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DRUG DISCOVERY AND EVALUATION: PHARMACOLOGICAL ASSAYS

Springer *The 4th edition of this successful reference book contains an updated selection of the most frequently used assays for reliably detecting the pharmacological effects of potential drugs. Effects covered include cardiovascular, analgesic, endocrine, psychotropic, respiratory, renal and immunomodulatory activities. Each of the more than 1,000 assays comprises a detailed protocol outlining the purpose and rationale of the method, a critical assessment of the results and their pharmacological and clinical relevance. In addition, animal models of rare diseases are described. For this 4th edition, all existing chapters have been revised and completely updated. A large number of assays were added. Sections that have been specifically enlarged include - Pharmacological assays in thrombosis and haemostasis, - Antidiabetic activity (includes completely new chapters such as Biochemical Methods in Diabetology), - Anti-atherosclerotic activity. New chapters are added such as Auditory Pharmacology, Oncology Activity, Stem Cells, Omics, Personalized Medicine, etc.*

DRUG DISCOVERY AND EVALUATION: METHODS IN CLINICAL PHARMACOLOGY

Springer Science & Business Media *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".

DRUG DISCOVERY AND EVALUATION

PHARMACOLOGICAL ASSAYS

Springer Science & Business Media *This reference book contains a comprehensive selection of the most frequently used assays for reliably detecting pharmacological effects of potential drugs, including tests for cardiovascular, analgesic, psychotropic, metabolic, endocrine, respiratory, renal, and immunomodulatory activities. Each of the over 700 assays comprises a detailed protocol with the purpose and rationale of the method, a description of the experimental procedure, a critical assessment of the results and their pharmacological and clinical relevance, and pertinent references. Identification of specific tests is facilitated by the enclosed CD-ROM which allows for a quick and full text research. An appendix with guidelines and legal regulations for animal experiments in various countries will help to plan these experiments properly in accordance with the welfare of laboratory animals.*

DRUG DISCOVERY AND EVALUATION

SAFETY AND PHARMACOKINETIC ASSAYS ; WITH 125 TABLES

Springer Science & Business Media *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.*

DRUG DISCOVERY AND EVALUATION

PHARMACOLOGICAL ASSAYS

Springer *Comprehensive reference on 700 of the most frequently used assays for reliably detecting pharmacological effects of potential drugs. For practitioners and students. Includes a full-text CD-ROM.*

DRUG DISCOVERY AND EVALUATION

PHARMACOLOGICAL ASSAYS

Springer

DRUG DISCOVERY AND EVALUATION: SAFETY AND PHARMACOKINETIC ASSAYS

Springer *-A landmark in the continuously changing world of drugs -Essential reading for scientists and managers in the pharmaceutical industry involved in drug finding, drug development and decision making in the development process -Of use for government institutions and committees working on official guidelines for drug evaluation worldwide*

DRUG DISCOVERY AND EVALUATION: METHODS IN CLINICAL PHARMACOLOGY

Springer *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".*

EVALUATION OF ENZYME INHIBITORS IN DRUG DISCOVERY

A GUIDE FOR MEDICINAL CHEMISTS AND PHARMACOLOGISTS

John Wiley & Sons

DRUG DISCOVERY TOXICOLOGY

FROM TARGET ASSESSMENT TO TRANSLATIONAL BIOMARKERS

John Wiley & Sons *As a guide for pharmaceutical professionals to the issues and practices of drug discovery toxicology, this book integrates and reviews the strategy and application of tools and methods at each step of the drug discovery process. • Guides researchers as to what drug safety experiments are both practical and useful • Covers a variety of key topics – safety lead optimization, in vitro-in vivo translation, organ toxicology, ADME, animal models, biomarkers, and –omics tools • Describes what experiments are possible and useful and offers a view into the future, indicating key areas to watch for new predictive methods • Features contributions from firsthand industry experience, giving readers insight into the strategy and execution of predictive toxicology practices*

PRINCIPLES OF SAFETY PHARMACOLOGY

Springer *This book illustrates, in a comprehensive manner, the most current areas of importance to Safety Pharmacology, a burgeoning unique pharmacological discipline with important ties to academia, industry and regulatory authorities. It provides readers with a definitive collection of topics containing essential information on the latest industry guidelines and overviews current and breakthrough topics in both functional and molecular pharmacology. An additional novelty of the book is that it constitutes academic, pharmaceutical and biotechnology perspectives for Safety Pharmacology issues. Each chapter is written by an expert in the area and includes not only a fundamental background regarding the topic but also detailed descriptions of currently accepted, validated models and methods as well as innovative methodologies used in drug discovery.*

EVALUATION OF DRUG CANDIDATES FOR PRECLINICAL DEVELOPMENT

PHARMACOKINETICS, METABOLISM, PHARMACEUTICS, AND TOXICOLOGY

John Wiley & Sons *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.*

PHENOTYPIC DRUG DISCOVERY

Royal Society of Chemistry *Phenotypic drug discovery has been highlighted in the past decade as an important strategy in the discovery of new medical entities. How many marketed drugs are derived from phenotypic screens? From the most recent examples, what were the factors enabling target identification and validation? This book answers these questions by elaborating on fundamental capabilities required for phenotypic drug discovery and using case studies to illustrate approaches and key success factors. Written and edited by experienced practitioners from both industry and academia, this publication will equip researchers with a thought-provoking guide to the application and future development of contemporary phenotypic drug discovery for clinical success.*

ADVANCED ISSUE RESOLUTION IN SAFETY PHARMACOLOGY

Academic Press *Advanced Issue Resolution in Safety Pharmacology not only discusses unique issues that may emerge during the*

development of new medicines, but also provides detailed insights on how to resolve them. The book employs a valuable strategy that integrates preclinical findings with the clinical resolution of those findings. In addition, it introduces key interdisciplinary topics in an accessible and systematic format. Edited and written by leaders in the field of safety pharmacology, this book considerably advances the discussion on issue resolution topics, thus raising them to the next level of importance by providing scientists with an indispensable resource on solving safety issues. Focuses on pharmacology issues that result during drug development and provides de-risking techniques and practical advice Covers a broad selection of topics, including specialized animal models, PBPK modeling, the use of high frequency EEG in problem-solving, drug-induced self-injury, abuse potential liability, biomarkers, imaging, and much more Focuses on the resolution of these issues in order to better address regulatory expectancies and develop safer, more effective drugs

ANIMAL AND TRANSLATIONAL MODELS FOR CNS DRUG DISCOVERY: NEUROLOGICAL DISORDERS

Academic Press *Neurological Disorders is written for researchers in both academia and the pharmaceutical industry who use animal models in research and development of drugs for neurological disorders such as neurofibromatosis, Alzheimer's disease, Parkinson's disease, Huntington disease, ALS, and the epilepsies. Neurological Disorders has introductory chapters expressing the view of the role and relevance of animal models for drug discovery and development for the treatment of psychiatric disorders from the perspective of (a) academic basic neuroscientific research, (b) applied pharmaceutical drug discovery and development, and (c) issues of clinical trial design and regulatory agencies limitations. Each volume examines the rationale, use, robustness and limitations of animal models in each therapeutic area covered and discuss the use of animal models for target identification and validation. The clinical relevance of animal models is discussed in terms of major limitations in cross-species comparisons, clinical trial design of drug candidates, and how clinical trial endpoints could be improved. The aim of this series of volumes on Animal and Translational Models for CNS Drug Discovery is to identify and provide common endpoints between species that can serve to inform both the clinic and the bench with the information needed to accelerate clinically-effective CNS drug discovery. This is the second volume in the three volume-set, Animal and Translational Models for CNS Drug Discovery 978-0-12-373861-5, which is also available for purchase individually. Clinical, academic, government and industry perspectives fostering integrated communication between principle participants at all stages of the drug discovery process Critical evaluation of animal and translational models improving transition from drug discovery and clinical development Emphasis on what results mean to the overall drug discovery process Exploration of issues in clinical trial design and conductance in each therapeutic area*

IMPROVING AND ACCELERATING THERAPEUTIC DEVELOPMENT FOR NERVOUS SYSTEM DISORDERS

WORKSHOP SUMMARY

National Academies Press *Improving and Accelerating Therapeutic Development for Nervous System Disorders is the summary of a workshop convened by the IOM Forum on Neuroscience and Nervous System Disorders to examine opportunities to accelerate early phases of drug development for nervous system drug discovery. Workshop participants discussed challenges in neuroscience research for enabling faster entry of potential treatments into first-in-human trials, explored how new and emerging tools and technologies may improve the efficiency of research, and considered mechanisms to facilitate a more effective and efficient development pipeline. There are several challenges to the current drug development pipeline for nervous system disorders. The fundamental etiology and pathophysiology of many nervous system disorders are unknown and the brain is inaccessible to study, making it difficult to develop accurate models. Patient heterogeneity is high, disease pathology can occur years to decades before becoming clinically apparent, and diagnostic and treatment biomarkers are lacking. In addition, the lack of validated targets, limitations related to the predictive validity of animal models - the extent to which the model predicts clinical efficacy - and regulatory barriers can also impede translation and drug development for nervous system disorders. Improving and Accelerating Therapeutic Development for Nervous System Disorders identifies avenues for moving directly from cellular models to human trials, minimizing the need for animal models to test efficacy, and discusses the potential benefits and risks of such an approach. This report is a timely discussion of opportunities to improve early drug development with a focus toward preclinical trials.*

DRUG DISCOVERY AND DEVELOPMENT, THIRD EDITION

CRC Press *Drug Discovery and Development, Third Edition presents up-to-date scientific information for maximizing the ability of a multidisciplinary research team to discover and bring new drugs to the marketplace. It explores many scientific advances in new drug discovery and development for areas such as screening technologies, biotechnology approaches, and evaluation of efficacy and safety of drug candidates through preclinical testing. This book also greatly expands the focus on the clinical pharmacology, regulatory, and business aspects of bringing new drugs to the market and offers coverage of essential topics for companies involved in drug development. Historical perspectives and predicted trends are also provided. Features: Highlights emerging scientific fields relevant to drug discovery such as the microbiome, nanotechnology, and cancer immunotherapy; and novel research tools such as CRISPR and DNA-encoded libraries Case study detailing the discovery of the anti-cancer drug, lorlatinib Venture capitalist commentary on trends and best practices in drug discovery and development Comprehensive review of regulations and their impact on drug development,*

highlighting special populations, orphan drugs, and pharmaceutical compounding Multidiscipline functioning of an Academic Research Enterprise, plus a chapter on Ethical Concerns in Research Contributions by 70+ experts from industry and academia specialists who developed and are practitioners of the science and business

DRUG DISCOVERY AND DEVELOPMENT - E-BOOK

TECHNOLOGY IN TRANSITION

Elsevier Health Sciences *The modern pharmacopeia has enormous power to alleviate disease, and owes its existence almost entirely to the work of the pharmaceutical industry. This book provides an introduction to the way the industry goes about the discovery and development of new drugs. The first part gives a brief historical account from its origins in the mediaeval apothecaries' trade, and discusses the changing understanding of what we mean by disease, and what therapy aims to achieve, as well as summarising case histories of the discovery and development of some important drugs. The second part focuses on the science and technology involved in the discovery process: the stages by which a promising new chemical entity is identified, from the starting point of a medical need and an idea for addressing it. A chapter on biopharmaceuticals, whose discovery and development tend to follow routes somewhat different from synthetic compounds, is included here, as well as accounts of patent issues that arise in the discovery phase, and a chapter on research management in this environment. The third section of the book deals with drug development: the work that has to be undertaken to turn the drug candidate that emerges from the discovery process into a product on the market. The definitive introduction to how a pharmaceutical company goes about its business of discovering and developing drugs. The second edition has a new editor: Professor Raymond Hill ● non-executive director of Addex Pharmaceuticals, Covagen and of Orexo AB ● Visiting Industrial Professor of Pharmacology in the University of Bristol ● Visiting Professor in the School of Medical and Health Sciences at the University of Surrey ● Visiting Professor in Physiology and Pharmacology at the University of Strathclyde ● President and Chair of the Council of the British Pharmacological Society ● member of the Nuffield Council on Bioethics and the Advisory Council on Misuse of Drugs. New to this edition: Completely rewritten chapter on The Role of Medicinal Chemistry in the Drug Discovery Process. New topic - DMPK Optimization Strategy in drug discovery. New chapter on Scaffolds: Small globular proteins as antibody substitutes. Totally updated chapters on Intellectual Property and Marketing 50 new illustrations in full colour Features Accessible, general guide to pharmaceutical research and development. Examines the interfaces between cost and social benefit, quality control and mass production, regulatory bodies, patent management, and all interdisciplinary intersections essential to effective drug development. Written by a strong team of scientists with long experience in the pharmaceutical industry. Solid overview of all the steps from lab bench to market in an easy-to-understand way which will be accessible to non-specialists. From*

customer reviews of the previous edition: '... it will have everything you need to know on this module. Deeply referenced and, thus, deeply reliable. Highly Commended in the medicine category of the BMA 2006 medical book competition Winner of the Royal Society of Medicine Library Prize for Medical Book of the Year

PHARMACOLOGY IN DRUG DISCOVERY AND DEVELOPMENT

UNDERSTANDING DRUG RESPONSE

Academic Press *Pharmacology in Drug Discovery and Development: Understanding Drug Response, Second Edition, is an introductory resource illustrating how pharmacology can be used to furnish the tools necessary to analyze different drug behavior and trace this behavior to its root cause or molecular mechanism of action. The concepts discussed in this book allow for the application of more predictive pharmacological procedures aimed at increasing therapeutic efficacy that will lead to more successful drug development. Chapters logically build upon one another to show how to characterize the pharmacology of any given molecule and allow for more informed predictions of drug effects in all biological systems. New chapters are dedicated to the interdisciplinary drug discovery environment in both industry and academia, and special techniques involved in new drug screening and lead optimization. This edition has been fully revised to address the latest advances and research related to real time kinetic assays, pluridimensional efficacy, signaling bias, irreversible and chemical antagonism, allosterically-induced bias, pharmacokinetics and safety, target and pathway validation, and much more. With numerous valuable chapter summaries, detailed references, practical examples and case studies throughout, Dr. Kenakin successfully navigates a highly complex subject, making it accessible for students, professors, and new researchers working in pharmacology and drug discovery. Includes example-based cases that illustrate how the pharmacological concepts discussed in this book lead to practical outcomes for further research Provides vignettes on those researchers and scientists who have contributed significantly to the fields of pharmacology and drug discovery throughout history Offers sample questions throughout the book and an appendix containing answers for self-testing and retention*

NETWORK PHARMACOLOGY

Springer Nature

DRUG REPURPOSING

HYPOTHESIS, MOLECULAR ASPECTS AND THERAPEUTIC APPLICATIONS

BoD – Books on Demand *Drug repurposing or drug repositioning is a new approach to presenting new indications for common commercial and clinically approved existing drugs. For example, chloroquine, an old antimalarial drug, showed promising results for treating COVID-19, interfering with MDR in several types of cancer, and chemosensitizing human leukemic cells.This book focuses on the hypothesis, risk/benefits, and economic impacts of drug repurposing on drug discovery in dermatology, infectious diseases, neurological disorders, cancer, and orphan diseases. It brings together up-to-date research to provide readers with an informative, illustrative, and easy-to-read book useful for students, clinicians, and the pharmaceutical industry.*

DRUG-LIKE PROPERTIES: CONCEPTS, STRUCTURE DESIGN AND METHODS

FROM ADME TO TOXICITY OPTIMIZATION

Elsevier *Of the thousands of novel compounds that a drug discovery project team invents and that bind to the therapeutic target, typically only a fraction of these have sufficient ADME/Tox properties to become a drug product. Understanding ADME/Tox is critical for all drug researchers, owing to its increasing importance in advancing high quality candidates to clinical studies and the processes of drug discovery. If the properties are weak, the candidate will have a high risk of failure or be less desirable as a drug product. This book is a tool and resource for scientists engaged in, or preparing for, the selection and optimization process. The authors describe how properties affect in vivo pharmacological activity and impact in vitro assays. Individual drug-like properties are discussed from a practical point of view, such as solubility, permeability and metabolic stability, with regard to fundamental understanding, applications of property data in drug discovery and examples of structural modifications that have achieved improved property performance. The authors also review various methods for the screening (high throughput), diagnosis (medium throughput) and in-depth (low throughput) analysis of drug properties. * Serves as an essential working handbook aimed at scientists and students in medicinal chemistry * Provides practical, step-by-step guidance on property fundamentals, effects, structure-property relationships, and structure modification strategies * Discusses improvements in pharmacokinetics from a practical chemist's standpoint*

PET FOR DRUG DEVELOPMENT AND EVALUATION

Springer Science & Business Media *Can drug development and evaluation be improved by the use of positron emission tomography (PET)? PET is now well established and many PET centres participate in networks that warrant the quality of their research. PET allows one to follow the effect of a drug on a variety of patients' metabolic parameters. In addition, PET may be used to*

follow the fate in vivo of a compound, allowing visualisation of its binding to specific receptors and a direct study of the mechanism of drug action in normal and pathological situations. The book shows the fields in which PET offers new and unique information for the development of drugs (conception, toxicity, pharmacokinetics and metabolism, clinical research, and relations between clinical and biological effects) and evaluates fields in which PET may shorten the development time of drugs. Audience: Professionals in the pharmaceutical industry in all areas of drug discovery and pharmacology, pre-clinical testing, pharmacokinetics and metabolism, clinical evaluation, registration and regulatory affairs. Government health authority representatives who assess data and documentation on new drug development and radiopharmaceuticals. Academic experts concerned with any of these areas.

PHARMACOLOGY FOR CHEMISTS

DRUG DISCOVERY IN CONTEXT

Royal Society of Chemistry *Assuming little previous knowledge of biology, this book aids graduate chemists to close the gap in their knowledge of pharmacology and make the link between medicinal chemistry and the way in which drugs act on the body. The availability of receptor structures has revolutionized drug discovery and development necessitating an up-to-date source of information for chemists entering this new pharmacological world. Chapters, written by experts with an appreciation of most graduate chemists' knowledge, explain the history of pharmacology, the relationship between receptor structure and function and receptor pharmacology relevant to drug design. Importantly, as drugs are normally discovered in test rather than therapeutic systems, this text describes how pharmacology provides methods to characterize drug activity through scales that allow prediction of drug effect in all systems. Moreover, it outlines the relationship between drug distribution in the body and the action of drugs in particular organ systems relevant to disease. Readers will also find information on pharmacokinetics and drug metabolism, safety pharmacology and toxicology, clinical and regulatory pharmacology and the use of imaging techniques. Carefully edited for relevance to the modern chemist, this unique textbook will be an essential resource for chemists planning to work in drug discovery, or postgraduate students and practicing chemists interested in expanding their pharmacology knowledge*

DRUG DISCOVERY

PRACTICES, PROCESSES, AND PERSPECTIVES

John Wiley & Sons *Sets forth the history, state of the science, and future directions of drug discovery Edited by Jie Jack Li and Nobel laureate E. J. Corey, two leading pioneers in drug discovery and medicinal chemistry, this book synthesizes great moments in history,*

the current state of the science, and future directions of drug discovery into one expertly written and organized work. Exploring all major therapeutic areas, the book introduces readers to all facets and phases of drug discovery, including target selection, biological testing, drug metabolism, and computer-assisted drug design. Drug Discovery features chapters written by an international team of pharmaceutical and medicinal chemists. Contributions are based on a thorough review of the current literature as well as the authors' firsthand laboratory experience in drug discovery. The book begins with the history of drug discovery, describing groundbreaking moments in the field. Next, it covers such topics as: Target identification and validation Drug metabolism and pharmacokinetics Central nervous system drugs In vitro and in vivo assays Cardiovascular drugs Cancer drugs Each chapter features a case study, helping readers understand how science is put into practice throughout all phases of drug discovery. References at the end of each chapter serve as a gateway to groundbreaking original research studies and reviews in the field. Drug Discovery is ideal for newcomers to medicinal chemistry and drug discovery, providing a comprehensive overview of the field. Veterans in the field will also benefit from the perspectives of leading international experts in all aspects of drug discovery.

ORAL BIOAVAILABILITY ASSESSMENT

BASICS AND STRATEGIES FOR DRUG DISCOVERY AND DEVELOPMENT

John Wiley & Sons *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*

A COMPREHENSIVE GUIDE TO TOXICOLOGY IN PRECLINICAL DRUG DEVELOPMENT

Academic 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

DRUG DISCOVERY AND DEVELOPMENT E-BOOK

TECHNOLOGY IN TRANSITION

Elsevier Health Sciences *With unprecedented interest in the power that the modern therapeutic armamentarium has to combat disease, the new edition of Drug Discovery and Development is an essential resource for anyone interested in understanding how drugs and other therapeutic interventions are discovered and developed, through to clinical research, registration, and market access. The text has been thoroughly updated, with new information on biopharmaceuticals and vaccines as well as clinical development and target identification. Drug discovery and development continues to evolve rapidly and this new edition reflects important changes in the landscape. Edited by industry experts Raymond Hill and Duncan Richards, this market-leading text is suitable for undergraduates and graduates undertaking degrees in pharmacy, pharmacology, toxicology, and clinical development through to those embarking on a career in the pharmaceutical industry. Key stages of drug discovery and development Chapters outline the contribution of individual disciplines to the overall process Supplemented by specific chapters on different modalities Includes coverage of Oligonucleotide therapies; cell and gene therapy Now comes with online access on StudentConsult*

BASIC PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT

Academic Press *Basic Principles of Drug Discovery and Development presents the multifaceted process of identifying a new drug in the modern era, which requires a multidisciplinary team approach with input from medicinal chemists, biologists, pharmacologists, drug metabolism experts, toxicologists, clinicians, and a host of experts from numerous additional fields. Enabling technologies such as high throughput screening, structure-based drug design, molecular modeling, pharmaceutical profiling, and translational medicine are critical to the successful development of marketable therapeutics. Given the wide range of disciplines and techniques that are required for cutting edge drug discovery and development, a scientist must master their own fields as well as have a fundamental*

understanding of their collaborator's fields. This book bridges the knowledge gaps that invariably lead to communication issues in a new scientist's early career, providing a fundamental understanding of the various techniques and disciplines required for the multifaceted endeavor of drug research and development. It provides students, new industrial scientists, and academics with a basic understanding of the drug discovery and development process. The fully updated text provides an excellent overview of the process and includes chapters on important drug targets by class, in vitro screening methods, medicinal chemistry strategies in drug design, principles of in vivo pharmacokinetics and pharmacodynamics, animal models of disease states, clinical trial basics, and selected business aspects of the drug discovery process. Provides a clear explanation of how the pharmaceutical industry works, as well as the complete drug discovery and development process, from obtaining a lead, to testing the bioactivity, to producing the drug, and protecting the intellectual property Includes a new chapter on the discovery and development of biologics (antibodies proteins, antibody/receptor complexes, antibody drug conjugates), a growing and important area of the pharmaceutical industry landscape Features a new section on formulations, including a discussion of IV formulations suitable for human clinical trials, as well as the application of nanotechnology and the use of transdermal patch technology for drug delivery Updated chapter with new case studies includes additional modern examples of drug discovery through high through-put screening, fragment-based drug design, and computational chemistry

HANDBOOK OF ASSAY DEVELOPMENT IN DRUG DISCOVERY

CRC Press *The need to screen targets faster and more efficiently, coupled with advances in parallel and multiplex chemical synthesis, has contributed to the increasing use of multiwell assays for drug discovery. The Handbook of Assay Development in Drug Discovery is a reference that describes the complete armament of tools currently available for performing various assay techniques. Featuring contributions from assay developers in the pharmaceutical and vendor communities, the book presents descriptions of methods, laboratory guidelines and protocols used to perform such methods, specific examples of each assay system, and troubleshooting tools. The handbook describes biochemical assay classes as well as non-class specific assay development for cell-based assays. It covers a wide range of target classes—including kinases, proteases, nuclear receptors, and GPCRs—and describes currently employed methods and assay types, such as radioligand binding assays, image analysis assays, enzyme fragment complementation, and bioluminescent and fluorescent-based assays. Designed as a guide to running an assay from start to finish, the Handbook of Assay Development in Drug Discovery is an ideal bench top companion for discovery researchers, laboratory managers, academics, and other scientists involved in drug discovery screening, lead profiling, therapeutic target evaluation, and assay development and implementation in the pharmaceutical and biotechnology industries. Daniel E. Levy, editor of the Drug Discovery Series, is the founder of DEL BioPharma, a consulting service for drug discovery programs. He also maintains a blog that explores*

organic chemistry.

PREDICTIVE ADMET

INTEGRATED APPROACHES IN DRUG DISCOVERY AND DEVELOPMENT

John Wiley & Sons *This book helps readers integrate in silico, invitro, and in vivo ADMET (absorption,distribution, metabolism, elimination and toxicity) and PK(pharmacokinetics) data with routine testing applications so thatpharmaceutical scientists can diagnose ADMET problems and presentappropriate recommendations to move drug discovery programsforward. The book introduces the current clinical practice for drugdiscovery and development along with the impact on early riskassessment; consolidates the tools and models to intelligentlyintegrate existing in silico, invitro and in vivo ADMET data; anddemonstrates successful cases and lessons learned from real drugdiscovery and development. In short, it is a book aimed to providea practical road map for drug discovery and development scientiststo generate efficacious and safe drugs for unmet medical needs.*

QUALITY CONTROL AND EVALUATION OF HERBAL DRUGS

EVALUATING NATURAL PRODUCTS AND TRADITIONAL MEDICINE

Elsevier *Quality Control and Evaluation of Herbal Drugs brings together current thinking and practices for evaluation of natural products and traditional medicines. The use of herbal medicine in therapeutics is on the rise in both developed and developing countries and this book facilitates the necessary development of quality standards for these medicines.This book elucidates on various challenges and opportunities for quality evaluation of herbal drugs with several integrated approaches including metabolomics, chemoprofiling, marker analysis, stability testing, good practices for manufacturing, clinical aspects, Ethnopharmacology and Ethnomedicine inspired drug development. Written by Prof. Pulok K Mukherjee, a leader in this field; the book highlights on various methods, techniques and approaches for evaluating the purity, quality, safety and efficacy of herbal drugs. Particular attention is paid to methods that assess these drugs' activity, the compounds responsible and their underlying mechanisms of action. The book describes the quality control parameters followed in India and other countries, including Japan, China, Bangladesh, and other Asian countries, as well as the regulatory profiles of the European Union and North America. This book will be useful in bio-prospecting of natural products and traditional medicine-inspired drug discovery and development. Provides new information on the research and development of natural remedies - essential reading on the study and use of natural resources for preventative or healing purposes Brings together current thinking and practices in quality control and standardization of herbal drugs highlighting several integrated*

approaches for metabolomics, chemo-profiling and marker analysis Aids in developing knowledge of various techniques including macroscopy, microscopy, HPTLC, HPLC, LC-MS/MS, GC-MS etc. with the development of integrated methods for evaluation of botanicals used in traditional medicine Assessment of herbal drugs through bio-analytical techniques, bioassay guided isolation, enzyme inhibition, pharmacological, microbiological, antiviral assays and safety related quality issues References global organizations, such as the WHO, USFDA, CDSCO, AYUSH, TCM and others to serve as a comprehensive document for enforcement agencies, NGOs and regulatory authorities

DRUG DISCOVERY AND DEVELOPMENT

FROM TARGETS AND MOLECULES TO MEDICINES

Springer Nature *This book describes the processes that are involved in the development of new drugs. The authors discuss the history, role of natural products and concept of receptor interactions with regard to the initial stages of drug discovery. In a single, highly readable volume, it outlines the basics of pharmacological screening, drug target identification, and genetics involved in early drug discovery. The final chapters introduce readers to stem therapeutics, pharmacokinetics, pharmacovigilance, and toxicological testing. Given its scope, the book will enable research scholars, professionals and young scientists to understand the key fundamentals of drug discovery, including stereochemistry, pharmacokinetics, clinical trials, statistics and toxicology.*

ATKINSON'S PRINCIPLES OF CLINICAL PHARMACOLOGY

Academic Press *Atkinson’s Principles of Clinical Pharmacology, Fourth Edition is the essential reference on the pharmacologic principles underlying the individualization of patient therapy and contemporary drug development. This well-regarded survey continues to focus on the basics of clinical pharmacology for the development, evaluation and clinical use of pharmaceutical products while also addressing the most recent advances in the field. Written by leading experts in academia, industry, clinical and regulatory settings, the fourth edition has been thoroughly updated to provide readers with an ideal reference on the wide range of important topics impacting clinical pharmacology. Presents the essential knowledge for effective practice of clinical pharmacology Includes a new chapter and extended discussion on the role of personalized and precision medicine in clinical pharmacology Offers an extensive regulatory section that addresses US and international issues and guidelines Provides extended coverage of earlier chapters on transporters, pharmacogenetics and biomarkers, along with further discussion on "Phase 0" studies (microdosing) and PBPK*

OPTIMIZATION IN DRUG DISCOVERY

IN VITRO METHODS

Springer Science & Business Media *Recent reports of drug attrition rates have revealed that a significant number of drug candidates fail in the later stage of clinical development due to absorption, distribution, metabolism, elimination and toxicity issues. Lead optimization in drug discovery, a process of attempting to uncover and correct these defects, is highly beneficial in lowering the cost and time to develop therapeutic drugs by reducing drug candidate failures in development. This book provides the assays utilized in drug discovery to rapidly screen for compounds with favorable drug-like properties. A total of 25 chapters, contributed by many experts in the field, cover a wide spectrum of subjects including physicochemical properties, absorption, plasma binding, metabolism, drug interactions, and toxicity, making this an essential book for all pharmacologists and pharmaceutical scientists.*

EVALUATION OF ENZYME INHIBITORS IN DRUG DISCOVERY

A GUIDE FOR MEDICINAL CHEMISTS AND PHARMACOLOGISTS

John Wiley & Sons *Offers essential guidance for discovering and optimizing novel drug therapies Using detailed examples, Evaluation of Enzyme Inhibitors in Drug Discovery equips researchers with the tools needed to apply the science of enzymology and biochemistry to the discovery, optimization, and preclinical development of drugs that work by inhibiting specific enzyme targets. Readers will applaud this book for its clear and practical presentations, including its expert advice on best practices to follow and pitfalls to avoid. This Second Edition brings the book thoroughly up to date with the latest research findings and practices. Updates explore additional forms of enzyme inhibition and special treatments for enzymes that act on macromolecular substrates. Readers will also find new discussions detailing the development and application of the concept of drug-target residence time. Evaluation of Enzyme Inhibitors in Drug Discovery begins by explaining why enzymes are such important drug targets and then examines enzyme reaction mechanisms. The book covers: Reversible modes of inhibitor interactions with enzymes Assay considerations for compound library screening Lead optimization and structure-activity relationships for reversible inhibitors Slow binding and tight binding inhibitors Drug-target residence time Irreversible enzyme inactivators The book ends with a new chapter exploring the application of quantitative biochemical principles to the pharmacologic evaluation of drug candidates during lead optimization and preclinical development. The Second Edition of Evaluation of Enzyme Inhibitors in Drug Discovery continues to offer a treatment of enzymology applied to drug discovery that is quantitative and mathematically rigorous. At the same time, the clear and simple presentations*

demystify the complex science of enzymology, making the book accessible to many fields— from pharmacology to medicinal chemistry to biophysics to clinical medicine.

DRUG DISCOVERY AND EVALUATION: PHARMACOLOGICAL ASSAYS

Springer Science & Business Media *Now expanded and updated to include molecular biology and genetic engineering techniques. The second edition of this successful reference book contains a comprehensive selection of the most frequently used assays for reliably detecting the pharmacological effects of potential drugs. Each of the more than 1000 assays comprises a detailed protocol outlining the purpose and rationale of the method, a critical assessment of the results and their pharmacological and clinical relevance. The enclosed and fully searchable CD ROM allows easy identification of specific tests. An appendix with up-to-date guidelines and legal regulations for animal experiments in various countries will help the reader to plan experiments more effectively.*

DRUG DISCOVERY AND DEVELOPMENT

NEW ADVANCES

BoD – Books on Demand *The process of drug discovery and development is a complex multistage logistics project spanned over 10-15 years with an average budget exceeding 1 billion USD. Starting with target identification and synthesizing anywhere between 10k to 15k synthetic compounds to potentially obtain the final drug that reaches the market involves a complicated maze with multiple inter- and intra-operative fields. Topics described in this book emphasize the progresses in computational applications, pharmacokinetics advances, and molecular modeling developments. In addition the book also contains special topics describing target deorphaning in Mycobacterium tuberculosis, therapy treatment of some rare diseases, and developments in the pediatric drug discovery process.*

DRUG DISCOVERY AND EVALUATION: PHARMACOLOGICAL ASSAYS

Springer Science & Business Media *The new edition of this successful reference offers both cutting-edge and classic pharmacological methods. Thoroughly revised and expanded to two volumes, it offers an updated selection of the most frequently used assays for reliably detecting the pharmacological effects of potential drugs. Every chapter has been updated, and numerous assays have been added. Each of the more than 1,000 assays comprises a detailed protocol outlining purpose and rationale, and a critical assessment of the results and their pharmacological and clinical relevance.*

CASE STUDIES IN MODERN DRUG DISCOVERY AND DEVELOPMENT

John Wiley & Sons *Learn why some drug discovery and development efforts succeed . . . and others fail Written by international experts in drug discovery and development, this book sets forth carefully researched and analyzed case studies of both successful and failed drug discovery and development efforts, enabling medicinal chemists and pharmaceutical scientists to learn from actual examples. Each case study focuses on a particular drug and therapeutic target, guiding readers through the drug discovery and development process, including drug design rationale, structure-activity relationships, pharmacology, drug metabolism, biology, and clinical studies. Case Studies in Modern Drug Discovery and Development begins with an introductory chapter that puts into perspective the underlying issues facing the pharmaceutical industry and provides insight into future research opportunities. Next, there are fourteen detailed case studies, examining: All phases of drug discovery and development from initial idea to commercialization Some of today's most important and life-saving medications Drugs designed for different therapeutic areas such as cardiovascular disease, infection, inflammation, cancer, metabolic syndrome, and allergies Examples of prodrugs and inhaled drugs Reasons why certain drugs failed to advance to market despite major research investments Each chapter ends with a list of references leading to the primary literature. There are also plenty of tables and illustrations to help readers fully understand key concepts, processes, and technologies. Improving the success rate of the drug discovery and development process is paramount to the pharmaceutical industry. With this book as their guide, readers can learn from both successful and unsuccessful efforts in order to apply tested and proven science and technologies that increase the probability of success for new drug discovery and development projects.*