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An Implementation Guide Springer International Cooperation, Convergence and Harmonization of Pharmaceutical RegulationsA Global PerspectiveAcademic Press

Pharmaceutical Excipients Academic Press

A key text for all those involved in pharmacovigilance. Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication. This book explores the methods used to investigate new adverse drug reactions, discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues. Stephens' Detection of New Adverse Drug Reactions provides comprehensive and up-to-date coverage of material fundamentally important to all those active in the field, whether they work in the pharmaceutical industry, drug regulatory authorities or in academia. The fifth edition of this classic reference work includes new chapters on: * vaccine safety surveillance * managing drug safety issues with marketed products * operational aspects of drug safety function * safety of biotechnology products * future of pharmacovigilance Reviews of previous editions: "This book surpasses all its educational aims. Not only is the subject matter covered comprehensively but the material is presented in a very user-friendly manner. The editors have succeeded in producing a highly-specific, definitive reference book which doubles as a most enjoyable read." Commended by the 1999 BMA Medical Book Competition "For anyone entering the field of adverse reaction monitoring one could not wish for a better primer" International Journal of Risk and Safety in Medicine

Drug Benefits and Risks Wiley-VCH

Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

Stephens' Detection of New Adverse Drug Reactions Springer Science & Business Media

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

Regulatory Affairs in the Pharmaceutical Industry John Wiley & Sons

Highly Commended at the BMA Medical Book Awards 2015 Mann ' s

Pharmacovigilance is the definitive reference for the science of detection, assessment, understanding and prevention of the adverse effects of medicines, including vaccines and biologics. Pharmacovigilance is increasingly important in improving drug safety for patients and reducing risk within the practice of pharmaceutical medicine. This new third edition covers the regulatory basis and the practice of pharmacovigilance and spontaneous adverse event reporting throughout the world. It examines signal detection and analysis, including the use of population-based databases and pharmacoepidemiological methodologies to proactively monitor for and assess safety signals. It includes chapters on drug safety practice in specific organ classes, special populations and special products, and new developments in the field. From an international team of expert editors and contributors, Mann ' s Pharmacovigilance is a reference for everyone working within pharmaceutical companies, contract research organisations and medicine regulatory agencies, and for all researchers and students of pharmaceutical medicine. The book has been renamed in honor of Professor Ronald Mann, whose vision and leadership brought the first two editions into being, and who dedicated his long career to improving the safety and safe use of medicines.

Cobert's Manual Of Drug Safety And Pharmacovigilance (Third Edition)

International Cooperation, Convergence and Harmonization of Pharmaceutical RegulationsA Global Perspective

This is an inclusive reference exploring the scientific basis and practice of drug therapy. The key concept is to look at the balance between the benefits and risks of drugs but in this context also the social impact which drugs have in modern societies is highlighted. Taking an evidence-based approach to the problem, the practice of clinical pharmacology and pharmacotherapy in the developing as well as the developed world is examined. For this purpose the book * Covers general clinical pharmacology, pharmacology of various drug groups and the treatments specific to various diseases * Gives guidance on how doctors should act so that drugs can be used effectively and safely * Encourages the rational use of drugs in society This book brings together a large amount of excellent content that will be invaluable for anyone working within, or associated with, the field of clinical pharmacology and pharmacotherapy - undergraduates, postgraduates, regulatory authorities and the pharmaceutical industry.

Mann's Pharmacovigilance Routledge

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

Vaccine Development and Manufacturing Genealogical Publishing Com

In recent years the MBR market has experienced unprecedented growth. The best practice in the field is constantly changing and unique quality requirements and management issues are regularly emerging. Membrane Biological Reactors: Theory, Modeling, Design, Management and Applications to Wastewater Reuse comprehensively covers the salient features and emerging issues associated with the MBR technology. The book provides thorough coverage starting from biological aspects and fundamentals of membranes, via modeling and design concepts, to practitioners ' perspective and good application examples. Membrane Biological Reactors focuses on all the relevant emerging issues raised by including the latest research from renowned experts in the field. It is a valuable reference to the academic and professional community and suitable for undergraduate and postgraduate teaching in Environmental Engineering, Chemical Engineering and Biotechnology.

Regulated Bioanalysis: Fundamentals and Practice Popular Prakashan

Praise for the previous edition: " Contains something for everyone involved in lubricant technology " — Chemistry & Industry This completely revised third edition incorporates the latest data available and reflects the knowledge of one of the largest companies active in the business. The authors take into account the interdisciplinary character of the field, considering aspects of engineering, materials science, chemistry, health and safety. The result is a volume providing chemists and engineers with a clear interdisciplinary introduction and guide to all major lubricant applications, focusing not only on the various products but also on specific application engineering criteria. A classic reference work, completely revised and updated (approximately 35% new material) focusing on sustainability and the latest developments, technologies and processes of this multi billion dollar business Provides chemists and engineers with a clear interdisciplinary introduction and guide to all major lubricant applications, looking not only at the various products but also at

specific application engineering criteria All chapters are updated in terms of environmental and operational safety. New guidelines, such as REACH, recycling alternatives and biodegradable base oils are introduced Discusses the integration of micro- and nano-tribology and lubrication systems Reflects the knowledge of Fuchs Petrolub SE, one of the largest companies active in the lubrication business 2 Volumes wileyonlinelibrary.com/ref/lubricants

Quality by Design for Biopharmaceutical Drug Product Development Springer Science & Business Media

Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine - from beginning to end - addressing all classes of vaccines from a processing, production, and regulatory viewpoint. It will provide comprehensive information on the various fields involved in the production of vaccines, from fermentation, purification, formulation, to regulatory filing and facility designs. In recent years, there have been tremendous advances in all aspects of vaccine manufacturing. Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation. Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in-depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues. This book will provide insight to the issues scientists face when producing a vaccine, the steps that are involved, and will serve as a reference tool regarding state-of-the-art vaccine manufacturing technologies and facility set-up. Highlights include: Comprehensive coverage of vaccine production : from a process point of view- fermentation to purification to formulation developments; from a production point of view - from facility design to manufacturing; and from a regulatory point of view - requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines, an area not covered by other books currently on the market

The Assessment of Systemic Exposure in Toxicity Studies Springer

It is beyond dispute that both China and the European Union stand to gain from promoting low-carbon development through the dissemination of clean and renewable energy sources, as this inevitably leads to increased environmental protection. The depletion of fossil fuel resources and the accompanying changes in the global energy mix make Europe and China not only competitors in the global economic race, but also nolens volens partners. Their pragmatic partnership is characterized, on the one hand, by the need to take action to reduce the consumption of fossil fuels and, on the other, by the desire to minimize the negative environmental impact of their use. Hence, the existing and emerging cooperation between the two actors, while challenging for a number of reasons, is not only an attempt to set up channels to exchange vital information, but also an exercise in setting the standards under which further cooperation will be forged.

Earth Matters Springer Science & Business Media

The detection and evaluation of adverse drug reactions is crucial for understanding the safety of medicines and for preventing harm in patients. Not only is it necessary to detect new adverse drug reactions, but the principles and practice of pharmacovigilance apply to the surveillance of a wide range of medicinal products. Stephens' Detection and Evaluation of Adverse Drug Reactions provides a comprehensive review of all aspects of adverse drug reactions throughout the life cycle of a medicine, from toxicology and clinical trials through to pharmacovigilance, risk management, and legal and regulatory requirements. It also covers the safety of biotherapeutics and vaccines and includes new chapters on pharmacogenetics, proactive risk management, societal considerations, and the safety of drugs used in oncology and herbal medicines. This sixth edition of the classic text on drug safety is an authoritative reference text for all those who work in pharmacovigilance or have an interest in adverse drug reactions, whether in regulatory authorities, pharmaceutical companies, or academia. Praise for previous editions "This book presents a comprehensive and wide-ranging overview of the science of pharmacovigilance. For those entering or already experienced in the pharmaceutical sciences, this is an essential work. ” - from a review in E-STREAMS "...a key text in the area of pharmacovigilance...extensively referenced and well-written...a valuable resource..." - from a review in The Pharmaceutical Journal

John Wiley & Sons

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.

Well Dressed? John Wiley & Sons

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the

fundamentals of manufacturing controls and their regulatory importance

Regulations, Methodologies, and Best Practices John Wiley & Sons

This legendary work consists of alphabetically arranged genealogical tables of approximately 500 Rhode Island families, representing thousands of descendants of pre--1690 settlers, all carried to the third generation, and some--about 100 families--carried to the fourth.

Energy Autonomy in Action John Wiley & Sons

The book "Nanocosmetics and nanomedicines: new approaches for skin care" contains a summary of the most important nanocarriers for skin delivery. Although "nanocosmetics" is a subject widely commented in the academy and the beauty industry, a book covering the skin care treatments using nanotechnological approaches with cosmetics and nanomedicines is still missing, therefore the need for this publication. This book is divided in three parts: The first one (Part A) is devoted to a brief review on the main topics related to the skin delivery and to the introduction of the subject "nanocosmetics". The second part (Part B) presents different types of nanocarriers applied as skin delivery systems for cosmetics or drugs. The last part (Part C) shows a wide range of applications of nanotechnology on the skin care area as well as on dermatocosmetic and dermatological fields.

Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics Springer Science & Business Media

Completely revised and updated, Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, risk management, quality/compliance, and in government and legal professions.This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance), and provides essential information on drug safety and regulations in the United States, Europe Union, and more, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions.Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, teaches the daily practice of drug safety in industry, hospitals, the FDA and other health agencies — both in the United States and around the world — and provides critical information about what to do when confronted with a drug safety problem.

The Present and Future Sustainability of Clothing and Textiles in the United Kingdom John Wiley & Sons

The greatest challenge of our time is to build a world based on the sustainable use of renewable power. Our massive dependence on fossil fuels has upset the very climatic system that made human evolution possible. The global economy and its financial system are in jeopardy, running hot on overtly cheap yet increasingly costly and fast depleting oil. A 100% renewable world is seen by many as an impossible dream in anything but the very long term. But not only do a growing number of initiatives and plans dare to make the change but many have already achieved it.This rich collection presents a series of pioneering efforts and their champions, and the paths to their successes. Ranging from initiatives by individuals to visions for companies, communities and entire countries, it defeats tired economic and technical counter-arguments, showing how the schemes featured not only can and do work but do so economically and with available technology. The book is introduced by incisive writing by Peter Droege, explaining the challenges and framing a roadmap towards a 100% renewable reality.

Studies for Our Global Future Academic Press

This volume gives an overview of the applications of organometallic chemistry in process chemistry relevant to the current topics in synthetic chemistry. This volume starts with an introduction on the historical development of organometallics in process chemistry and is followed by chapters dealing with the last five years' development in various organometallic reaction types such as the challenging cross coupling process, construction of 3.1.0 bicycles, pressure and transfer hydrogenations of historically challenging compounds such as esters, utilization of carbon dioxide for making organic compounds by flow process, drug synthesis and metal detection and scavenging in the finished APIs. A chapter by Colacot et.al., is also devoted to the process development and structural understanding of organometallic catalysts with particular emphasis to LnPd(0) catalysts. An academia – industry collaborated chapter on the use of water as a solvent for organometallic processes is included in this book.

100% Renewable Springer Nature

This teacher's guide helps students explore the connection between human population growth and the well-being of the planet. Twelve readings and 34 activities introduce high school students to global society and environmental issues such as climate change, biodiversity loss, gender equality, economics, poverty, energy, wildlife endangerment, waste disposal, food and hunger, water resources, air pollution, deforestation, and population dynamics. Teaching strategies include role playing simulations, laboratory experiments, problem-solving challenges, and mathematical exercises, cooperative learning projects, research, and discussion. These activities were designed to develop a number of student skills including critical thinking, research, public speaking, writing, data collection and analysis, cooperation, decision making, creative problem solving, reading comprehension, conflict resolution and values clarification. Each chapter and activity can be used alone to illustrate points or be inserted into existing curriculum. Activity subject areas are listed along with a quick list reference of the summary of activities. A reference guide of activities linked to National Standards is also included. Contains suggested resources, including books, periodicals, audiovisuals, hardbooks and wall charts, software, and internet sites, for each topic area. (SJR)