Division Of Bioequivalence Review Anda No Drug Product

Organizational Telephone DirectoryLocation DirectoryFDA Quality Standards for Generic Drug ProductsAcademic 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.

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 therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

Praise for the First Edition of Design and Analysis of Clinical Trials "An excellent book, providing a discussion of the clinical trial process from designing the study through analyzing the data, and to regulatory requirement . . . could easily be used as a classroom text to understand the process in the new drug development area." –Statistical Methods in Medicine A complete and balanced presentation now revised, updated, and expanded As the field of research possibilities expands, the need for a working understanding of how to carry out clinical trials only increases. New developments in the theory and practice of clinical research include a growing body of literature on the subject, new technologies and methodologies, and new guidelines from the International Conference on Harmonization (ICH). Design and Analysis of Clinical Trials, Second Edition provides both a comprehensive, unified presentation of principles and methodologies for various clinical trials, and a well-balanced summary of current regulatory requirements. This unique resource bridges the gap between clinical and statistical disciplines, covering both fields in a lucid and accessible manner. Thoroughly updated from its first edition, the Second Edition of Design and Analysis of Clinical Trials features new topics such as: Clinical trials and regulations, especially those of the ICH Clinical significance, reproducibility, and generalizability Goals of clinical trials and target population New study designs and trial types Sample size determination on equivalence and noninferiority trials, as well as comparing variabilities Also, three entirely new chapters cover: Designs for cancer clinical trials Preparation and implementation of a clinical protocol Data management of a clinical trial Written with the practitioner in mind, the presentation assumes only a minimal mathematical and statistical background for its reader. Instead, the writing emphasizes real-life examples and illustrations from clinical case studies, as well as numerous references-280 of them new to the Second Edition-to the literature. Design and Analysis of Clinical Trials, Second Edition will benefit academic, pharmaceutical, medical, and regulatory scientists/researchers, statisticians, and graduate-level students in these areas by serving as a useful, thorough reference source for clinical research.

The thoroughly revised Fifth Edition of New Drug Approval Process supplies readers with the latest global changes that affect pharmaceutical product approval and influence how new products are researched and marketed.Updated chapters include:advances in international regulatory requirements, including ICH guidelines and harmonizationa step-by-step

Providing methodologies that can serve as a reference point for new formulations, the second volume covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution, and other similar products.Highlights from Uncompressed Solid Products, Volume Two include:the fundamental issues of good manufacturin

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Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and

technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Marking the 200th National Meeting of the American Chemical Society, The Division of Nuclear Chemistry and Technology hosted a group of about 90 scientists from 15 different countries to discuss the new trends in radiopharmaceutical synthesis, quality assurance and regulatory control. This event took place in Washington, D.C. on August 27-30, 1990. When I first suggested the idea for this symposium, a group of scientists who pioneered the proposed topics offered their help to organize and run such a big task with me. Their names are listed here in appreciation. Thomas E. Boothe Cyclotron Facility, Mt. Sinai Medical Center, Miami Beach, Florida, USA Robert F. Dannals Division of Nuclear Medicine, The Johns Hopkins Medical Institutions, Baltimore, Maryland, USA Anthony L. Feliu Julich Nuclear Research Center, Julich, Germany Joanna S. Fowler Chemistry Department, Brookhaven National Laboratory, Upton, New York, USA George W. Kabalka Department of Chemistry, University of Tennessee, Knoxville, Tennessee, USA Hank F. Kung Department of Radiology, University of Pennsylvania, Philadelphia, Pennsylvania, USA James F. Lamb Imagents, Inc., Houston, Texas, USA Harold A. O'Brien, Jr. Los Alamos National Laboratory, Los Alamos, New Mexico, USA Joseph R. Peterson Dept. of Chemistry, University of Tennessee, Knoxville, Tennessee, USA Hernan Vera Ruiz International Atomic Energy Agency, Vienna, Austria Roy S. Tilbury University of Texas, M. D. Anderson Cancer Center, Houston, Texas, USA In addition, a number of distinguished colleagues have participated in the process of reviewing the manuscripts presented in this volume. Their effort is sincerely acknowledged.

FDA Quality Standards for Generic Drug Products features the history and evolution of the FDA’s generic drug program, along with an overview of the quality assessment process performed by the FDA and an in-depth look at quality standards for a variety of dosage forms. Chapters cover important topics such as quality by design, the ANDA structure, CMC, process analytical technology and other emerging technologies, design of experiments and statistics and the similarities and differences between the FDA and international regulatory agencies. Edited and written by experienced leaders in the field, this book contains case studies throughout and provides insider perspectives on what the future may hold for generic drugs. An essential resource for pharmaceutical, regulatory and academic scientists, this book can be used to establish the necessary procedures and specifications in order to seek approval to develop quality products more quickly and easily. Highlights recent developments regarding quality by design and quality standards associated with particular dosage forms, including complex generic drug products Offers an overview of the FDA’s current assessment process for ANDAs, from filing to approval, and discuses important considerations regarding post-approval changes and lifecycle management Written by FDA scientists who actively review ANDAs and develop regulatory policies associated with generic drugs

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined.The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.