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The Role of NIH in Drug Development Innovation and Its Impact on Patient Access National Academies of Sciences, Engineering, and Medicine,Health and Medicine Division,Board on Health Sciences Policy,Board on Health Care Services,2020-01-27 To explore the role of the National Institutes of Health (NIH) in innovative drug development and its impact on patient access, the Board on Health Care Services and the Board on Health Sciences Policy of the National Academies jointly hosted a public workshop on July 24–25, 2019, in Washington, DC. Workshop speakers and participants discussed the ways in which federal investments in biomedical research are translated into innovative therapies and considered approaches to ensure that the public has affordable access to the resulting new drugs. This publication summarizes the presentations and discussions from the workshop.

Sample Preparation of Pharmaceutical Dosage Forms Beverly Nickerson,2011-08-05 This book is intended to serve as a resource for analysts in developing and troubleshooting sample preparation methods. These are critical activities in providing accurate and reliable data throughout the lifecycle of a drug product. This book is divided into four parts: • Part One covers dosage form and diluent properties that impact sample preparation of pharmaceutical dosage forms and the importance of sampling considerations in generating data representative of the drug product batch. • Part Two reviews specific sample preparation techniques typically used with pharmaceutical dosage forms. • Part Three discusses sample preparation method development for different types of dosage forms including addressing drug excipient interactions and post extraction considerations, as well as method validation and applying Quality by Design (QbD) principles to sample preparation methods. • Part Four examines additional topics in sample preparation including automation, investigating aberrant potency results, green chemistry considerations for sample preparation and the ideal case where no sample preparation is required for sample analysis.

Application of Nanotechnology in Drug Delivery Ali Demir Sezer,2014-07-25 This book collects reviews and original articles from eminent experts working in the interdisciplinary arena of nanotechnology use in drug delivery. From their direct and recent experience, the readers can achieve a wide vision on the new and ongoing potentialities of nanotechnology application of drug delivery. Since the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges, there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery. On the other hand, this reference discusses advances in design, optimization, and adaptation of gene delivery systems for the treatment of cancer, cardiovascular, pulmonary, genetic, and infectious diseases, and considers assessment and review procedures involved in the development of gene-based pharmaceuticals.

Food, Drug, Cosmetic Law Reporter ,1963

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Low-Dimensional and Nanostructured Materials and Devices Hilmi Ünlü,Norman J. M. Horing,Jaroslav Dabrowski,2015-12-01 This book focuses on the fundamental phenomena at nanoscale. It covers synthesis, properties, characterization and computer modelling of nanomaterials, nanotechnologies, bionanotechnology, involving nanodevices. Further topics are imaging, measuring, modeling and manipulating of low dimensional matter at nanoscale. The topics covered in the book are of vital importance in a wide range of modern and emerging technologies employed or to be employed in most industries, communication, healthcare, energy, conservation , biology, medical science, food, environment, and education, and consequently have great impact on our society.

Official Gazette of the United States Patent and Trademark Office United States. Patent and Trademark Office,2001

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Continuous Renal Replacement Therapy John A. Kellum,Rinaldo Bellomo,Claudio Ronco,2016 Continuous Renal Replacement Therapy (CRRT) is the standard of care for management of critically ill patients with acute renal failure. Part of the Pittsburgh Critical Care series, Continuous Renal Replacement Therapy provides concise, evidence-based, bedside guidance about this treatment modality, offering quick reference answers to clinicians' questions about treatments and situations encountered in daily practice. Organized into sections on theory, practice, special situations, and organizational issues, this volume provides a complete view of CRRT theory and practice. Tables summarize and highlight key points, and key studies and trials are included in each chapter. The second edition has been updated to include a new chapter on the use of biomarkers to aid in patient selection and timing, extensive revisions on terminology and nomenclature to match current standards, and the most up-to-date information on newly developed CRRT machines.

Making Medicines Affordable National Academies of Sciences, Engineering, and Medicine,Health and Medicine Division,Board on Health Care Services,Committee on Ensuring Patient Access to Affordable Drug Therapies,2018-03-01 Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicines—and health care at large—more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription drugs—coupled with the broader trends in overall health care costs—is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.

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Advanced Pharmaceutical and Herbal Nanoscience for Targeted Drug Delivery Systems Part I Swarnlata Saraf,Ram Kumar Sahu,Vivek Dave,2022-05-26 This 2-part reference informs readers about the application of drug delivery technologies to herbal medicines. Chapters cover a broad range of major topics on the subject of targeted drug delivery systems. These topics include the application of drug delivery systems for herbal nanomedicines, drug development issues, emerging technologies, adaptations for clinical use, market prospects and challenges of industrial commercialization. Chapters have been contributed by several experts in pharmaceutical chemistry and blend theoretical knowledge with practical aspects of drug delivery. Part I covers the following topics: - Introduction to nanotechnology and herbal-based nanoparticulate systems - Nucleic acid-based therapeutic drug delivery systems - Herbal bioactives: a booster dose for advanced pharmaceutical nanoscience - Pulmonary nano-drug delivery systems - Application of nano-drug delivery systems in improving the therapeutic efficacy of bioactive natural products - PEGylated liposomes - Insulin liposomes - Aquasomes: a promising novel drug carrier - Nanoparticle-aided herbal drugs: therapeutic implications on cholinergic dysfunction with relevance to Alzheimer's disease - Vitamins based nanomedicine approach - Recent advances in tumor targeting drug delivery systems: fundamentals of advanced pharmaceutical nanoscience - Niosomes: a revolutionary progress in the field of pharmaceutical sciences - Infectious diseases: pharmaceutical nanoscience for targeted drug delivery This reference is a valuable resource for scholars that creates awareness of novel drug delivery systems as well as their promising applications in drug targeting, and nanotherapeutics for specific diseases.

The Science and Business of Drug Discovery Edward D. Zanders,2020-11-09 The Science and Business of Drug Discovery is written for those who want to learn about the biopharmaceutical industry and its products whatever their level of technical knowledge. Its aim is to demystify the jargon used in drug development, but in a way that avoids over simplification and the resulting loss of key information. Each of the twenty chapters is illustrated with figures and tables which clarify some of the more technical points being made. Also included is a drug discovery case history which draws the relevant material together into a single chapter. In recognizing that it is difficult to navigate through the many external resources dealing with drug development, the book has been written to guide the reader towards the most appropriate information sources, including those listed in the two appendices. The following topics are covered: Different types of drugs: from small molecules to stem cells Background to chemistry of small and large molecules Historical background to drug discovery, pharmacology and biotechnology The drug discovery pipeline: from target discovery to marketed medicine Commercial aspects of drug discovery Challenges to the biopharmaceutical industry and its responses Material of specific

interest to technology transfer executives, recruiters and pharmaceutical translators

Nanobiotechnology Alok Dhawan, Sanjay Singh, Ashutosh Kumar, Rishi Shanker, 2018-03-26 This book combines the contributions from the experts of material science, molecular biology, toxicology bio-organic and bio-inorganic chemistry, toxicologists and environmental and food technology etc. to fathom the full scope of current and future of developments in the area of Nanobiotechnology. Provides brief overview of nanobiotechnology for general readers who are not familiar with the research fields and presents a strong overview of most of the critical areas in field This book can also be used as text book for graduate students as an essential reference material, and as an reading material for general readers having a curiosity in Nanobiotechnology.

Drug Repurposing David Cavalla, 2022-01-31 Drug repurposing is the development of existing drugs for new uses: given that 9 in 10 drugs that enter drug development are never marketed and therefore represent wasted effort, it is an attractive as well as inherently more efficient process. Three repurposed drugs can be brought to market for the same cost as one new chemical entity; and they can also be identified more quickly, an important benefit for patients whose diseases are progressing faster than therapeutic innovation. But repurposing also requires a fresh look at configuring pharmaceutical R&D, considering clinical, regulatory and patent issues much earlier than would otherwise be the case; a holistic gedanken experiment almost needs to be undertaken at the very start of any repurposing development. In addition to new ways of thinking, the discovery of repurposing opportunities can take advantage of artificial intelligence techniques to match the perfect new use for an existing drug. And while repurposing of medicines has been in the mind of every doctor since Hypocrates, modern clinical practice will simply have to adapt to new repurposing techniques in an age where the number of known diseases is increasing much faster than the healthcare dollars available.

Anti-Inflammatory Drug Discovery Jeremy I. Levin, Stefan Laufer, 2012-07-18 Anti-Inflammatory Drug Discovery provides a comprehensive review of recent medicinal chemistry approaches to a variety of important therapeutic targets and provides a key reference for those interested in the prosecution of modern drug discovery programs directed at anti-inflammatory mechanisms of action. The editors, with extensive experience in this field, have selected key thought-leaders who will bring their experience to the medicinal chemistry literature for each target, ranging from components of the arachadonic acid cascade, to kinases, GPCRs, sphingolipids and others, to summarize its background biology and detail new insights, major advances and issues related to bringing new anti-inflammatory therapies to market. Consisting of five main sections key targets covered will include the AA Cascade: mPGES1, cPLA2, Leukotriene A4 Hydrolase, CRTH2; Kinases: P38/PDE4, MAPKAP Kinase 2 (MK2), Syk Kinase Inhibitors, Jak Kinases, IKK, Bruton's Tyrosine Kinase; GPCRs: CCR1, CCR2 Antagonists, CB2 Agonists; Sphingolipids: S1P1 Receptor Agonists, Sphingosine Lyase and Sphingosine Kinase 1 and a final miscellaneous section that looks at Non-Steroidal Dissociated Glucocorticoid Receptor Agonists. The book will be essential reading for pharmacologists, medicinal chemists and pharmaceutical scientists working in industry and academia.

2017 Oncology Nursing Drug Handbook Wilkes, Margaret Barton-Burke, 2016-11-29 Written especially for nurses caring for patients with cancer, the 2017 Oncology Nursing Drug Handbook uniquely expresses drug therapy in terms of the nursing process: nursing diagnoses, etiologies of toxicities, and key points for nursing assessment, intervention, and evaluation. Updated annually, this essential reference provides valuable information on effective symptom management, patient education, and chemotherapy administration. Completely revised and updated, the 2017 Oncology Nursing Drug Handbook includes separate chapters on molecular and immunologic/biologic targeted therapies. These chapters provide fundamental reviews to assist nurses in understanding the cellular communication pathways disrupted by cancer. It also offers simplified content, attention to understanding the immune checkpoint inhibitors, new information about immunotherapy, new drugs and their indications, and updated indications and side effects for recently FDA approved drugs. New drugs include: alectin

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