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KEY=PRA - INGRID CARRILLO

Method Validation in Pharmaceutical Analysis

A Guide to Best Practice

John Wiley & Sons Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Good Design Practices for GMP Pharmaceutical Facilities

CRC Press 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.

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition

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.

Sterile Processing of Pharmaceutical Products

Engineering Practice, Validation, and Compliance in Regulated Environments

John Wiley & Sons Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and

manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.

Analytical Testing for the Pharmaceutical GMP Laboratory

John Wiley & Sons Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations, working processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations. Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource: Describes the structure, roles, core guidelines, and GMP regulations of the FDA and ICH. Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs. Examines control strategies established from quality systems supported by real-world case studies. Explains the use of dissolution testing for products such as extended-release capsules, aerosols, and inhalers. Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance. Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations. Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs). Analytical Testing for the Pharmaceutical GMP Laboratory is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.

Introduction to Toxicological Screening Methods and Good Laboratory Practice

Springer Nature This book focuses on the principles, methods, and interpretation involved in establishing the safety, risk, and hazard assessment of small molecules. It presents the regulatory requirements for risk and hazard identification as per the guidelines of the Organization for Economic Cooperation and Development (OECD), Paris, and the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use ICH and Schedule Y, India. It serves as reference material for undergraduate and postgraduate pharmacy degree students as well as senior researchers to learn about the principles, methods, and interpretations of systemic dosage (acute and repeated dose) and genotoxicity (in vitro and in vivo), special toxicological investigations such as reproductive and developmental toxicology, carcinogenicity, and toxicokinetics using animal models or in vitro methods, as applicable. This book is the first of its kind in providing information on the principles and methods of implementation of Good Laboratory Practice based on the guidelines of OECD. It includes detailed chapters about the regulatory requirements and guidelines in pharmaceutical products and agrochemicals. It also describes the infrastructure needed for preclinical studies, including in vivo and in vitro facilities.

Handbook of Stability Testing in Pharmaceutical Development

Regulations, Methodologies, and Best Practices

Springer Science & Business Media This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Good Clinical Practice eRegs & Guides - For Your Reference Book 3

eRegs And Guides Good Clinical Practice eRegs & Guides provides a reference to key US FDA Guides and regulations via your electronic reader. An excellent way to access the reference documents on your e-reader. No need to carry paper books and you can search for key terms. In this issue you will find: ICH Q8 Pharmaceutical Development ICH Q9 Quality Risk Management ICH Q10 Pharmaceutical Quality System

The Clinical Practice of Drug Information

Jones & Bartlett Publishers "This resource will educate students and pharmacists on traditional drug information topics while providing an extensive background on more recent practice areas. This is a user-friendly text with multiple examples that can be used in education and training, as well as clinical practice. Each chapter includes learning objectives, key terms, example

Policies and Methods Used by Federal Departments to Award Recognition to Drug Abuse Prevention Programs

DIANE Publishing An examination of the policies & methods used by the Departments of Education & Health & Human Services to award federal recognition to drug abuse prevention programs. Charts & tables.

Pharmacy Practice Research Methods

Springer Nature The first edition of Pharmacy Practice Research Methods provided a contemporary overview of pharmacy practice research, discussing relevant theories, methodologies, models and techniques. It included chapters on a range of quantitative, qualitative, action research and mixed methods as well as management theories underpinning change in pharmacy practice. This new edition of the book is much broader and more diversified. It includes the quality improvement methods in pharmacy practice research, focusing on the key differences between high and low-income countries with regard to pharmacy practice research, as well as the main challenges faced when conducting such research – areas of significant global interest. In addition, a number of the chapters covering fast-moving fields where new methods have been developed and published have been updated. Featuring seven new topics and presenting future trends, the book also explains in detail methods used in covert and overt observations in pharmacy practice, as well as methods involved in realist research, which are important to countries seeking to produce evidence-based information in this area.

Leachables and Extractables Handbook

Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products

John Wiley & Sons A practical and science-based approach for addressing toxicological concerns related to leachables and extractables associated with inhalation drug products Packaging and device components of Orally Inhaled and Nasal Drug Products (OINDP)—such as metered dose inhalers, dry powder inhalers, and nasal sprays—pose potential safety risks from leachables and extractables, chemicals that can be released or migrate from these components into the drug product. Addressing the concepts, background, historical use, and development of safety thresholds and their utility for qualifying leachables and extractables in OINDP, the Leachables and Extractables Handbook takes a practical approach to familiarize readers with the recent recommendations for safety and risk assessment established through a joint effort of scientists from the FDA, academia, and industry. Coverage includes best practices for the chemical evaluation and management of leachables and extractables throughout the pharmaceutical product life cycle, as well as: Guidance for pharmaceutical professionals to qualify and risk-assess container closure system leachables and extractables in drug products Principles for defining toxicological safety thresholds that are applicable to OINDP and potentially applicable to other drug products Regulatory perspectives, along with an appendix of key terms and definitions, case studies, and sample protocols Analytical chemists, packaging and device engineers, formulation development scientists, component suppliers, regulatory affairs specialists, and toxicologists will all benefit from the wealth of information offered in this important text.

Corrupt Horseracing Practices

Hearings Before the Subcommittee on Criminal Justice of

the Committee on the Judiciary, House of Representatives, Ninety-seventh Congress, Second Session, on H.R. 2331 ... September 30 and December 15, 1982

Basic Laboratory Methods for Biotechnology

Textbook and Laboratory Reference

CRC Press Basic Laboratory Methods for Biotechnology, Third Edition is a versatile textbook that provides students with a solid foundation to pursue employment in the biotech industry and can later serve as a practical reference to ensure success at each stage in their career. The authors focus on basic principles and methods while skillfully including recent innovations and industry trends throughout. Fundamental laboratory skills are emphasized, and boxed content provides step by step laboratory method instructions for ease of reference at any point in the students' progress. Worked through examples and practice problems and solutions assist student comprehension. Coverage includes safety practices and instructions on using common laboratory instruments. Key Features: Provides a valuable reference for laboratory professionals at all stages of their careers. Focuses on basic principles and methods to provide students with the knowledge needed to begin a career in the Biotechnology industry. Describes fundamental laboratory skills. Includes laboratory scenario-based questions that require students to write or discuss their answers to ensure they have mastered the chapter content. Updates reflect recent innovations and regulatory requirements to ensure students stay up to date. Tables, a detailed glossary, practice problems and solutions, case studies and anecdotes provide students with the tools needed to master the content.

Good Manufacturing Practices for Pharmaceuticals

A Plan for Total Quality Control from Manufacturer to Consumer: Fifth Edition,

CRC Press Highlighting key issues and differences among GMPs of Europe, Canada, and the WHO, this reference examines US law and governmental policy affecting domestic and multinational pharmaceutical manufacturing. The book recommend pragmatic ways to interpret and comply with FDA CGMP regulation and related criteria. They focus on geographical redistribution of manufacturing facilities, accommodation of a diversity of regulatory and statutory governance, adaptation to disparate human resources, and new growth areas of manufacture and distribution of homeopathic remedies and dietary supplements, in addition to the greater quality control required of pharmacists and other authorized dispensers.

Introduction to Hospital and Health-System Pharmacy Practice

ASHP Written by leaders and experts in hospital and health-system practices and published by ASHP, the voice of the health-system pharmacy profession, Introduction to Hospital and Health-System Pharmacy Practice is required reading for students and practitioners alike. It's a comprehensive manual for institutional pharmacy: legal and regulatory issues, medication safety, informatics, and more. Straightforward definitions and clear explanations provide a basic foundation for on-the-job training in hospitals and health-systems. It's the only introductory textbook available in institutional pharmacy practice.This practical guide offers a highly readable introduction to key areas of pharmacy practice, including: Managing medication use Managing medication distribution Using technology in health systems Budgeting & finance responsibilities Administering and prepping sterile products Managing people Training options for careers Each chapter presents learning objectives and answers the "so what?" so common among student questions. Chapter reviews, discussion guidelines, key word definitions and interactive exercises augment the learning process.Written by hospital pharmacists for future hospital pharmacists, it's everything important you need to know from the name you trust.For additional product resources about this publication, visit www.ashp.org/pharmacypractice

Drug Testing Guidelines And Practices For Juvenile Probation And Parole Agencies

DIANE Publishing Will assist agencies across the country in developing judicially acceptable programs that will provide the information needed to confirm or disprove drug use among juveniles. Represents an amalgamation of the best drug testing practices

currently conducted by more than 125 probation and parole agencies in the U.S. Drug testing refers to urinalysis because it offers the most inexpensive and least intrusive method for identifying illegal drug use. Includes 14 forms, glossary, references and selected readings.

Handbook of Institutional Pharmacy Practice

ASHP This comprehensive text provides fundamental information on a broad spectrum of essential topics in health-system pharmacy practice. From an overview of health delivery systems and hospital pharmacy through various practice settings such as home care, long term care, hospice and palliative care, ambulatory care, and managed care this text focuses on various elements important to health-system pharmacies. The Handbook of Institutional Pharmacy Practice is the first step in developing a career in pharmacy and provides opportunities for study in career enhancement. New chapters included in the FOURTH EDITION: Integrity of the Drug Supply Overview of the History of Hospital Pharmacy in the United States Interprofessional Teams/Collaborative Practice Models Development, Implementation and Monitoring Therapeutic Plans and Evidence-Based Medicine

Good Manufacturing Practices for Pharmaceuticals

CRC Press With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace, pharmaceutical manufacturers, suppliers, contractors, and distributors are impacted by continual change. Offering a wide assortment of policy and guidance document references and interpretations, this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide. An essential companion for every pharmaceutical professional, this guide is updated and expanded by a team of industry experts, each member with extensive experience in industry or academic settings.

Introduction to Acute and Ambulatory Care Pharmacy Practice

ASHP Learn How to Thrive in Today’s Institutional Pharmacy Practice Landscape The Only Comprehensive Introductory Guide, Updated and Expanded With ASHP’s Introduction to Acute and Ambulatory Care Pharmacy Practice, 2nd Edition, pharmacy students and technicians can gain a professional head start by learning essential vocabulary, legal and regulatory issues, and the core clinical and administrative pharmacy operations in various practice settings. It is also a useful reference for new practitioners and anyone else interested in institutional pharmacy’s current financial, technological, and distributional systems. Written by David A. Holdford, RPh, MS, PhD, FAPhA, with additional content from 27 leading experts, the second edition provides a thorough introduction to all aspects of the institutional pharmacy practice in both hospital and outpatient settings, with a special focus on the developing role of technicians. It has been thoroughly updated to cover all current developments, and is clearly written, with Key Facts, What Ifs and other learning enhancements that make terms, concepts, and processes easy to understand and apply. 2 New and 18 Updated Chapters Cover Topics including: Key legal and regulatory issues Managing medication use and distribution Professional terminology Technology and automation Financial management, inventory, and cost control Sterile product preparation and administration Managing people and leadership Careers and training options The expanding role of pharmacy technicians Along with an understanding of the workings of institutional practice, students and new pharmacists can acquire the terminology that enables them to speak knowledgeably, along with insight into professional opportunities, including some non-traditional ones.

American Probation and Parole Association's Drug Testing Guidelines and Practices for Juvenile Probation and Parole Agencies

Remington's Practice of Pharmacy

A Treatise on the Making, Standardizing, and Dispensing, of Official, Unofficial, and Extemporaneous Pharmaceutical Preparations, with Descriptions of Medicinal Substances, Their Properties, Uses, and Doses,

and Such Other Professional Service in Connection with Community Health as the Pharmacist May be Called Upon to Render, Intended for the Use of Pharmacists and Physicians and as a Text-book for Students; Over Eight Hundred Illustrations

Good Laboratory Practice Regulations

Marcel Dekker Incorporated

Principles and Practice of Pharmaceutical Medicine

John Wiley & Sons Principles and Practice of Pharmaceutical Medicine begins with a detailed overview of its origins, and goes on to examine current career opportunities, education and training. Encompassing the entire spectrum of pharmaceutical medicine, it also discusses international drug development and registration, including animal toxicology and human volunteers, pharmacoeconomics and statistics, medical services, legal and ethical issues and business aspects. It is the most up-to-date guide to drug development and marketing, and the only book with an international outlook. * The authors are all experts in their field and include an assessment of the current status of their specialities * This book provides an insight into how things may develop in the future * It is designed to be a guide for those who are actually practicing pharmaceutical medicine

A Text Book of Clinical Pharmacy Practice

Essential Concepts and Skills

Orient Blackswan The Majority Of Clinical Pharmacy Textbooks Focus On Disease States And Applied Therapeutics. This Book Is Different. It Aims To Provide Readers With A Comprehensive Description Of The Concepts And Skills That Are The Foundation For Current Clinical Pharmacy Practice. It Seeks To Answer The Question How Do Clinical Pharmacists Practice? Rathar Than What Do Clinical Pharmacists Need To Know About Drugs And Therapeutics? The Book Is Divided Into Three Sections, And Each Chapter Is Self-Contained And Can Be Read Independently. Section I Provides An Overview Of The Current Status Of Clinical Pharmacy Practice In India And Other Countries. Section Ii Includes Chapters On The Key Concepts, Skills And Competencies Required For Effective Clinical Practice. Section Iii Covers Topics Of Interest To Graduate And Postgraduate Students, And More Experienced Clinical Pharmacists And Researchers.This Book Will Be Useful For All Students Of Pharmacy And Pharmacists Working In Hospital Pharmacy, Community Pharmacy, Drug Or Medical Information, Clinical Research, Government And Nongovernment Organisations, Teaching And Research.

Clinical Trial Methodology

CRC Press Now viewed as its own scientific discipline, clinical trial methodology encompasses the methods required for the protection of participants in a clinical trial and the methods necessary to provide a valid inference about the objective of the trial. Drawing from the authors' courses on the subject as well as the first author's more than 30 years working in the pharmaceutical industry, Clinical Trial Methodology emphasizes the importance of statistical thinking in clinical research and presents the methodology as a key component of clinical research. From ethical issues and sample size considerations to adaptive design procedures and statistical analysis, the book first covers the methodology that spans every clinical trial regardless of the area of application. Crucial to the generic drug industry, bioequivalence clinical trials are then discussed. The authors describe a parallel bioequivalence clinical trial of six formulations incorporating group sequential procedures that permit sample size re-estimation. The final chapters incorporate real-world case studies of clinical trials from the authors' own experiences. These examples include a landmark Phase III clinical trial involving the treatment of duodenal ulcers and Phase III clinical trials that contributed to the first drug approved for the treatment of Alzheimer's disease. Aided by the U.S. FDA, the U.S. National Institutes of Health, the pharmaceutical industry, and academia, the area of clinical trial methodology has evolved over the last six decades into a scientific discipline. This guide explores the processes essential for developing and conducting a quality clinical trial protocol and providing quality data collection, biostatistical analyses, and a clinical study report, all while maintaining the highest standards of ethics and excellence.

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations

Best Practices Guide to Electronic Records Compliance

CRC Press Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.

American Probation and Parole Association's Drug Testing Guidelines and Practices for Adult Probation and Parole Agencies

Handbook of Sepsis

Springer This practically oriented book provides an up-to-date overview of all significant aspects of the pathogenesis of sepsis and its management, including within the intensive care unit. Readers will find information on the involvement of the coagulation and endocrine systems during sepsis and on the use of biomarkers to diagnose sepsis and allow early intervention. International clinical practice guidelines for the management of sepsis are presented, and individual chapters focus on aspects such as fluid resuscitation, vasopressor therapy, response to multiorgan failure, antimicrobial therapy, and adjunctive immunotherapy. The closing section looks forward to the coming decade, discussing novel trial designs, sepsis in low- and middle-income countries, and emerging management approaches. The book is internatio nal in scope, with contributions from leading experts worldwide. It will be of value to residents and professionals/practitioners in the fields of infectious diseases and internal medicine, as well as to GPs and medical students.

Bioequivalence Studies in Drug Development Methods and Applications

John Wiley & Sons Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. Bioequivalence Studies in Drug Development focuses on the planning, conducting, analysing and reporting of bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. Reviews the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. Bioequivalence Studies in Drug Development is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

Encyclopedia of Pharmacy Practice and Clinical Pharmacy

Academic Press Encyclopedia of Pharmacy Practice and Clinical Pharmacy covers definitions, concepts, methods, theories and applications of clinical pharmacy and pharmacy practice. It highlights why and how this field has a significant impact on healthcare. The work brings baseline knowledge, along with the latest, most cutting-edge research. In addition, new treatments, algorithms, standard treatment guidelines, and pharmacotherapies regarding diseases and disorders are also covered. The book's main focus lies on the pharmacy practice side, covering pharmacy practice research, pharmacovigilance, pharmacoeconomics, social and administrative pharmacy, public health pharmacy, pharmaceutical systems research, the future of pharmacy, and new interventional models of pharmaceutical care. By providing concise expositions on a broad range of topics, this book is an excellent resource for those seeking information beyond their specific areas of expertise. This outstanding reference is essential for anyone involved in the study of pharmacy practice. Provides a 'one-stop' resource for access to information written by world-leading scholars in the field Meticulously organized, with articles split into three clear sections, it is the ideal resource for students, researchers and professionals to find relevant information Contains concise and accessible chapters that are ideal as an authoritative introduction for non-specialists and readers from the undergraduate level upwards Includes multimedia options, such as hyperlinked references and further readings, cross-references and videos

Essentials of Laboratory Animal Science: Principles and Practices

Springer Nature This book comprehensively reviews the anatomy, physiology, genetics and pathology of laboratory animals as well as the principles and practices of using laboratory animals for biomedical research.It covers the design of buildings used for laboratory animals, quality control of laboratory animals, and toxicology, and discusses various animal models used for human diseases. It also highlights aspects, such as handling and restraint and administration of drugs, as well as breeding and feeding of laboratory animals, and provides guidelines for developing meaningful experiments using laboratory animals.Further, the book discusses various alternatives to animal experiments for drug and chemical testing, including their advantages over the current approaches. Lastly, it examines the potential effect of harmful pathogens on the physiology of laboratory animals and discusses the state of art in in vivo imaging techniques.The book is a useful resource for research scientists, laboratory animal veterinarians, and students of laboratory animal medicine.

Principles and Practice of Clinical Trials

Springer Nature This is a comprehensive major reference work for our SpringerReference program covering clinical trials. Although the core of the Work will focus on the design, analysis, and interpretation of scientific data from clinical trials, a broad spectrum of clinical trial application areas will be covered in detail. This is an important time to develop such a Work, as drug safety and efficacy emphasizes the Clinical Trials process. Because of an immense and growing international disease burden, pharmaceutical and biotechnology companies continue to develop new drugs. Clinical trials have also become extremely globalized in the past 15 years, with over 225,000 international trials ongoing at this point in time. Principles in Practice of Clinical Trials is truly an interdisciplinary that will be divided into the following areas: 1) Clinical Trials Basic Perspectives 2) Regulation and Oversight 3) Basic Trial Designs 4) Advanced Trial Designs 5) Analysis 6) Trial Publication 7) Topics Related Specific Populations and Legal Aspects of Clinical Trials The Work is designed to be comprised of 175 chapters and approximately 2500 pages. The Work will be oriented like many of our SpringerReference Handbooks, presenting detailed and comprehensive expository chapters on broad subjects. The Editors are major figures in the field of clinical trials, and both have written textbooks on the topic. There will also be a slate of 7-8 renowned associate editors that will edit individual sections of the Reference.

Contemporary Drug Information

An Evidence-based Approach

Lippincott Williams & Wilkins This innovative textbook teaches the basics of drug information, literature evaluation, and biostatistics, and relates these topics to evidence-based pharmaceutical care. Readers will learn what to look for in studies, how to critique them, and how to apply them in clinical pharmacy practice. A major focus is critical appraisal of evidence derived from different types of studies—cases, cohorts, surveys, randomized controlled clinical trials, pharmacoeconomic studies, and systematic reviews. Concluding chapters discuss clinical decision-making using evidence from studies.

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence

Science, Applications, and Beyond

John Wiley & Sons Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook

Bentham Science Publishers Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Research Methods in Pharmacy Practice

Methods and Applications Made Easy

Elsevier Health Sciences This is a comprehensive guide to applying research methods to practice problems. It uses case-based examples and activities rooted in practice to support development of knowledge, skills, and confidence in applying evidence-based research methods. An array of different methodologies and qualitative/quantitative methods are described. Examples of topics include distinction between methodologies and methods, ethics protocols, as well as design/implementation/data analysis/interpretation of findings using methods such as surveys, interviews, focus groups, observational research, database mining, text and document analysis, quality improvement (PDSA cycles), economic (cost/benefit) evaluations. Perfect for MPharm students doing their research thesis, but relevant to all bioscience students undertaking research projects. Use of pharmacy practice case examples (in community, hospital, ambulatory, primary care and other settings) throughout. Examples of how to tackle a research question from different perspectives, e.g. which is the best way to answer each question and why. Inter-professional practice and research emphasized. Self-assessment and self-reflection questions to help readers confirm their understanding/learning. A one-stop research-method teaching resource for faculty.

Good Pharmaceutical Freeze-Drying Practice

CRC Press This text is devoted to pharmaceutical freeze-drying in all its forms and in all its technological variations. Whether you freeze-dry nonsterile tablets or you lyophilize injectables, this book covers all the technological and regulatory requirements. Written by a panel of leading practitioners in the pharmaceutical industry -- production experts, regulatory inspectors, technical consultants, and equipment suppliers -- the information is relevant, usable, and timely. Practical, "how to" chapters serve as training aids, and each section stands on its own as a concise, easy-to-access resource for both managers and technicians.

Principles and Practice of Pharmaceutical Medicine

John Wiley & Sons The new edition of Principles and Practice of Pharmaceutical Medicine is a comprehensive reference guide to all aspects of pharmaceutical medicine. New content includes chapters and coverage on regulatory updates, increasing international harmonization, transitional and probabilistic approaches to drug development, the growing sophistication and regulatory importance of pharmacovigilance, personalized medicine and growth in biotechnology as a source of new experimental drugs.

Good Clinical, Laboratory and Manufacturing Practices

Techniques for the QA Professional

Royal Society of Chemistry Quality assurance and good laboratory practices are becoming essential knowledge for professionals in all sorts of industries. This includes internal and external audit procedures for compliance with the requirements of good clinical, laboratory and manufacturing practices. Spanning chemical, cosmetic and manufacturing industries, Good Clinical, Laboratory and Manufacturing Practices: Techniques for the QA professional is aimed at: chemists, clinicians, ecotoxicologists, operation managers, pharmaceutical process managers, quality assurance officers, technicians and toxicologists. In addition sections on harmonisation of quality systems will be of value to safety, health and environment advisors. This comprehensive and high level reference will be an indispensable guide to research laboratories in academia and industry. Additional training material is also included.