the practical, pharmaceutical applications of the field.

Absorption and Drug Development - Alex Avdeef 2003-09-19

Many times drugs work fine when tested outside the body, but when they are tested in the body they fail. One of the major reasons a drug fails is that it cannot be absorb by the body in a way to have the effect it was intended to have. Permeability, Solubility, Dissolution, and Charged State of Ionizable Molecules: Helps drug discovery professionals to eliminate poorly absorbable molecules early in the drug discovery process, which can save drug companies millions of dollars. Extensive tabulations, in appendix format, of properties and structures of about 200 standard drug molecules.

Cytochrome P450 2E1: Its Role in Disease and Drug Metabolism - Aparajita Dey 2013-02-12

The book deals with various clinical aspects of cytochrome P450 2E1 (CYP2E1) which is a potent source for oxidative stress. Oxidative stress is critical for pathogenesis of diseases and CYP2E1 is a major contributor

for oxidative stress. Several clinical disorders are associated with changes in regulation of CYP2E1 and the consequent abnormalities which include alcoholic liver disease, alcoholic pancreatitis, carcinogenesis, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, obesity, hepatitis C virus infection, reproductive organ toxicity, hepatocellular and cholestatic liver cirrhosis, inhibition of bone repair, cross-tolerance in smokers and people treated with nicotine, disorders of central nervous system, changes in metabolism of protoxicants in the circulatory system and susceptibility to human papillomavirus infection. Hence, CYP2E1 emerges as a new and potent player in aggravating injury and furthering disease complications.