Handbook Of Bioequivalence Testing Second Edition Drugs And The Pharmaceutical Sciences

KIRSTEN SMALL

Topical Drug Bioavailability, Bioequivalence, and Penetration CRC Press
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
Patient Safety in Developing Countries CRC Press
As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have m
Handbook of Bioequivalence Testing CRC Press
Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutica
Good Laboratory Practice for Nonclinical Studies Wiley
This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.
Continuous Pharmaceutical Processing and Process Analytical Technology CRC Press
Project managers in drug development are the driving force behind the coordination of efforts. This book provides a practical reference for project managers in the pharmaceutical and biotech drug development industry, with the goal of assisting in creating an efficient and effective team structure and environment. The text details the role of project managers at each stage of drug development, the key interfaces that the PM will need to work closely with, and essential tools of the trade including frequently used techniques and methodologies. This book is useful for both entry-level and advanced-level PMs, as well as non-project managers from other functions. Features Includes authors' recent experience with improved tactics and technologies/software at various stages of drug development. Provides the most up-to-date and best practices, techniques, and methodologies in project management. Details the role of the PM at each stage of drug development, including working with the key interfaces throughout the process. Diverse audience including nonproject managers in clinical development, clinical operations, regulatory affairs, medical affairs, clinical pharmacology, and biostatistics. Provides templates and timelines for critical paths from development to commercialization and has potential as a textbook on relevant courses.
Neuropsychopharmacology CRC Press
The GLP regulations have been enacted since 1978 and are currently under a proposed FDA amendment to revise terminology and accommodate other changes relating to advances in technology related to the industry. This book provides a unique opportunity to access interpretation of the 21CFR58 regulatory requirements from leading industry experts with a vast knowledge and expertise in their fields. The approach used takes the regulations, provides interpretations and references to examples and regulatory actions. Data integrity and the use of electronic systems in compliance with 21CFR11 Electronic Records: Electronic Signatures are also discussed. • Unique volume covering FDA inspections of GLP facilities • Provides a detailed interpretation of GLP Regulations • Presents the latest on electronic data management in GLP • Describes GLP and computer systems validation • Can be referenced repeatedly in supporting daily hands on implementation of the CFR requirements
Pharmaceutical Statistics CRC Press
The over-riding premise for biotechnology in this book is bringing novel products to market to substantially advance patient care and disease mitigation. Biotechnology, over its relatively brief existence of 40 years, has experienced a mercurial growth. The vast educational need for biotechnology information in this rapidly burgeoning field is a basic rationale here. However a more prominent underpinning is that, bringing biotech products to market for patient care involves success in the following four areas of engagement simultaneously - scientific advances for healthcare technologies, novel and varied products for untreated diseases, regulatory authorities, and biotech companies. Features Comprehensive coverage of biotechnology science topics used in development and manufacturing Addresses all the scientific technologies within biotechnology responsible for products on the market and the pipeline Presents business issues such as marketing and sales of the products, as well as companies engaged, and how biotech business has evolved
Handbook of Pharmaceutical Granulation Technology CRC Press
This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.
Gene Delivery CRC Press
Theoretical discussions covering granulation and engineering perspectives. Covers new advances in expert systems, process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies
Modern Pharmaceutics, Two Volume Set CRC Press
Dissolution testing is used in the pharmaceutical industry to determine a drug's bioavailability and the bioequivalence of two drugs. Hanson details the techniques used, and provides guidelines for starting and operating a program. First published "nearly ten years ago." Available from Aster Publishing Corporation, 859 Willamette Street, Eugene OR 97440. Annotation copyrighted by Book News, Inc., Portland, OR
Good Design Practices for GMP Pharmaceutical Facilities CRC Press
This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan

Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. Iain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

The Future of Pharmaceuticals CRC Press

Gene delivery is a transport of genes of therapeutic values into the chromosomes of the cells or tissues which can be targeted to replace the faulty genes. In last two decades lot of research efforts are dedicated to gene delivery for therapeutic applications. Today gene therapy is promising approach in treatment of genetic diseases including mitochondrial related diseases like blindness, muscular dystrophy, cystic fibrosis, and some cancers. Gene Delivery Systems: Nano Delivery Technologies observes the exploration of nanotechnology for gene therapy and gene delivery. Written by prominent authors in the field, this book covers various aspects of gene delivery including challenges in delivering gene therapy, advances in genome editing, RNA-based gene therapy, Green nanoparticles for oligonucleotide delivery. Additional features include" Provides the most up to date information on the development of gene therapy, from the technology involved to gene correction and genome editing. Includes knowledge of the current application of CRISPR/Cas9 gene-editing technique; an approach that has recently been given the Noble Prize. Examines the development of mRNA vaccines for Covid -19 in challenging pandemic scenario Discusses siRNA, mRNA, and DNA plasmids.

Pharmaceutical Inhalation Aerosol Technology, Third Edition CRC Press

The first edition of Pharmaceutical Extrusion Technology, published in 2003, was deemed the seminal book on pharmaceutical extrusion. Now it is expanded and improved, just like the usage of extrusion has expanded, improved and evolved into an accepted manufacturing technology to continuously mix active pharmaceutical ingredients with excipients for a myriad of traditional and novel dosage forms. Pharmaceutical Extrusion Technology, Second Edition reflects how this has spawned numerous research activities, in addition to hardware and process advancements. It offers new authors, expanded chapters and contains all the extrusion related technical information necessary for the development, manufacturing, and marketing of pharmaceutical dosage forms. Key Features: Reviews how extrusion has become an accepted technology to continuously mix active pharmaceutical ingredients with excipients Focuses on equipment and process technology Explains various extrusion system configurations as a manufacturing methodology for a variety of dosage forms Presents new opportunities available only via extrusion and future trends Includes contributions of experts from the process and equipment fields

Handbook of Pharmaceutical Manufacturing Formulations CRC Press

What’s the Deal with Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Strategic Elements explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters. This includes principal patents and intellectual property, regulatory pathways, and concerns about affordability on a global scale. It addresses the complexity of biosimilar products, and it discusses the utilization of biosimilars and related biological drugs in expanding world markets. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume examines the science, technology, finance, legality, ethics, and politics of biosimilar drugs. It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars, and it provides detailed descriptions of the legal, regulatory, and commercial characteristics. The book also presents a global strategy on how to build, take to market, and manage the next generation of biosimilars throughout their life cycle.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition CRC Press

Describes technologies that are significantly enhancing the delivery of drugs and biologics Presents new data on mobile and wearable point-of-care testing systems Features hot topics such as electrospinning, 3D printing and micro-needles Focuses on additive manufacturing (AM) which can be used to provide customized treatment for patients Will appeal to experienced researchers and those considering entering the field of emerging technologies for the manufacturing of drug delivery devises

Handbook of Basic Pharmacokinetics-- Including Clinical Applications CRC Press

This new edition brings you up-to-date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceutics helps you stay current

International Pharmaceutical Product Registration, Second Edition CRC Press

Aqueous-based film coating has become routine in the pharmaceutical industry. This process eliminates the use of organic solvents and thus avoids economic, environmental, and toxicological issues related to residual solvents and solvent recovery. Aqueous-based coating, however, is complex and many variables may impact the final product and its performance. This fourth edition of Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms aims to provide insight into the factors and parameters that should be considered and controlled for the successful development and commercialization of a coated product. The fourth edition has been revised and expanded to reflect the most recent scientific advancements from the literature. The contributing authors explain in detail, using illustrated examples, appropriate steps to solve and ideally avoid formulation, processing, and stability problems and to achieve an optimized dosage form. Trade names and chemical names of commercially marketed coatings are used throughout the text to help familiarize the reader with the various materials available for pharmaceutical applications. This book will be a valuable resource for anyone in the pharmaceutical industry working in the area of aqueous-based film coating.

Biosimilarity Elsevier

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent.

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition CRC Press

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Purification of Biotechnological Products CRC Press

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made

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