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Sterile Product Development Disinfection and Decontamination Advanced Issue Resolution in Safety Pharmacology Innovative Dosage Forms Principles and Practices of Lyophilization in Product Development and Manufacturing Advanced Vaccination Technologies for Infectious and Chronic Diseases Nanoengineered Biomaterials for Advanced Drug Delivery Development of Biopharmaceutical Drug-Device Products Advanced Clinical Naturopathic Medicine Advanced Drug Delivery Poorly Soluble Drugs Nanopharmaceutical Advanced Delivery Systems Drug Delivery to the Brain Biologics, Biosimilars, and Biobetters Formulation of Monoclonal Antibody Therapies Developing Drug Products in an Aging Society Translating Molecular Biomarkers into Clinical Assays Smart Food Industry: The Blockchain for Sustainable Engineering Biosimilars Ophthalmic Product Development Pharmaco-Imaging in Drug and Biologics Development Dosage Form Design Considerations Challenges in Protein Product Development Pharmaceutical Formulations for Older Patients The Science and Regulations of Naturally Derived Complex Drugs Pharmaceutical Biotechnology □□□□□□□□□□□0.1□□□□ Contract Issues and Quality Standards for Managed Care Overcoming Obstacles in Drug Discovery and Development Antibody-Drug Conjugates Formulating Poorly Water Soluble Drugs Health Promotion and Disease Prevention for Advanced Practice: Integrating Evidence-Based Lifestyle Concepts Continuous Pharmaceutical Processing Pediatric Formulations Practical Statistics for Pharmaceutical Analysis FDA Bioequivalence Standards Microdialysis in Drug Development Regulated Bioanalysis: Fundamentals and Practice Non-Biological Complex Drugs Drug Product Development for the Back of the Eye

Sterile Product Development 2013-10-12

this comprehensive book encompasses various facets of sterile product development key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book formulation approaches that discuss a variety of dosage forms including protein therapeutics lipid based controlled delivery systems pegylated biotherapeutics nasal dosage form and vaccines process container closure and delivery considerations including freeze thaw process challenges best practices for technology transfer to enable commercial product development innovations and advancement in aseptic fill finish operations approaches to manufacturing lyophilized parenteral products pen auto injector delivery devices and associated container closure integrity testing hurdles for sterile product closures regulatory and quality aspects in the areas of particulate matter and appearance evaluation sterile filtration admixture compatibility considerations sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers this book is a useful resource to scientists and researchers in both industry and academia and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development

Disinfection and Decontamination *2018-11-20*

this book describes various methods of decontamination and how the methods work there is a discussion of the various cleaning and disinfection methods utilized along with details of how to qualify these methods it also describes new technologies that may be useful in the battle for decontamination across industries finally this book provides a single resource on how one can address contamination issues for a variety of manufacturing processes and industries explores new technologies that may be useful in the battle for decontamination examines various methods of decontamination and how the methods work addresses contamination issues for a variety of manufacturing processes and industries describes how to detect contaminants as well as how to deal with contaminants that are present includes methods for both decontamination reaction and preventing contamination proactive

Advanced Issue Resolution in Safety Pharmacology 2018-09-05

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

Innovative Dosage Forms *2019-12-04*

teaches future and current drug developers the latest innovations in drug formulation design and optimization this highly accessible practice oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies including the use of functional excipients to enhance solubility and stability it covers oral intravenous topical and parenteral administration routes the book also discusses safety aspects of drugs and excipients as well as regulatory issues relevant to formulation innovative dosage forms design and development at early stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development it then offers readers reliable strategies for the formulation development of poorly soluble drugs the book also studies the role of reactive impurities from the excipients on the formulation shelf life preclinical formulation assessment of new chemical entities and regulatory aspects for formulation design other chapters cover innovative formulations for special indications including oncology injectables delayed release and

depot formulations accessing pharmacokinetics of various dosage forms physical characterization techniques to assess amorphous nature novel formulations for protein oral dosage and more provides information that is essential for the drug development effort presents the latest advances in the field and describes in detail innovative formulations such as nanosuspensions micelles and cocrystals describes current approaches in early pre formulation to achieve the best in vivo results addresses regulatory and safety aspects which are key considerations for pharmaceutical companies includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design innovative dosage forms design and development at early stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists pharmaceutical chemists and pharmacologists

Principles and Practices of Lyophilization in Product Development and Manufacturing *2023-04-24*

the biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as antibody drug conjugates adcs bispecific t cell engager bites dual variable domain dvd chimeric antigen receptor modified tcells cart that are currently being used as therapeutic agents for immunology and oncology disease conditions in addition to other pharmaceuticals and biopharmaceuticals all these novel formats are fragile with respect to their stability structure under processing conditions meaning marginal stability in the liquid state and often require lyophilization to enhance their stability and shelf life this book contains chapters topics that will describe every aspect of the lyophilization process and product development and manufacturing starting from the overview of lyophilization process equipment required characterization of the material design and development of the formulation and lyophilization process various techniques for characterization of the product scale up tech transfer and validation it also describes the application of cfd coupled with mathematical modeling in the lyophilization process and product development scale up and manufacturing additionally principles and practice of lyophilization process and product development contains an entire dedicated section on preservation of biologicals comprised of nine chapters written by experts and including case studies

Advanced Vaccination Technologies for Infectious and Chronic Diseases *2024-03-25*

the role of vaccines is emerging and even critical to ending infectious and chronic diseases and pandemics alike the design and development of new vaccines could lead to improved health handbook on advanced vaccination technologies for infectious and chronic disease discusses these new developments and introduces the reader to the current state of the science and the outlook going forward from the discovery of vaccines to the clinical trials of personalized vaccines handbook on advanced vaccination technologies for infectious and chronic diseases is a valuable reference for occupational health professionals whose role involves supervision of immunization programs such as those working in the national health service some sectors of higher education and the pharmaceutical industry offers comprehensive coverage of different vaccine platforms and their development includes information on the regulatory perspective of vaccine development describes different delivery approaches for vaccinology explains the clinical development of vaccines along with novel platforms covers all recent developments of vaccine production technologies new types of vaccines and ongoing research that could prevent future pandemics

Nanoengineered Biomaterials for Advanced Drug Delivery *2020-06-17*

nanoengineered biomaterials for advanced drug delivery explores the latest advances in the applications of nanoengineered biomaterials in drug delivery systems the book covers a wide range of biomaterials and nanotechnology techniques that have been used for the delivery of different biological molecules and drugs in the human body it is an important resource for biomaterials scientists and engineers working in biomedicine and those wanting to learn more on how nanoengineered biomaterials are being used to enhance drug delivery for a variety of diseases nanoengineered biomaterials have enhanced properties that make them more effective than conventional biomaterials as both drug delivery agents and in the creation of new drug delivery systems as nanoengineering becomes more cost effective nanoengineered biomaterials have become more widely used within biomedicine offers an informed overview on how nanoengineering biomaterials enhance their properties for drug delivery applications discusses the major applications of nanoengineered biomaterials for drug delivery outlines the major challenges for successfully implementing nanoengineered biomaterials into existing drug delivery systems

Development of Biopharmaceutical Drug-Device Products *2020-03-13*

the biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as antibody drug conjugates adcs bispecific t cell engager bites dual variable domain dvd antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of quality by design qbd elements demonstrating an in depth understanding of product and process based on sound science drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products a survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development the new book entitled development of biopharmaceutical drug device products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies with insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products it covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them it also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design this involves the evolving regulatory framework with perspectives from both the us and eu industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device finally case studies are provided throughout the typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field

Advanced Clinical Naturopathic Medicine *2020-10-15*

advanced clinical naturopathic medicine engages the reader and evolves their knowledge and understanding from the fundamental clinical naturopathic medicine to a more specialised focus written by leah hechtman it concentrates on advanced topics commonly encountered in clinical practice including new advancements and cutting edge research as well as foundational aspects of clinical practice this new title showcases how transformative and effective naturopathy is and offers insight into the depth of naturopathic practice and its vital role in the healthcare system with the profession constantly evolving and naturopathy more often incorporated into specialty practices this publication is a timely resource to guide clinicians and students through complicated areas of expertise and specialisation while keeping the primary principle of patient centred care at the forefront of the reader s mind systematic text structure to support reader engagement that follows on from the clinical naturopathic medicine format integrative naturopathic treatments for all complex conditions and topics detailed and extensively referenced interaction tables for nutritional supplemental and dietary and herbal medicines plus pharmaceutical medications rigorously researched from the latest scientific papers and historical texts skilfully bridges foundational traditional principles and practice of naturopathy with evidence based medicine to assist readers with their integration into the current healthcare system enhanced ebook version included with purchase

Advanced Drug Delivery *2013-08-26*

provides both fundamentals and new and emerging applications advanced drug delivery brings readers fully up to date with the state of the science presenting the basics formulation strategies and therapeutic applications of advanced drug delivery the book demonstrates how core concepts of pharmaceutical sciences chemistry and molecular biology can be combined and applied in order to spark novel ideas to design and develop advanced drug delivery systems for the treatment of a broad range of human diseases advanced drug delivery features contributions from an international team of pharmaceutical scientists chapters reflect a thorough review and analysis of the literature as well as the authors firsthand experience developing drug delivery systems the book is divided into four parts part i

introduction and basics of advanced drug delivery explores physiological barriers stability transporters and biomaterials in drug delivery part ii strategies for advanced drug delivery offers tested and proven strategies for advanced delivery of both small molecules and macromolecules part iii translational research of advanced drug delivery focuses on regulatory considerations and translational applications of advanced drug delivery systems for the treatment of cardiovascular diseases cancer sexually transmitted diseases ophthalmic diseases and brain diseases part iv future applications of advanced drug delivery in emerging research areas examines stem cell research cell based therapeutics tissue engineering and molecular imaging each chapter provides objectives and assessment questions to help readers grasp key concepts and assess their knowledge as they progress through the book advanced drug delivery is recommended for graduates and upper level undergraduates in the pharmaceutical sciences who need a solid foundation in the basics it is also recommended for pharmaceutical professionals who want to take advantage of new and emerging applications in advanced drug delivery systems

Poorly Soluble Drugs *2017-01-06*

this book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations such drug products are vis à vis their physical and chemical properties inherently incompatible with aqueous dissolution however dissolution methods are required for product development and selection as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding the percentage of poorly soluble drugs defined in classes 2 and 4 of the biopharmaceutics classification system bcs has significantly increased in the modern pharmaceutical development pipeline this book provides a thorough exposition of general method development strategies for such drugs including instrumentation and media selection the use of compendial and non compendial techniques in product development and phase appropriate approaches to dissolution development emerging topics in the field of dissolution are also discussed including biorelevant and biphasic dissolution the use on enzymes in dissolution testing dissolution of suspensions and drug release of non oral products of particular interest to the industrial pharmaceutical professional a brief overview of the formulation and solubilization techniques employed in the development of bcs class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies including nanosuspensions lipid based formulations and stabilized amorphous drug formulations

Nanopharmaceutical Advanced Delivery Systems *2020-12-29*

the book provides a single volume covering detailed descriptions about various delivery systems their principles and how these are put in use for the treatment of multiple diseases it is divided into four sections where the first section deals with the introduction and importance of novel drug delivery system the second section deals with the most advanced drug delivery systems like microbubbles dendrimers lipid based nanoparticles nanofibers microemulsions etc describing the major principles and techniques of the preparations of the drug delivery systems the third section elaborates on the treatments of diverse diseases like cancer topical diseases tuberculosis etc the fourth and final section provides a brief informative description about the regulatory aspects of novel drug delivery system that is followed in various countries

Drug Delivery to the Brain 2013-12-03

the development of new cns drugs is notoriously difficult drugs must reach cns target sites for action and these sites are protected by a number of barriers the most important being the blood brain barrier bbb many factors are therefore critical to consider for cns drug delivery e g active passive transport across the bbb intra brain distribution and central systemic pharmacokinetics to name a few neurological disease and trauma conditions add further complexity because cns barriers drug distribution and pharmacokinetics are dynamic and often changed by disease trauma knowledge of all these factors and their interplay in different conditions is of utmost importance for proper cns drug development and disease treatment in recent years much information has become available for a better understanding of the many factors important for cns drug delivery and how they interact to affect drug action this book describes small and large drug delivery to the brain with an emphasis on the physiology of the bbb and the principles and concepts for drug delivery across the bbb and distribution within the brain it contains methods

descriptions for studying drug delivery routes and approaches of administering drugs into the brain the influence of disease and drug industry perspectives therewith it contributes to an in depth understanding of the interplay between brain patho physiology and drug characteristics furthermore the content is designed to be both cutting edge and educational so that the book can be used in high level training of academic and industry scientists with full references to original publications

Biologics, Biosimilars, and Biobetters 2021-01-05

a comprehensive primer and reference this book provides pharmacists and health practitioners the relevant science and policy concepts behind biologics biosimilars and biobetters from a practical and clinical perspective explains what pharmacists need to discuss the equivalence efficacy safety and risks of biosimilars with physicians health practitioners and patients about guides regulators on pragmatic approaches to dealing with these drugs in the context of rapidly evolving scientific and clinical evidence balances scientific information on complex drugs with practical information such as a checklist for pharmacists

Formulation of Monoclonal Antibody Therapies 2023-05-20

formulation of monoclonal antibody therapies from lab to market covers a wide range of topics about therapeutic monoclonal antibodies mabs with a focus on formulation aspects therapeutic monoclonal antibodies are used for treatment of chronic diseases it brings together a comprehensive knowledge in one accessible volume starting with foundational information on monoclonal antibodies the book then discusses the importance of biopharmaceutical products monoclonal antibodies and biosimilars in treatment of chronic diseases pharmaceutical aspects of mabs and how it can be administered it also covers the industrial point of view and the clinical application of mabs including in oncology general medicine rheumatology hematology dermatology gastrointestinal tract metabolic diseases and dentistry formulation of monoclonal antibody therapies from lab to market is essential reading for researchers in biotechnology and biopharmaceutical fields academics and pharmaceutical industrial scientists and university students in pharmaceutical and biopharmaceutical sciences covers details of recent advances in using mabs examines how to overcome the challenges for formulations of therapeutic mabs includes clinical application of mabs

Developing Drug Products in an Aging Society *2016-10-20*

this book aims to address the major aspects of future drug product development and therapy for older adults giving practical guidance for the rational product and clinical development and prescribing of drug products to this ever growing segment of the population with authors coming from key aging markets such as europe the usa china and japan the book will provide valuable information for students scientists regulators practitioners and other healthcare professionals from academia industry and regulatory bodies

Translating Molecular Biomarkers into Clinical Assays 2016-08-22

this handbook covers established and advanced techniques for biomarker analysis such as guidelines and strategies for assay validation methods different mathematical models that are necessary in contemporary drug discovery and development and evaluation of new cytometry methods expertly curated by two practicing professionals in drug development and biotherapeutics individual chapters are selected for novel and sound research information is chosen based on its relevance to lab applications and clinical trials such as the topic of selecting animal models for their relevancy to humans the book is multifaceted discussing the ethics and issues with biospecimens and providing an in depth analysis to the differences between pre clinical and clinical assay development the book is an essential read for general readers who need an introduction to the history and background of biomarkers and it also provides critical analyses of various new validation methods for practitioners and researchers

Smart Food Industry: The Blockchain for Sustainable Engineering *2023-12-01*

smart food industry the blockchain for sustainable engineering volume i fundamentals technologies and management is a comprehensive overview of the current state of knowledge about food engineering and processing under sustainable engineering perspective this book includes disruptive approaches that will potentially enable the food industry for the transition to sustainable production divided into four parts the book explores i fundamentals of sustainable food ii conventional technologies in the food industry iii sustainabile emerging technologies in food industries and iv sustainable management in food industries the book is an invaluable reference resource for students researchers graduates and professionals in general who wish to gain knowledge in the engineering and food processing area as well as about sustainable food industry practices

Biosimilars *2018-12-13*

this book provides a comprehensive overview of the biosimilar regulatory framework the development process and clinical aspects for development of biosimilars the development path of a biosimilar is just as unique as a development path of a new drug tailored by the mechanism of action the quality of the molecule published information on the reference product the current competitive environment the target market and regulatory guidance and most importantly the emerging totality of evidence for the proposed biosimilar during development for the ease of readers the book comprises of six sections as follows section i business health economics and intellectual property landscape for biosimilars section ii regulatory aspects of development and approval for biosimilars section iii biopharmaceutical development and manufacturing of biosimilars section iv analytical similarity considerations for biosimilars section v clinical aspects of biosimilar development section vi biosimilars global development and clinical experience chapters have been written by one or more experts from academia industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development the authors and editors have an expertise in commercialization and pricing of biosimilars intellectual property considerations for biosimilars chemistry manufacturing controls cmc and analytical development for biosimilars regulatory and clinical aspects of biosimilar development besides the industry practitioners the book includes several contributions from regulators across the globe

Ophthalmic Product Development *2022-03-11*

this is a comprehensive textbook addressing the unique aspects of drug development for ophthalmic use beginning with a perspective on anatomy and physiology of the eye the book provides a critical appraisal of principles that underlie ocular drug product development the coverage encompasses topical and intraocular formulations small molecules and biologics including protein and gene therapies conventional formulations including solutions suspensions and emulsions novel formulations including nanoparticles microparticles and hydrogels devices and specialty products critical elements such as pharmacokinetics influence of formulation technologies and ingredients as well as impact of disease conditions on products development are addressed products intended for both the front and the back of the eye are discussed with an eye towards future advances font face font family cambria math panose 1 2 4 5 3 5 4 6 3 2 4 mso font charset 0 mso generic font family roman mso font pitch variable mso font signature 3 0 0 0 1 0 font face font family calibri panose 1 2 15 5 2 2 2 4 3 2 4 mso font charset 0 mso generic font family swiss mso font pitch variable mso font signature 469750017 1073732485 9 0 511 0 p msonormal li msonormal div msonormal mso style unhide no mso style qformat yes mso style parent margin 0cm mso pagination widow orphan font size 12 0pt font family times new roman serif mso fareast font family calibri mso fareast theme font minor latin mso ansi language en us mso fareast language en us msochpdefault mso style type export only mso default props yes font family calibri sans serif mso ascii font family calibri mso ascii theme font minor latin mso fareast font family calibri mso fareast theme font minor latin mso hansi font family calibri mso hansi theme font minor latin mso bidi font family times new roman mso bidi theme font minor bidi mso ansi language en us mso fareast language en us div wordsection1 page wordsection1

Pharmaco-Imaging in Drug and Biologics Development 2013-11-08

the volume aim to be a comprehensive overview of the drug and biologic development process that is often called the valley of death pre ind through approval where high costs of studies and high rates of product failure are part of the drug development landscape imaging tools can serve in this period by adding high value data the images and the kinetic information they can provide and cost effective development alternative tools which potentially improve pivotal study designs imaging may identify safety issues early such as unwanted organ or tissue distributions and then can serve advanced development with added certainty of a drug or biologic s success to senior corporate management and investors there are numerous textbooks reference texts and treatises on medical imaging technologies teaching tools on medical cases and physics books on the science of detector and computer interface systems rarely in each of these are examples of medical imaging protocols and animal models of disease i e a text on methodology in drug development is currently unavailable

Dosage Form Design Considerations *2018-07-28*

dosage form design parameters volume i examines the history and current state of the field within the pharmaceutical sciences presenting key developments content includes drug development issues the scale up of formulations regulatory issues intellectual property solid state properties and polymorphism written by experts in the field this volume in the advances in pharmaceutical product development and research series deepens our understanding of dosage form design parameters chapters delve into a particular aspect of this fundamental field covering principles methodologies and the technologies employed by pharmaceutical scientists in addition the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnology and related industries examines the history and recent developments in drug dosage forms for pharmaceutical sciences focuses on physicochemical aspects prefomulation solid state properties and polymorphism contains extensive references for further discovery and learning that are appropriate for advanced undergraduates graduate students and those interested in drug dosage design

Challenges in Protein Product Development *2018-06-20*

in this volume the authors discuss the many significant challenges currently faced in biotechnology dosage form development providing guidance shared experience and thoughtful reflection on how best to address these potential concerns as the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs often the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability manufacturing and preclinical or clinical expectations as well as the evolving regulatory expectations and landscape further there have been new findings that require close assessment as for example those related to excipient quality processing viscosity and device compatibility and administration solubility and opalescence and container closure selection the literature varies widely in its discussion of these critical elements and consensus does not exist this topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally therefore this book is of interest for business leaders researchers formulation and process development scientists analytical scientists qa and qc officers regulatory staff manufacturing leaders and regulators active in the pharmaceutical and biotech industry and expert reviewers in regulatory agencies

Pharmaceutical Formulations for Older Patients *2023-12-12*

pharmaceutical formulation design affects patient acceptability adherence and pharmacokinetics of the drug this is particularly important for older patients because of the physiological changes due to ageing and clinical social circumstances related to medicine taking this book provides a comprehensive review in the design of formulations to meet the needs of older patients an overview of the key clinical social and pharmaceutical factors affecting medication optimization safety and acceptability in older adults is included followed by patient centric considerations including regulatory requirements dosage form design and human factor studies advanced pharmaceutical technologies are discussed for their potential use in older adults such as 3d printing long acting oral formulations and novel vaccine

technologies the unique focus of the book will be of interest to pharmaceutical scientists in both industry and academia in searching for better formulations for older patients

The Science and Regulations of Naturally Derived Complex Drugs *2019-04-23*

this volume in the aaps advances series covers various quality safety and clinical aspects of drug development that are relevant to new and or generic drugs containing a complex mixture of molecules specific topics discussed include raw materials sourcing manufacturing controls characterization identification of critical product quality components and attributes identification of impurities particularly as they bear on toxicity and immunogenicity clinical trial study design considerations and the regulatory science applications to development of such complex mixtures complex mixtures are challenging to characterize and analyze using standard methods further challenges extend throughout the product development cycle from raw material control to clinical study design the regulatory landscape is rapidly changing as new types of complex mixtures are introduced into clinical trials and to the market e g traditional chinese medicines and medical marijuana products while older products are facing generic competition for the first time e g enoxaparin the future outlook for complex generic drug products as opposed to the more commonly developed targeted single agent drug products is not clear the risks pertaining to lack of a full understanding of raw material control process and controls in manufacture as well as characterization of a complex mixture were seen vividly during the heparin crisis of 2008 as such powerful lessons have been learned about the regulatory science specific to complex products the science and regulations of naturally derived complex drugs addresses the interests among industry academics and government on the issues surrounding the future development of mixtures for medicinal use

Pharmaceutical Biotechnology *2019-04-13*

this introductory text explains both the basic science and the applications of biotechnology derived pharmaceuticals with special emphasis on their clinical use it serves as a complete one stop source for undergraduate graduate pharmacists pharmaceutical science students and for those in the pharmaceutical industry the fifth edition completely updates the previous edition and also includes additional coverage on the newer approaches such as oligonucleotides sirna gene therapy and nanotech and enzyme replacement therapy

新薬の狩人たち□成功率0.1%の探求 *2018-06-15*

ケシの実 青カビ ブタの膵臓 人類はあらゆる材料を駆使して新薬を創りだしてきた 創薬の第一線で35年にわたり活躍する研究者が 先人たちの飽くなき挑戦の歴史を描き出す 薬に対するあなたの理解を一変させる科学ノンフィクション 解説 佐藤健太郎

Contract Issues and Quality Standards for Managed Care *1996*

overcoming obstacles in drug discovery and development uses real world case studies to illustrate how critical thinking and problem solving skills are applied in the discovery and development of drugs it also shows how developing critical thinking to overcome issues plays an essential role in the process modern drug discovery and development is a highly complex undertaking that requires scientific and professional expertise to be successful after the identification of a molecular entity for treating a medical condition challenges inevitably arise during the subsequent development to understand and characterize the biological profile feedback from scientists is used to fine tune the molecular entity to obtain an effective and safe product in this process the discovery team may identify unexpected safety issues and new medical disorders for treatment by the molecular entity invariably inherent in this complex undertaking are miscues mistakes and unexpected problems that can derail development and throw timetables into disarray potentially leading to failure in the development of a medically useful drug addressing critical unexpected problems during development often requires scientists to utilize critical thinking and imaginative problem solving skills overcoming obstacles in drug discovery and development will be essential to young scientists to help learn the skills to successfully face challenges learn from mistakes and further develop critical thinking skills it will also be beneficial to experienced researchers who can learn from the case studies of successful and unsuccessful drug development provides real world case studies in drug discovery and the development of drugs illustrates the use of critical thinking and problem solving in approaching

preclinical and clinical problems in drug discovery and development illustrates and analyses examples of successes and failures in drug discovery and development that have not previously been reported

Overcoming Obstacles in Drug Discovery and Development *2023-05-18*

providing practical and proven solutions for antibody drug conjugate adc drug discovery success in oncology this book helps readers improve the drug safety and therapeutic efficacy of adcs to kill targeted tumor cells discusses the basics drug delivery strategies pharmacology and toxicology and regulatory approval strategies covers the conduct and design of oncology clinical trials and the use of adcs for tumor imaging includes case studies of adcs in oncology drug development features contributions from highly regarded experts on the frontlines of adc research and development

Antibody-Drug Conjugates *2016-11-14*

the objective of this volume is to consolidate within a single text the most current knowledge practical methods and regulatory considerations pertaining to formulations development with poorly water soluble molecules a pharmaceutical scientist s approach toward solubility enhancement of a poorly water soluble molecule typically includes detailed characterization of the compound s physiochemical properties solid state modifications advanced formulation design non conventional process technologies advanced analytical characterization and specialized product performance analysis techniques the scientist must also be aware of the unique regulatory considerations pertaining to the non conventional approaches often utilized for poorly water soluble drugs one faced with the challenge of developing a drug product from a poorly soluble compound must possess at minimum a working knowledge of each of the abovementioned facets and detailed knowledge of most in light of the magnitude of the growing solubility problem to drug development this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop

Formulating Poorly Water Soluble Drugs 2016-12-16

health promotion and disease prevention for advanced practice integrating evidence based lifestyle concepts addresses concepts to change the trajectory of healthcare in the united states and globally it provides practical evidence based approaches to reduce the pandemic of preventable lifestyle related chronic diseases such as type 2 diabetes which cause 85 of ill health and 80 of healthcare costs in the united states this unique text takes a deep dive into the literature regarding lifestyle concepts and practical management of lifestyle related chronic diseases it addresses the root causes of diseases and approaches for patient centered care strategies for health promotion reimbursement and trending telehealth delivery of health care health promotion and disease prevention for advanced practice integrating evidence based lifestyle concepts is the only resource that provides evidence based practical approaches to encouraging patient adherence to healthy behaviors

Health Promotion and Disease Prevention for Advanced Practice: Integrating Evidence-Based Lifestyle Concepts *2023-10-13*

continuous pharmaceutical manufacturing is currently receiving much interest from industry and regulatory authorities with the joint aim of allowing rapid access of novel therapeutics and existing medications to the public without compromising high quality research groups from different academic institutions have significantly contributed to this field with an immense amount of published research addressing a variety of topics related to continuous processing the book is structured to have individual chapters on the different continuous unit operations involved in drug substance and drug product manufacturing a wide spectrum of topics are covered including basic principles of continuous manufacturing applications of continuous flow chemistry in drug synthesis continuous crystallization continuous drying feeders and blenders roll compaction and continuous wet granulation the underlying theme for each of these chapters is to present to the reader

the recent advances in modeling experimental investigations and equipment design as they pertain to each individual unit operation the book also includes chapters on quality by design qbd and process analytical technology pat for continuous processing process control strategies including new concepts of quality by control qbc real time process management and plant optimization business and supply chain considerations related to continuous manufacturing as well as safety guidelines related to continuous chemistry a separate chapter is dedicated to discussing regulatory aspects of continuous manufacturing with description of current regulatory environment quality gmp aspects as well as regulatory gaps and challenges our aim from publishing this book is to make it a valuable reference for readers interested in this topic with a desire to gain a fundamental understanding of engineering principles and mechanistic studies utilized in understanding and developing continuous processes in addition our advanced readers and practitioners in this field will find that the technical content of continuous pharmaceutical processing is at the forefront of recent technological advances with coverage of future prospects and challenges for this technology

Continuous Pharmaceutical Processing *2020-06-10*

until the 1990s it was generally accepted that medicines were first developed for adults and their use in children was investigated later if at all one of the main tasks of hospital pharmacies was the manufacturing of child appropriate formulations in a more or less makeshift way the first change came in 1997 with u s legislation that rewarded manufacturers to do voluntary pediatric research ten years later the european union passed legislation that required manufacturers to discuss all pediatric aspects including formulations with the regulatory authorities as a condition of starting the registration procedure in consequence manufacturers must now cover all age groups including the youngest ones so far pediatric formulations were more a focus for academic researchers through the changed regulatory environment there is now a sudden high commercial demand for age appropriate formulations this book begins by highlighting the anatomical physiological and developmental differences between adults and children of different ages it goes on to review the existing technologies and attempts to draw a roadmap to better innovative formulations in particular for oral administration the regulatory clinical ethical and pharmaceutical framework is also addressed

Pediatric Formulations *2014-01-30*

this is an introductory statistics book designed to provide scientists with practical information needed to apply the most common statistical tests to laboratory research data the book is designed to be practical and applicable so only minimal information is devoted to theory or equations emphasis is placed on the underlying principles for effective data analysis and survey the statistical tests it is of special value for scientists who have access to minitab software examples are provides for all the statistical tests and explanation of the interpretation of these results presented with minitab similar to results for any common software package the book is specifically designed to contribute to the aaps series on advances in the pharmaceutical sciences it benefits professional scientists or graduate students who have not had a formal statistics class who had bad experiences in such classes or who just fear don t understand statistics chapter 1 focuses on terminology and essential elements of statistical testing statistics is often complicated by synonyms and this chapter established the terms used in the book and how rudiments interact to create statistical tests chapter 2 discussed descriptive statistics that are used to organize and summarize sample results chapter 3 discussed basic assumptions of probability characteristics of a normal distribution alternative approaches for non normal distributions and introduces the topic of making inferences about a larger population based on a small sample from that population chapter 4 discussed hypothesis testing where computer output is interpreted and decisions are made regarding statistical significance this chapter also deasl with the determination of appropriate sample sizes the next three chapters focus on tests that make decisions about a population base on a small subset of information chapter 5 looks at statistical tests that evaluate where a significant difference exists in chapter 6 the tests try to determine the extent and importance of relationships in contrast to fifth chapter chapter 7 presents tests that evaluate the equivalence not the difference between levels being tested the last chapter deals with potential outlier or aberrant values and how to statistically determine if they should be removed from the sample data each statistical test presented includes an example problem with the resultant software output and how to interpret the results minimal time is spent on the mathematical calculations or theory for those interested in the associated equations supplemental figures are presented for each test with respective formulas in addition appendix d presents the equations and proof for every output result for the various examples examples and results from the appropriate statistical results are displayed using minitab 18Ò in addition to the results the required steps to analyze data using minitab are presented with the examples for those having access to this software numerous other software packages are available including based data analysis with excel

Practical Statistics for Pharmaceutical Analysis 2019-12-10

this comprehensive reference provides an in depth discussion on state of the art regulatory science in bioequivalence in sixteen chapters the volume explores a broad range of topics pertaining to bioequivalence including its origin and principles statistical considerations food effect studies conditions for waivers of bioequivalence studies biopharmaceutics classification systems biopharmaceutics drug disposition classification system bioequivalence modeling simulation and best practices in bioanalysis it also discusses bioequivalence studies with pharmacodynamic and clinical endpoints as well as bioequivalence approaches for highly variable drugs narrow therapeutic index drugs liposomes locally acting gastrointestinal drug products topical products and nasal and inhalation products fda bioequivalence standards is written by fda regulatory scientists who develop regulatory policies and conduct regulatory assessment of bioequivalence as such both practical case studies and fundamental science are highlighted in these chapters the book is a valuable resource for scientists who work in the pharmaceutical industry regulatory agencies and academia as well as undergraduate and graduate students looking to expand their knowledge about bioequivalence standards

FDA Bioequivalence Standards 2014-09-05

a vast number of diagnostic and therapeutic decisions are based on measuring blood concentrations of molecules yet most biochemical and pharmacological events actually take place in the tissues microdialysis is a key semi invasive sampling technique to measure in vivo drug penetration to the target site in humans the method being feasible in virtually every organ authored by international experts in this cutting edge field this book will provide a comprehensive overview of microdialysis and its application for measuring drug distribution in drug development

Microdialysis in Drug Development *2012-09-13*

the editors have engaged leading scientists in the field to participate in the development of this book which is envisioned as a one of a kind contribution to the field the book is a comprehensive text that puts fundamental bioanalytical science in context with current practice its challenges and ongoing developments it expands on existing texts on the subject by covering regulated bioanalysis of both small and large molecule therapeutics from both a scientific and regulatory viewpoint the content will be useful to a wide spectrum of readers from those new to bioanalysis to those developing their experience in the laboratory or working in one of the many critical supporting roles to seasoned practitioners looking for a solid source of information on this exciting and important discipline

Regulated Bioanalysis: Fundamentals and Practice 2017-04-24

the rise of bio and nano technology in the last decades has led to the emergence of a new and unique type of medicine known as non biological complex drugs nbcds this book illustrates the challenges associated with nbcd development as well as the complexity of assessing the effects of manufacturing changes on innovator and follow on batches of nbcds it also touches upon proven marketing authorization requirements for biosimilars that could be effective in evaluating follow on nbcds including a demonstration of control over the manufacturing process and a need for detailed physico chemical characterization and pre clinical tests this book is meant to be used for years to come as a standard reference work for the development of nbcds moreover this book aims to stimulate discussions and further our thinking to ensure that decisions regarding the approval of complex drugs are made with relevant scientific data on the table

Non-Biological Complex Drugs *2015-06-24*

this comprehensive volume discusses approaches for a systematic selection of delivery systems for various classes of therapeutic agents including small molecule protein and nucleic acid drugs specific topics covered in this book include solution suspension gel nanoparticle microparticle and implant dosage forms refillable and microneedle devices intravitreal suprachoroidal intrascleral transscleral systemic and topical routes of delivery physical methods including iontophoresis for drug delivery rational selection of routes of administration and delivery systems noninvasive and continuous drug monitoring regulatory path to drug product

development clinical endpoints for drug product development emerging and existing drugs and drug targets drug product development for the back of the eye is authored by renowned ocular drug delivery experts representing academic clinical and industrial organizations and serves as indispensable resource for ophthalmic researchers drug formulation scientists drug delivery and drug disposition scientists as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases this book is also relevant for students in various disciplines including ophthalmology pharmaceutical sciences drug delivery and biomedical engineering refillable and microneedle devices intravitreal suprachoroidal intrascleral transscleral systemic and topical routes of delivery physical methods including iontophoresis for drug delivery rational selection of routes of administration and delivery systems noninvasive and continuous drug monitoring regulatory path to drug product development clinical endpoints for drug product development emerging and existing drugs and drug targets drug product development for the back of the eye is authored by renowned ocular drug delivery experts representing academic clinical and industrial organizations and serves as indispensable resource for ophthalmic researchers drug formulation scientists drug delivery and drug disposition scientists as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases this book is also relevant for students in various disciplines including ophthalmology pharmaceutical sciences drug delivery and biomedical engineering refillable and microneedle devices intravitreal suprachoroidal intrascleral transscleral systemic and topical routes of delivery physical methods including iontophoresis for drug delivery rational selection of routes of administration and delivery systems noninvasive and continuous drug monitoring regulatory path to drug product development clinical endpoints for drug product development emerging and existing drugs and drug targets drug product development for the back of the eye is authored by renowned ocular drug delivery experts representing academic clinical and industrial organizations and serves as indispensable resource for ophthalmic researchers drug formulation scientists drug delivery and drug disposition scientists as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases this book is also relevant for students in various disciplines including ophthalmology pharmaceutical sciences drug delivery and biomedical engineering

Drug Product Development for the Back of the Eye 2011-08-03

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