A Practical To Drug Development In Academia The Spark Approach

Transporters in Drug Discovery and Development
A Comprehensive Guide to Toxicology in Nonclinical Drug Development
The Science and Practice of Ethnobridging
From Fundamentals to Output
Pharmaceutical Preformulation and Formulation
Drug Metabolism in Drug Design and Development
The Practice of Medicinal Chemistry
Design of Hybrid Molecules for Drug Development
The Nonhuman Primate in Nonclinical Drug Development and Safety Assessment
Technology in Transition
Bioequivalence Studies in Drug Development
A Practical Guide to Drug Development in Academia
Artificial Intelligence for Drug Development, Precision Medicine, and Healthcare
Adventures in Medicinal Chemistry
Principles and Practice of Pharmaceutical Medicine
Concepts, Algorithms, and Case Studies
The Future of Pharmaceutical Product Development and Research
New Drug Development
Pharmaceutical Toxicology in Practice
Medicinal Chemistry 2.0
Basic Concepts and Practice
Detailed Concepts and Best Practice
Chemical Sciences in Early Drug Discovery
Workshop Summary
The SPARK Approach
The Ups and Downs in Drug Design
Radiotracers in Drug Development
Drug Discovery in Cancer Epigenetics
Improving and Accelerating Therapeutic Development for Nervous System Disorders
A Guide to Non-clinical Development
Principles of Anticancer Drug Development
Biomarkers in Drug Development
Design, Methodology, and Analysis
Methods and Applications
Real-World Evidence in Drug Development and Evaluation
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Bayesian Analysis with R for Drug Development
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Basic Principles of Drug Discovery and Development

GAVIN RAMOS

Transporters in Drug Discovery and Development Elsevier Although there are numerous books on drug metabolism, Radiotracers in Drug Development is unique in explaining how radiotracers are used to elucidate a drug's absorption, distribution, metabolism, and excretion (ADME). Covering traditional and recent technologies and applications, the book takes a strong industrial approach, discussing the b

A Comprehensive Guide to Toxicology in Nonclinical Drug Development CRC Press The long awaited second edition of Principles and Practice of Pharmaceutical Medicine provides an invaluable guide to all areas of drug development and medical aspects of marketing. The title has been extensively revised and expanded to include the latest regulatory and scientific developments. New chapters include: European Regulations Ethics of Pharmaceutical Medicine Licensing and Due Diligence Pharmacogenomics Encompassing the entire spectrum of pharmaceutical medicine, it is the most up-to-date international guide currently available. Review of the first edition: “This book was a joy to read and a joy to review. All pharmaceutical physicians should have a copy on their bookshelves, all pharmaceutical companies should have copies in their libraries.” —BRITISH ASSOCIATION OF PHARMACEUTICAL PHYSICIANS

The Science and Practice of Ethnobridging CRC Press The essentials of drug metabolism vital to developing new therapeutic entities Information on the metabolism and disposition of candidate drugs is a critical part of all aspects of the drug discovery and development process. Drug metabolism, as practiced in the pharmaceutical industry today, is a complex, multidisciplinary field that requires knowledge of sophisticated analytical technologies and expertise in mechanistic and kinetic enzymology, organic reaction mechanism, pharmacokinetic analysis, animal physiology, basic chemical toxicology, preclinical pharmacology, and molecular biology. With chapters contributed by experts in their specific areas, this reference covers: * Basic concepts of drug metabolism * The role of drug metabolism in the pharmaceutical industry * Analytical techniques in drug metabolism * Common experimental approaches and protocols Drug Metabolism in Drug Design and Development emphasizes practical considerations such as the data needed, the experiments and analytical methods typically employed, and the interpretation and application of data. Chapters highlight facts, common protocols, detailed experimental designs, applications, and limitations of techniques. This is a comprehensive, hands-on reference for drug metabolism researchers as well as other professionals involved in pre-clinical drug discovery and development.

From Fundamentals to Output Springer Science & Business Media Drug development is an

iterative process. The recent publications of regulatory guidelines further entail a lifecycle approach. Blending data from disparate sources, the Bayesian approach provides a flexible framework for drug development. Despite its advantages, the uptake of Bayesian methodologies is lagging behind in the field of pharmaceutical development. Written specifically for pharmaceutical practitioners, Bayesian Analysis with R for Drug Development: Concepts, Algorithms, and Case Studies, describes a wide range of Bayesian applications to problems throughout pre-clinical, clinical, and Chemistry, Manufacturing, and Control (CMC) development. Authored by two seasoned statisticians in the pharmaceutical industry, the book provides detailed Bayesian solutions to a broad array of pharmaceutical problems. Features Provides a single source of information on Bayesian statistics for drug development Covers a wide spectrum of pre-clinical, clinical, and CMC topics Demonstrates proper Bayesian applications using real-life examples Includes easy-to-follow R code with Bayesian Markov Chain Monte Carlo performed in both JAGS and Stan Bayesian software platforms Offers sufficient background for each problem and detailed description of solutions suitable for practitioners with limited Bayesian knowledge Harry Yang, Ph.D., is Senior Director and Head of Statistical Sciences at AstraZeneca. He has 24 years of experience across all aspects of drug research and development and extensive global regulatory experiences. He has published 6 statistical books, 15 book chapters, and over 90 peer-reviewed papers on diverse scientific and statistical subjects, including 15 joint statistical works with Dr. Novick. He is a frequent invited speaker at national and international conferences. He also developed statistical courses and conducted training at the FDA and USP as well as Peking University. Steven Novick, Ph.D., is Director of Statistical Sciences at AstraZeneca. He has extensively contributed statistical methods to the biopharmaceutical literature. Novick is a skilled Bayesian computer programmer and is frequently invited to speak at conferences, having developed and taught courses in several areas, including drug-combination analysis and Bayesian methods in clinical areas. Novick served on IPAC-RS and has chaired several national statistical conferences.

Pharmaceutical Preformulation and Formulation John Wiley & Sons

A guide through the maze of the pharmaceutical research and development process, Medical Writing in Drug Development fills a gap in the libraries of technical writers, college instructors, and corporate professionals associated with the pharmaceutical process. As it discusses critical information, such as strategies and techniques pivotal to crafting documents for drug development, it also overviews drug research, document types, the roles of professional writers, and information technology. In no time at all, you will be creating persuasive technical documents, building complex facts into coherent messages, and contributing to the

effective marketing of new products with promotional pieces that meet legal and ethical standards. Medical Writing in Drug Development helps medical writers and scientific, regulatory, and marketing professionals develop a working knowledge of the technical documents crucial to successful drug research. New and seasoned professional writers alike will benefit from the book's detailed discussions of: using abstracts, slides, and posters to present up-to-the-minute research how patient-education materials, health-economic assessments, and electronic journals provide ongoing challenges in medical writing a dossier approach that expedites regulatory submissions for international drug development structural constraints and rhetorical approaches toward regulatory documents presenting intricate information in scientifically unbiased, yet technically convincing language the effects of electronic publishing, computer graphics, and related technology on the practice of medical writing within pharmaceutical research Practical as a foundation text for undergraduate, graduate, and certificate programs in pharmaceutical or medical technical writing, Medical Writing in Drug Development will help you develop practical strategies for handling journal manuscripts, conference materials, and promotional pieces. No other text will clarify the main aspects of the pharmaceutical research and development process while offering you insight on the key issues dominating the healthcare arena.

Drug Metabolism in Drug Design and Development

John Wiley & Sons

Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. Bioequivalence Studies in Drug Development focuses on the planning, conducting, analysing and reporting of bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. Reviews the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. Bioequivalence Studies in

Drug Development is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

The Practice of Medicinal Chemistry CRC Press

The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences, also highlighting key developments, research and future opportunities. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development. Each chapter covers fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and the pharmaceutical industry. The book focuses on excipients, radiopharmaceuticals, and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice (GMP) guidelines. Researchers and students will find this book to be a comprehensive resource for those working in, and studying, pharmaceuticals, cosmetics, biotechnology, foods and related industries. Provides an overview of practical information for clinical trials Outlines how to ensure an environment that follows Good Manufacturing Practice (GMP) Examines recent developments and suggests future directions for drug production methods and techniques

Design of Hybrid Molecules for Drug Development John Wiley & Sons

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.

The Nonhuman Primate in Nonclinical Drug Development and Safety Assessment CRC Press

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug

development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Technology in Transition

CRC Press

"A lot of hard-won knowledge is laid out here in a brief but informative way. Every topic is well referenced, with citations from both the primary literature and relevant resources from the internet." Review from Nature Chemical Biology Written by the founders of the SPARK program at Stanford University, this book is a practical guide designed for professors, students and clinicians at academic research institutions who are interested in learning more about the drug development process and how to help their discoveries become the novel drugs of the future. Often many potentially transformative basic science discoveries are not pursued because they are deemed ‘too early’ to attract industry interest. There are simple, relatively cost-effective things that academic researchers can do to advance their findings to the point that they can be tested in the clinic or attract more industry interest. Each chapter broadly discusses an important topic in drug development, from preclinical work in assay design through clinical trial design, regulatory issues and marketing assessments. After the practical overview provided here, the reader is encouraged to consult more detailed texts on specific topics of interest. "I would actually welcome it if this book’s intended audience were broadened even more. Younger scientists starting out in the drug industry would benefit from reading it and getting some early exposure to parts of the process that they’ll eventually have to understand. Journalists covering the industry (especially the small startup companies) will find this book a good reality check for many an over-hopeful press release. Even advanced investors who might want to know what really happens in the labs will find information here that might otherwise be difficult to track down in such a concentrated form."

Bioequivalence Studies in Drug Development

Woodhead Publishing

Theory of Drug Development presents a formal quantitative framework for understanding drug development that goes beyond simply describing the properties of the statistics in individual studies. It examines the drug development process from the perspectives of drug companies and regulatory agencies. By quantifying various ideas underlying drug development, the book shows how to systematically address

problems, such as: Sizing a phase 2 trial and choosing the range of p-values that will trigger a follow-up phase 3 trial Deciding whether a drug should receive marketing approval based on its phase 2/3 development program and recent experience with other drugs in the same clinical area Determining the impact of adaptive designs on the quality of drugs that receive marketing approval Designing a phase 3 pivotal study that permits the data-driven adjustment of the treatment effect estimate Knowing when enough information has been gathered to show that a drug improves the survival time for the whole patient population Drawing on his extensive work as a statistician in the pharmaceutical industry, the author focuses on the efficient development of drugs and the quantification of evidence in drug development. He provides a rationale for underpowered phase 2 trials based on the notion of efficiency, which leads to the identification of an admissible family of phase 2 designs. He also develops a framework for evaluating the strength of evidence generated by clinical trials. This approach is based on the ratio of power to type 1 error and transcends typical Bayesian and frequentist statistical analyses.

A Practical Guide to Drug Development in Academia John Wiley & Sons

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

Artificial Intelligence for Drug Development, Precision Medicine, and Healthcare John Wiley & Sons

Design of Hybrid Molecules for Drug Development reviews the principles, advantages, and limitations involved with designing these groundbreaking compounds. Beginning with an introduction to hybrid molecule design and background as to their need, the book goes on to explore a range of important hybrids, with hybrids containing natural products, molecules containing NO- and H2S-donors, dual-acting compounds acting as receptor ligands and enzyme inhibitors, and

the design of photoresponsive drugs all discussed. Drawing on practical case studies, the hybridization of molecules for development as treatments for a number of key diseases is then outlined, including the design of hybrids for Alzheimer's, cancer, and malaria. With its cutting-edge reviews of breaking developments in this exciting field, the book offers a novel approach for all those working in the design, development, and administration of drugs for a range of debilitating disorders. Highlights an approach unimpaired by the limitations of the classical search for lead structures - one of the core problems in modern drug development processes, making the content of high relevance for both academic and non-academic drug development processes Pulls together research and design techniques in a novel way to give researchers the best possible platform from which to review the approaches and techniques applied Compares the advantages and disadvantages of these compounds Includes the very latest developments, such as photoactivatable and photo-responsive drugs

Adventures in Medicinal Chemistry Academic Press

Real-world evidence (RWE) has been at the forefront of pharmaceutical innovations. It plays an important role in transforming drug development from a process aimed at meeting regulatory expectations to an operating model that leverages data from disparate sources to aid business, regulatory, and healthcare decision making. Despite its many benefits, there is no single book systematically covering the latest development in the field. Written specifically for pharmaceutical practitioners, Real-World Evidence in Drug Development and Evaluation, presents a wide range of RWE applications throughout the lifecycle of drug product development. With contributions from experienced researchers in the pharmaceutical industry, the book discusses at length RWE opportunities, challenges, and solutions. Features Provides the first book and a single source of information on RWE in drug development Covers a broad array of topics on outcomes- and value-based RWE assessments Demonstrates proper Bayesian application and causal inference for real-world data (RWD) Presents real-world use cases to illustrate the use of advanced analytics and statistical methods to generate insights Offers a balanced discussion of practical RWE issues at hand and technical solutions suitable for practitioners with limited data science expertise

Principles and Practice of Pharmaceutical Medicine CRC Press

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

Concepts, Algorithms, and Case Studies CRC Press

Preclinical Drug Development, Second Edition discusses the broad and complicated realm of preclinical drug development. Topics range from assessment of pharmacology and toxicology to industry trends and regulatory expectations to requirements that support clinical trials. Highlights of the Second Edition include: PharmacokineticsModeling and simula

The Future of Pharmaceutical Product Development and Research CRC Press

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.

New Drug Development Springer Science & Business Media

The Nonhuman Primate in Drug Development and Safety Assessment is a valuable reference dedicated to compiling the latest research on nonhuman primate models in nonclinical safety assessment, regulatory toxicity testing and translational science. By covering important topics such as study planning and conduct, inter-species genetic drift, pathophysiology, animal welfare legislation, safety assessment of biologics and small molecules, immunotoxicology and much more, this book provides scientific and technical insights to help you safely and successfully use nonhuman primates in pharmaceutical toxicity testing. A comprehensive yet practical guide, this book is intended for new researchers or practicing toxicologists, toxicologic pathologists and pharmaceutical scientists working with nonhuman primates, as well as graduate students preparing for careers in this area. Covers important topics such as species selection, study design, experimental methodologies, animal welfare and the 3Rs (Replace, Refine and Reduce), social housing, regulatory guidelines, comparative physiology, reproductive biology, genetic polymorphisms and more Includes practical examples on techniques and methods to guide your daily practice Offers a companion website with high-quality color illustrations, reference

values for safety assessment and additional practical information such as study design considerations, techniques and procedures and dosing and sampling volumes

Pharmaceutical Toxicology in Practice
CRC Press
This book offers policy makers a hands-on approach, tested in the World Bank's field work in many countries, for developing policies that improve access to safe, effective medicines in health systems of low- and middle-income economies.

Medicinal Chemistry 2.0
Elsevier
This book acquaints students and practitioners in the related fields of pharmaceutical sciences, clinical trials, and evidence-based medicine with the necessary study design concepts and statistical practices to allow them to understand how drug developers plan and evaluate their drug development. Two goals of the book are to make the material accessible to readers with minimal background in research and to be straightforward enough for self-taught purposes. By bringing the topic from the early discovery phase to clinical trials and medical practice, the book provides an indispensable overview of an otherwise confusing and fragmented set of topics. The author's experience as a respected scientist, teacher of statistics, and one who has worked in the clinical trials arena makes him well suited to write such a treatise.

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