Drug And Biological Development From Molecule To Product And Beyond

Handbook of PreformulationNanocarriers for Drug DeliveryFreeze-Drying/Lyophilization of Pharmaceutical and Biological ProductsChemical and Biological Aspects of Drug DependencePharmaceutical Formulation Development of Peptides and ProteinsWater Properties in Food, Health, Pharmaceutical and Biological SystemsChemical and Biological TerrorismHandbook of Pharmaceutical Manufacturing FormulationsWater Properties of Food, Pharmaceutical, and Biological MaterialsDrugs Without Borders: Export of Finished DrugsDrug Design and Discovery in Alzheimer's DiseaseDrugs and DevelopmentA Comprehensive Guide to Toxicology in Nonclinical Drug DevelopmentDrug and Biological DevelopmentClinical Trials of Drugs and BiopharmaceuticalsBiological components of substance abuse and addiction.Pediatric Drug DevelopmentNever EnoughSystems Biology in Drug Discovery and DevelopmentBioinformatics and Computational Biology in Drug Discovery and DevelopmentAccelerating the Development of New Drugs and DiagnosticsImproving and Accelerating Therapeutic Development for Nervous System DisordersMolecular Insight of Drug DesignAdvances and Avenues in the Development of Novel Carriers for Bioactives and Biological AgentsChemical BiologyChirality and Biological Activity of DrugsBasic Principles of Drug Discovery and DevelopmentModern development of the chemical and biological sciencesChirality and Biological Activity of DrugsBiological Drug ProductsNew DrugsIntroduction to Biological and Small Molecule Drug Research and DevelopmentTapping Molecular WildernessPost-Genomic Approaches in Drug and Vaccine DevelopmentNanoscale Fabrication, Optimization, Scale-up and Biological Aspects of Pharmaceutical NanotechnologyHandbook of PreformulationBiomarkers, Diagnostics and Precision Medicine in the Drug IndustryThe Organic Chemistry of Drug Design and Drug ActionThe Analysis of Drugs in Biological FluidsFreeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Second Edition, Revised and Expanded

Handbook of Preformulation

Nanocarriers for Drug Delivery

Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products

An authoritative look at the application of chemical biology in drug discovery and development Based on the award-winning Wiley Encyclopedia of Chemical Biology published in 2008, this book explores the role of chemical biology in drug discovery and development. The first part of the book reviews key principles and techniques used in the design and evaluation of

drug candidates. The second part elucidates biological mechanisms of certain diseases, illuminating approaches to investigate and target these diseases. Comprising carefully selected reprints from the Encyclopedia as well as new contributions from leading scholars in the field, this book provides researchers in academia and industry with important information to aid in the development of novel agents to treat disease. Self-contained articles cover a variety of essential topics, including: The design, development, and optimization of drug candidates The pharmacokinetics and properties of drugs Drug transport and delivery Natural products and natural product models as pharmaceuticals Biological mechanisms underlying health and disease Treatment strategies for a range of diseases, from HIV to schizophrenia Chemical Biology is a top-notch guide and reference for anyone working in the areas of drug discovery and development, including researchers in chemical biology and other fields such as biochemistry, medicine, and pharmaceutical sciences.

Chemical and Biological Aspects of Drug Dependence

This book brings together the theoretical, commercial, and practical aspects of chirality and biological activity of drugs and acts as a ready reference for the effects of enantiomers of drug substances.

Pharmaceutical Formulation Development of Peptides and Proteins

Basic Principles of Drug Discovery and Development presents the multifaceted process of identifying a new drug in the modern era, providing comprehensive explanations of enabling technologies such as high throughput screening, structure based drug design, molecular modeling, pharmaceutical profiling, and translational medicine, all areas that have become critical steps in the successful development of marketable therapeutics. The text introduces the fundamental principles of drug discovery and development, also discussing important drug targets by class, in vitro screening methods, medicinal chemistry strategies in drug design, principles in pharmacokinetics and pharmacodynamics, animal models of disease states, clinical trial basics, and selected business aspects of the drug discovery process. It is designed to enable new scientists to rapidly understand the key fundamentals of drug discovery, including pharmacokinetics, toxicology, and intellectual property." Provides a clear explanation of how the pharmaceutical industry works Explains the complete drug discovery process, from obtaining a lead, to testing the bioactivity, to producing the drug, and protecting the intellectual propertyIdeal for anyone interested in learning about the drug discovery process and those contemplating careers in the industry Explains the transition process from academia or other industries

Water Properties in Food, Health, Pharmaceutical and Biological Systems

Nanoscale Fabrication, Optimization, Scale-up and Biological Aspects of Pharmaceutical Nanotechnology focuses on the

fabrication, optimization, scale-up and biological aspects of pharmaceutical nanotechnology. In particular, the following aspects of nanoparticle preparation methods are discussed: the need for less toxic reagents, simplification of the procedure to allow economic scale-up, and optimization to improve yield and entrapment efficiency. Written by a diverse range of international researchers, the chapters examine characterization and manufacturing of nanomaterials for pharmaceutical applications. Regulatory and policy aspects are also discussed. This book is a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about how nanomaterials can best be utilized. Shows how nanomanufacturing techniques can help to create more effective, cheaper pharmaceutical products Explores how nanofabrication techniques developed in the lab have been translated to commercial applications in recent years Explains safety and regulatory aspects of the use of nanomanufacturing processes in the pharmaceutical industry

Chemical and Biological Terrorism

This book is for readers with some background in science, concerning the search for drugs, starting from molecular diversity in nature or molecular wilderness. Drug molecules may be used as such, or as starting points for improved drugs obtained from the interface of chemistry and biology. In some cases, the essential molecular features for drug properties from natural molecules may be identified and modified to more effective ones. In other cases, nature provides the targets, such as essential enzymes from infectious microorganisms, from which synthetic drugs can be designed. The mechanisms of action of drugs can be discerned by studying target–drug interactions. Nature may fight back, as in cases when microorganisms become resistant to drugs, but we can again use the chemistry–biology interface to obtain drugs which overcome the resistance. The battle goes on, hopefully with victory for both humans and balance of nature. This book differs from those available on the subject of natural products and drugs derived therefrom in that it looks at the broad picture on how materials and organisms from nature affect our health and how we have combined our knowledge in chemistry, biology, and biodiversity to promote our wellness from resources in the "molecular wilderness," with caveats on sustainable utilization of these resources. It is therefore suitable, not only for readers interested in science and medicine, but also for those with interest in policy issues concerning sustainable development, environment, and issues concerning interaction of science and society in general.

Handbook of Pharmaceutical Manufacturing Formulations

Freeze-drying, or lyophilization, is a well established technology used in the preservation of numerous pharmaceutical and biological products. This highly effective dehydration method involves the removal of water from frozen materials via the direct sublimation of ice. In recent years, this process has met with many changes, as have the regulatio

Water Properties of Food, Pharmaceutical, and Biological Materials

Introduction to Biological and Small Molecule Drug Research and Development provides, for the first time, an introduction to the science behind successful pharmaceutical research and development programs. The book explains basic principles, then compares and contrasts approaches to both biopharmaceuticals (proteins) and small molecule drugs, presenting an overview of the business and management issues of these approaches. The latter part of the book provides carefully selected real-life case studies illustrating how the theory presented in the first part of the book is actually put into practice. Studies include Herceptin/T-DM1, erythropoietin (Epogen/Eprex/NeoRecormon), anti-HIV protease inhibitor Darunavir, and more. Introduction to Biological and Small Molecule Drug Research and Development is intended for late-stage undergraduates or postgraduates studying chemistry (at the biology interface), biochemistry, medicine, pharmacy, medicine, or allied subjects. The book is also useful in a wide variety of science degree courses, in post-graduate taught material (Masters and PhD), and as basic background reading for scientists in the pharmaceutical industry. For the first time, the fundamental scientific principles of biopharmaceuticals and small molecule chemotherapeutics are discussed side-by-side at a basic level Edited by three senior scientists with over 100 years of experience in drug research who have compiled the best scientific comparison of small molecule and biopharmaceuticals approaches to new drugs Illustrated with key examples of important drugs that exemplify the basic principles of pharmaceutical drug research and development

Drugs Without Borders: Export of Finished Drugs

This book brings together the theoretical, commercial, and practical aspects of chirality and biological activity of drugs and acts as a ready reference for the effects of enantiomers of drug substances.

Drug Design and Discovery in Alzheimer’s Disease

Drug development, the processes by which a chemical compound becomes a “drug” and is approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success.Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If you're involved in the pharmaceutical industry, NEW DRUGS will

provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compound's development. If you're a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with promising products.

Drugs and Development

Advances in technologies and knowledge are creating new avenues for research and opportunities for the discovery and clinical development of innovative therapies and diagnostics. However, despite these opportunities, only a small fraction of investigational products are successfully developed into cures and therapies that can be accessed by patients. One response to the ever-widening gap between the number and promise of basic scientific discoveries and the translation of those discoveries into therapies is a renewed emphasis on collaborative approaches among federal agencies, academia, and industry, all directed at the advancement of the drug development enterprise. The newly developed Cures Acceleration Network (CAN)-a part of the National Center for Advancing Translational Sciences (NCATS) within the National Institutes of Health (NIH)-has the potential to catalyze widespread changes in NCATS, NIH, and the drug development ecosystem in general. On June 4-5, 2012, the IOM Forum on Drug Discovery, Development, and Translation held, at the request of NCATS, a workshop-bringing together members of federal government agencies, the private sector, academia, and advocacy groups-to explore options and opportunities in the implementation of CAN. Accelerating the Development of New Drugs and Diagnostics: Maximizing the Impact of the Cures Acceleration Network: Workshop Summary summarizes the workshop.

A Comprehensive Guide to Toxicology in Nonclinical Drug Development

A comprehensive overview of the use of computational biology approaches in the drug discovery and development process.

Drug and Biological Development

Over the past decade, genome sequencing projects and the associated efforts have facilitated the discovery of several novel disease targets and the approval of several innovative drugs. To further exploit this data for human health and disease, there is a need to understand the genome data itself in detail, discover novel targets, understand their role in physiological pathways and associated diseases, with the aim to translate these discoveries to clinical and preventive medicine. It is equally important to understand the labors and limitations in integrating clinical phenotypes with genomic,

transcriptomic, proteomic and metabolomic approaches. This book focuses on some key advances in the field. Technical topics discussed in the book include: Drug discoveryTarget identification and prioritizationHypothesis driven multi-target drug designGenomics in vaccine developmentGene regulatory networks Vaccine design and developmentPrediction of drug side effects in silico

Clinical Trials of Drugs and Biopharmaceuticals

Biological components of substance abuse and addiction.

The threat of domestic terrorism today looms larger than ever. Bombings at the World Trade Center and Oklahoma City's Federal Building, as well as nerve gas attacks in Japan, have made it tragically obvious that American civilians must be ready for terrorist attacks. What do we need to know to help emergency and medical personnel prepare for these attacks? Chemical and Biological Terrorism identifies the R&D efforts needed to implement recommendations in key areas: pre-incident intelligence, detection and identification of chemical and biological agents, protective clothing and equipment, early recognition that a population has been covertly exposed to a pathogen, mass casualty decontamination and triage, use of vaccines and pharmaceuticals, and the psychological effects of terror. Specific objectives for computer software development are also identified. The book addresses the differences between a biological and chemical attack, the distinct challenges to the military and civilian medical communities, and other broader issues. This book will be of critical interest to anyone involved in civilian preparedness for terrorist attack: planners, administrators, responders, medical professionals, public health and emergency personnel, and technology designers and engineers.

Pediatric Drug Development

Advances and Avenues in the Development of Novel Carriers for Bioactives and Biological Agents provides sound data on the utility of biological and plant-based drugs and describes challenges faced in all aspects offering indispensable strategies to use in the development of bioactive medicines. Bioactive based medications are commonly used throughout the world and have been recognized by physicians and patients for their therapeutic efficacy. Bioactive formulations, including their subordinates and analogs, address 50% of all medicines in clinical practice. Novel bioactive medicine transporters can cure many disorders by both spatial and transitory approaches and have various justifications in medicinal potential. This book presents information on the utility of natural, plant, animal and bioengineered bioactive materials. It is a fundamental source of information and data for pharmacognosists, pharmaceutical analysts, drug transport scientists and pharmacologists working in bioactive medications. Advances information on various bioactive based medications, their

sources, clinical consequences and transport strategies Illustrates diverse transport systems for bioactives and derivatives, novel techniques for formulations, targeting strategies and fundamental qualities of developed bioactive carriers, and their safety concerns and standardization Discusses distinctive transport systems, stability, upgraded dissolvability, and enhanced bioavailability of bioactives

Never Enough

Unique and informative, Water Properties of Food, Pharmaceutical, and Biological Materials is based on lectures and papers given by leading international researchers at the 9th International Symposium of the Properties of Water in Foods (ISOPOW 9) that took place in September 2004. Each chapter presents an authoritative account of the latest research on the physical and chemical properties of water in relation to the stability of food, pharmaceutical, and biological materials. The first part of the text focuses on presentations given by invited speakers, whereas the second part is dedicated to oral presentations and discussions. Topics include the role of water in structural and functional properties, preserving biomolecule functionality in restricted water environments, and micro- and nano- techniques used for assessing water-solid interactions in food and drug development. This book is an invaluable resource that synthesizes cutting-edge information with innovative viewpoints from internationally esteemed researchers who participated in ISOPOW 2004.

Systems Biology in Drug Discovery and Development

The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therap

Bioinformatics and Computational Biology in Drug Discovery and Development

First published in 1972 this book guides the reader through the various elements behind drug dependency and addiction. Taking an objective view at the characteristics both chemical and biological, the criteria for evaluating dependency as well as the physiological effects drug dependency can have on the human body. Biological and Chemical Aspects of Drug Dependency is a useful reference for students of both medicine and psychology alike as well as for professionals in their respective fields.

Accelerating the Development of New Drugs and Diagnostics

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

Improving and Accelerating Therapeutic Development for Nervous System Disorders

Thoroughly acquainting the reader with freeze-drying fundamentals, Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Second Edition carves practical guidelines from the very latest theoretical research, technologies, and industrial procedures. It delineates the best execution of steps from closure preparation and regulatory control of products to equipment sterilization and process validation. With 13 new chapters providing state-of-the-art information, the book unveils innovations currently advancing the field, including LYOGUARD® packaging for bulk freeze-drying and the irradiation of pharmaceutical and biological products.

Molecular Insight of Drug Design

This new edition focuses on a variety of techniques available for the analysis of drugs in biological fluids. Over 150 figures and tables help to describe the latest advances and give examples of their applications. Current chiral analysis methods as well as discussions on the impact of chirality are described. Practical aspects of bioanalytical work, including many examples of laboratory problems not often reported in the scientific literature, are examined in depth.

Advances and Avenues in the Development of Novel Carriers for Bioactives and Biological Agents

This book offers a complete discussion of product development in the pharmaceutical and biotechnology industries from discovery, to product launch, through life cycle management. The book is organized for optimal usefulness in the education and training of health care professionals (MD, PharmD, PhD), at universities. The format is a set of figures, tables and lists, along with detailed narrative descriptions, including real-life examples, illustrations, controversies in industry, and references. The editors and authors of the book are industry and research experts in a variety of disciplines.

Chemical Biology

Drug Design and Discovery in Alzheimer’s Disease includes expert reviews of recent developments in Alzheimer's disease

(AD) and neurodegenerative disease research. Originally published by Bentham as Frontiers in Drug Design and Discovery, Volume 6and now distributed by Elsevier, this compilation of the sixteen articles, written by leading global researchers, focuses on key developments in the understanding of the disease at molecular levels, identification and validation of molecular targets, as well as innovative approaches towards drug discovery, development, and delivery. Beginning with an overview of AD pharmacotherapy and existing blockbuster drugs, the reviews cover the potential of both natural and synthetic small molecules; the role of cholinesterases in the on-set and progression of AD and their inhibition; the role of beta-site APP clearing enzyme-1 (BACE-1) in the production of ß-amyloid proteins, one of the key reasons of the progression of AD; and other targets identified for AD drug discovery. Edited and written by leading experts in Alzheimer's disease (AD) and other neurodegenerative disease drug development Describes existing drugs for AD and current molecular understanding of the condition Reviews recent advances in the field, including coverage of cholinesterases, BACE-1, and other drug development targets

Chirality and Biological Activity of Drugs

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

Basic Principles of Drug Discovery and Development

This title focuses on the comprehension of the properties of water in foods, enriched by the approaches from polymer and materials sciences, and by the advances of analytical techniques. The International Symposium on the Properties of Water (ISOPOW) promotes the exchange of knowledge between scientists involved in the study of food materials and scientists interested in water from a more basic point of view and the dialogue between academic and industrial scientists/technologists. This comprehensive book covers the topics presented at the 10th ISOPOW held in Bangkok,

Thailand in 2007, including water dynamics in various systems, the role of water in functional food and nano-structured biomaterials. Special features include: Latest findings in the properties of water in food, pharmaceutical and biological systems Coverage of the 10th International Symposium on the Properties of Water (ISOPOW) Includes water dynamics, water in foods stability, and water in micro and nano-structured food and biomaterials Reflects the vast array of research and applications of water world wide

Modern development of the chemical and biological sciences

The approaches in drug design are mainly comprised of these three multidisciplinary sciences. First, Bioinformatics has successfully gather biological data in form of biomolecular sequences, in order to construct knowledge on drug and vaccine design. It is of considerable importance for drug designers to comprehend the utilization of bioinformatics tools for resolving their research questions. Second, Nanotechnology has made possible the design and delivery of the nano-based drug. Third, Pharmaceutical Chemistry made it possible to investigate the adsorption, distribution, metabolism, and toxicology of the drug candidates in a fine-grained resolution.

Chirality and Biological Activity of Drugs

This is a new approach to the teaching of medicinal chemistry. The knowledge of the physical organic chemical basis of drug design and drug action allows the reader to extrapolate to the many related classes of drugs described in standard medicinal chemistry texts. Students gain a solid foundation to base future research endeavors upon: drugs not yet developed are thus covered! n Emphasizes the use of the principles of physical organic chemistry as a basis for drug design n Discusses organic reaction mechanisms of clinically important drugs with mechanistic schemes n Uses figures and literature references extensively throughout n This text is not merely a "compilation of drugs and uses," but features selected drugs as examples of the organic chemical basis for any and all drug design applications

Biological Drug Products

A NEW YORK TIMES BESTSELLER From a renowned behavioral neuroscientist and recovering addict, a rare page-turning work of science that draws on personal insights to reveal how drugs work, the dangerous hold they can take on the brain, and the surprising way to combat today's epidemic of addiction. Judith Grisel was a daily drug user and college dropout when she began to consider that her addiction might have a cure, one that she herself could perhaps discover by studying the brain. Now, after twenty-five years as a neuroscientist, she shares what she and other scientists have learned about addiction, enriched by captivating glimpses of her personal journey. In Never Enough, Grisel reveals the unfortunate bottom

line of all regular drug use: there is no such thing as a free lunch. All drugs act on the brain in a way that diminishes their enjoyable effects and creates unpleasant ones with repeated use. Yet they have their appeal, and Grisel draws on anecdotes both comic and tragic from her own days of using as she limns the science behind the love of various drugs, from marijuana to alcohol, opiates to psychedelics, speed to spice. With more than one in five people over the age of fourteen addicted, drug abuse has been called the most formidable health problem worldwide, and Grisel delves with compassion into the science of this scourge. She points to what is different about the brains of addicts even before they first pick up a drink or drug, highlights the changes that take place in the brain and behavior as a result of chronic using, and shares the surprising hidden gifts of personality that addiction can expose. She describes what drove her to addiction, what helped her recover, and her belief that a “cure” for addiction will not be found in our individual brains but in the way we interact with our communities. Set apart by its color, candor, and bell-clear writing, Never Enough is a revelatory look at the roles drugs play in all of our lives and offers crucial new insight into how we can solve the epidemic of abuse.

New Drugs

The first book to focus on comprehensive systems biology as applied to drug discovery and development Drawing on real-life examples, Systems Biology in Drug Discovery and Development presents practical applications of systems biology to the multiple phases of drug discovery and development. This book explains how the integration of knowledge from multiple sources, and the models that best represent that integration, inform the drug research processes that are most relevant to the pharmaceutical and biotechnology industries. The first book to focus on comprehensive systems biology and its applications in drug discovery and development, it offers comprehensive and multidisciplinary coverage of all phases of discovery and design, including target identification and validation, lead identification and optimization, and clinical trial design and execution, as well as the complementary systems approaches that make these processes more efficient. It also provides models for applying systems biology to pharmacokinetics, pharmacodynamics, and candidate biomarker identification. Introducing and explaining key methods and technical approaches to the use of comprehensive systems biology on drug development, the book addresses the challenges currently facing the pharmaceutical industry. As a result, it is essential reading for pharmaceutical and biotech scientists, pharmacologists, computational modelers, bioinformaticians, and graduate students in systems biology, pharmaceutical science, and other related fields.

Introduction to Biological and Small Molecule Drug Research and Development

Tested and proven solutions to the challenges of biologicaldrug product development Biological drug products play a central role in combating humandiseases; however, developing new successful biological drugspresents many challenges, including labor intensive productionprocesses, tighter regulatory controls, and increased marketcompetition. This book

reviews the current state of the science,offering readers a single resource that sets forth the fundamentalsas well as tested and proven development strategies for biologicaldrugs. Moreover, the book prepares readers for the challenges thattypically arise during drug development, offering straightforwardsolutions to improve their ability to pass through all theregulatory hurdles and deliver new drug products to the market. Biological Drug Products begins with generalconsiderations for the development of any biological drug productand then explores the strategies and challenges involved in thedevelopment of specific types of biologics. Divided into fiveparts, the book examines: Part 1: General Aspects Part 2: Proteins and Peptides Part 3: Vaccines Part 4: Novel Biologics Part 5: Product Administration/Delivery Each chapter has been prepared by one or more leading experts inbiological drug development. Contributions are based on acomprehensive review and analysis of the current literature as wellas the authors' first-hand experience developing and testing newdrugs. References at the end of each chapter serve as a gateway tooriginal research papers and reviews in the field. By incorporating lessons learned and future directions forresearch, Biological Drug Products enables pharmaceuticalscientists and students to improve their success rate in developingnew biologics to treat a broad range of human diseases.

Tapping Molecular Wilderness

The high failure rate in the pharmaceutical industry has positioned biomarkers and personalized medicine in the frontline, as possible solutions. If executed right, biomarkers and companion diagnostics (CDx) can potentially help the drug industry enhance the probability of success, accelerate the time to market, and, more importantly, benefit patients by supporting accurate diagnosis and selection of the most effective and least toxic therapies. This book aims to examine the challenges and limitations in biomarkers and laboratory tests. It also offers advice on best practices to ensure proper application of biomarkers and bridges the gap between diagnostic business development claims and real-life deliverables. The book covers biomarkers for different purposes, provides examples from different technologies, which includes standard-of-care approved assays as well as for-investigational-use and for-research-use-only assays. It also includes new data for biomarkers in different therapeutic indications and offers case studies and practical examples. This book serves as a reference to drug developers, IVD providers, clinical labs, healthcare givers, academicians, and researchers for best practices to help increase the probability of success in drug development and improve patient management. Provides the unique insight of an expert with extensive experience in diagnostics and clinical laboratory on one side and drug discovery and development on the other side Addresses the challenges of drug development and precision medicine and suggests how to eliminate or mitigate these challenges through better utilization of biomarkers and diagnostics in drug development and patient management Features case studies and real-life examples from different classes of biomarkers on different platforms for different therapeutic areas and includes more than 200 illustrations

Post-Genomic Approaches in Drug and Vaccine Development

Preformulation studies are the physical, chemical, and biological studies needed to characterize a drug substance for enabling the proper design of a drug product, whereas the effectiveness of a drug product is determined during the formulation studies phase. Though the two disciplines overlap in practice, each is a significantly distinct phase of

Nanoscale Fabrication, Optimization, Scale-up and Biological Aspects of Pharmaceutical Nanotechnology

Nano-carriers for Drug Delivery: Nanoscience and Nanotechnology in Drug Delivery presents recent discoveries in research on the pharmaceutical applications of the various types of nanosystem-based drug delivery systems. As many nanosystems have reached the market over the past decade, this book proves their benefits to patients. It explores these new carriers and the advances in drug delivery they have facilitated. Reflecting the interdisciplinary nature of the subject matter, the book includes experts from different fields, and with various backgrounds and expertise. It will appeal to researchers and students from different disciplines, such as materials science, technology and various biomedical fields. Coverage includes industrial applications that bridge the gap between lab-based research and practical industrial use. The resulting work is a reference and practical source of guidance for researchers, students and scientists working in the fields of nanotechnology, materials science and technology and biomedical science. Enables readers from different fields to access recent research and protocols across traditional boundaries Focuses on protocols and techniques, as well as the knowledge base of the field, thus enabling those in R&D to learn about, and successfully deploy, cutting-edge techniques Includes sections on nanocarrier systems

Handbook of Preformulation

Biomarkers, Diagnostics and Precision Medicine in the Drug Industry

Preformulation studies are the physical, chemical, and biological studies needed to characterize a drug substance for enabling the proper design of a drug product, whereas the effectiveness of a drug product is determined during the formulation studies phase. Though the two disciplines overlap in practice, each is a significantly distinct phase of new drug development. Entirely focused on preformulation principles, this fully revised and updated Handbook of Preformulation: Chemical, Biological, and Botanical Drugs, Second Edition provides detailed descriptions of preformulation methodologies, gives a state-of-the-art description of each technique, and lists the currently available tools useful in providing a

comprehensive characterization of a new drug entity. Features: Addresses the preformulation studies of three different types of new active entities - chemical, biological, and botanical, which is the latest established class of active ingredient classified by the FDA Illustrates the activities comprised in preformulation studies and establishes a method of tasking for drug development projects Includes extensive flow charts for characterization decision making Gives extensive theoretical treatment of principles important for testing dissolution, solubility, stability, and solid state characterization Includes over 50% new material

The Organic Chemistry of Drug Design and Drug Action

In a globalized world, people, ideas, organizations, and commoditiesincluding drugsflow rapidly from place to place and are tied together through the market, advanced communication systems, and rapid transportation technologies. Drug distribution and use both reflect and reinforce an exploitive political economy that has connected the West with developing nations since the rise of capitalism. Singers fast-moving, authoritative treatment examines the impact of legal and illegal drug distribution and use on relations among richer and poorer nations, in particular their influence on social and economic development in the Third World. Guided by a critical perspective and drawing on his own crosscultural research in Asia, Latin America, and the Caribbean, Singer analyzes drug-related developmental challenges around the world and assesses the impact of licit and illicit drug use, drug trafficking, the War on Drugs, and drug-related health consequences like HIV/AIDS.

The Analysis of Drugs in Biological Fluids

The pharmaceutical industry is on the verge of an exciting and challenging century. Advances in pharmaceutical sciences have dramatically changed the processes of discovery and development of new therapeutic drugs and, in turn, resulted in an extraordinary increase in the potential prophylactic and therapeutic interventions. In this atmosphere, an

Freeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Second Edition, Revised and Expanded

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.