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EUROPEAN PHARMACOPOEIA

PUBLISHED IN ACCORDANCE WITH THE CONVENTION ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA (EUROPEAN TREATY SERIES NO. 50)

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA 2015

Stationery Office Books (TSO) **The Pharmacopoeia of the People's Republic of China 2015 Edition is the 10th edition of the Chinese Pharmacopoeia. It provides the statutory requirements for foreign pharmaceutical companies producing medicines for the Chinese market.**

THE INTERNATIONAL PHARMACOPOEIA

World Health Organization **A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.**

VACCINE ANALYSIS: STRATEGIES, PRINCIPLES, AND CONTROL

Springer **This book is an indispensable tool for anyone involved in the research, development, or manufacture of new or existing vaccines. It describes a wide array of analytical and quality control technologies for the diverse vaccine modalities. Topics covered include the application of both classical and modern bio-analytical tools; procedures to assure safety and control of cross contamination; consistent biological transition of vaccines from the research laboratory to manufacturing scale; whole infectious**

attenuated organisms, such as live-attenuated and inactivated whole-cell bacterial vaccines and antiviral vaccines using attenuated or inactivated viruses; principles of viral inactivation and the application of these principles to vaccine development; recombinant DNA approaches to produce modern prophylactic vaccines; bacterial subunit, polysaccharide and glycoconjugate vaccines; combination vaccines that contain multiple antigens as well as regulatory requirements and the hurdles of licensure.

PRACTICAL PHARMACEUTICS

AN INTERNATIONAL GUIDELINE FOR THE PREPARATION, CARE AND USE OF MEDICINAL PRODUCTS

Springer **This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.**

BOTANICALS

METHODS AND TECHNIQUES FOR QUALITY & AUTHENTICITY

CRC Press **The international trade in plants is growing steadily as the worldwide demand for natural and botanical raw materials increases. Customers value natural products and botanicals as "green" alternatives—safer ingredients for their families which also represent an environmentally and socially responsible choice for the planet. In order to build assurance into the sourcing of natural ingredients, R&D organizations must have valid scientific matrices to authenticate the quality of those ingredients, provide traceability, and minimize risk. An assemblage of insight from expert contributors, Botanicals: Methods and Techniques for Quality & Authenticity compiles a range of methods and techniques that**

can be used to help guide quality and authenticity determinations. Topics include: Metabolic profiling, authentication of botanicals by morphology, and genetic methods of botanical authentication Tools for building models for the authentication of materials How multivariate statistics can play a role in determining botanical quality and authenticity Radiocarbon and stable isotope ratio analysis and emerging stable isotope tools NMR (nuclear magnetic resonance) spectroscopy, NIR (near-infrared), and HPTLC (high-performance thin-layer chromatography) methods for analysis The use of electronic sensing instruments and applications for analysis The contributors also discuss the challenge of identifying a botanical extract or preparation on the basis of its chemical content and discuss quality issues faced by botanicals used as cosmetic ingredients. The book provides you with a range of traditional, taxonomic, and newer analytical tools to assure the quality, authenticity, and traceability of botanical raw materials for dietary supplements, cosmetics, and natural products research.

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

FIFTY-THIRD REPORT

World Health Organization **The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.**

INTERNATIONAL PHARMACEUTICAL PRODUCT REGISTRATION, SECOND EDITION

CRC Press **Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product**

registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

PRODUCTION OF PLASMA PROTEINS FOR THERAPEUTIC USE

John Wiley & Sons **A comprehensive compilation on plasma protein production from the leading experts in the field, Production of Plasma Proteins for Therapeutic Use presents manufacturing, testing methods, and regulatory issues for plasma-derived therapeutics, a global US$10 billion industry. Culling material that until now have only been available in scattered forms across journals and books, the text features twenty-three detailed protein-by-protein chapters written by the major manufacturers of plasma protein products, addressing all aspects of these proteins, including biology, clinical use, manufacturing processes, and possible future improvements.**

NMR IN PHARMACEUTICAL SCIENCE

John Wiley & Sons **NMR in Pharmaceutical Sciences is intended to be a comprehensive source of information for the many individuals that utilize MR in studies of relevance to the pharmaceutical sector. The book is intended to educate and inform those who develop and apply MR approaches within the wider pharmaceutical environment, emphasizing the toolbox that is available to spectroscopists and radiologists. This book is structured on the key processes in drug discovery, development and manufacture, but underpinned by an understanding of fundamental NMR principles and the unique contribution that NMR (including MRI) can provide. After an introductory chapter, which constitutes an overview, the content is organised into five sections. The first section is on the basics of NMR theory and relevant experimental methods. The rest follow a sequence based on the chronology of drug discovery and development, firstly 'Idea to Lead' then 'Lead to Drug Candidate', followed by 'Clinical Development', and finally 'Drug Manufacture'. The thirty one chapters cover a vast range of topics from analytical chemistry, including aspects involved in regulatory matters and in the prevention of fraud, to clinical imaging studies. Whilst this comprehensive volume will be essential reading for many scientists based in pharmaceutical and related industries,**

it should also be of considerable value to a much wider range of academic scientists whose research is related to the various aspects of pharmaceutical R&D; for them it will supply vital understanding of pharmaceutical industrial concerns and the basis of key decision making processes. About eMagRes Handbooks eMagRes (formerly the Encyclopedia of Magnetic Resonance) publishes a wide range of online articles on all aspects of magnetic resonance in physics, chemistry, biology and medicine. The existence of this large number of articles, written by experts in various fields, is enabling the publication of a series of eMagRes Handbooks on specific areas of NMR and MRI. The chapters of each of these handbooks will comprise a carefully chosen selection of eMagRes articles. In consultation with the eMagRes Editorial Board, the eMagRes handbooks are coherently planned in advance by specially-selected Editors, and new articles are written to give appropriate complete coverage. The handbooks are intended to be of value and interest to research students, postdoctoral fellows and other researchers learning about the scientific area in question and undertaking relevant experiments, whether in academia or industry. Have the content of this handbook and the complete content of eMagRes at your fingertips! Visit: www.wileyonlinelibrary.com/ref/eMagRes

THERANOSTICS

AN OLD CONCEPT IN NEW CLOTHING

BoD – Books on Demand **In recent years, due to advancing technology and diagnostic and therapeutic techniques, medicine and health care have become more patient-oriented. This concept of personalized medicine or theranostics can be traced back to the beginnings of nuclear medicine when radioisotopes were uncovered as diagnostic and therapeutic tools. Nowadays, the field of theranostics is in flux, as new techniques and materials allow a growing range of applications beneficial for patients. This book examines new developments in theranostics and provides a comprehensive overview of the state of the art in this exciting discipline.**

PHARMACOLOGY FOR HEALTH PROFESSIONALS

Elsevier Australia **"Pharmacology for Health Professionals provides a comprehensive introduction to important pharmacology prinicples and concepts, with a strong focus on therapeutics." "The text has been extensively updated to reflect the latest information on the clinical use of drugs, local aspects of scheduling, drug legislation and ethics." -- Book Jacket.**

THE SCIENCE AND REGULATIONS OF NATURALLY DERIVED COMPLEX DRUGS

Springer **This volume in the AAPS Advances series covers various quality,**

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

MANUAL ON THE DEVELOPMENT AND USE OF FAO AND WHO SPECIFICATIONS FOR CHEMICAL PESTICIDES

SECOND EDITION

Food & Agriculture Org. **In 2001, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) agreed to develop specifications for pesticides jointly, thus providing unique, robust and universally applicable standards for pesticide quality. This joint programme is based on a memorandum of understanding between the two organizations. This 2021 second edition of the manual on development and use of FAO and WHO specifications for pesticides, which is only available online, supersedes the March 2020 third revision of the first edition and previous manuals and guidance documents published by either FAO or WHO on this subject. This manual provides the standard process, unified requirements and procedures, harmonized definitions and nomenclature, technical guidelines and standards applicable to pesticides for use in agriculture and public health. FAO and WHO specifications for pesticides based on this manual are developed through the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) and published on the web sites of the two organizations.**

INDIAN PHARMACOPOEIA 2018 (ADDENDUM 2021).

EUROPEAN PHARMACOPOEIA

The 7th edition of the European Pharmacopoeia was published July 15 2010 and consists of a two-volume main edition. It is complemented by non-cumulative supplements that are to be kept for the duration of the 7th Edition. Two supplements were published in 2010 and three supplements will be published in each 2011 and 2012. It contains information on all types of active substances used to prepare pharmaceutical products: various chemical substances, antibiotics, biological substances, vaccines for human or veterinary use, immunosera, radiopharmaceutical preparations, herbal drugs and homoepathic preparations. Over 1800 specific and general monographs are included.

REGULATORY GUIDANCE FOR ASSESSMENT AND MANAGEMENT OF APPLICATIONS FOR MARKETING AUTHORIZATION OF OXYTOCIN

World Health Organization **Oxytocin is the uterotonic recommended by WHO to prevent and treat postpartum haemorrhage. However, evidence shows that there is a widespread problem with the quality of oxytocin available in LMIC mainly due to storage conditions non-compliant with WHO recommendations. As a result of exposing oxytocin to temperature excursions, when oxytocin is used either as a prophylaxis or treatment for treat post-partum haemorrhage, the medicine is ineffective and the woman does not receive the treatment that she needs. This in turn leads to increased maternal morbidity and mortality. This guidance has been prepared to assist national medicines regulatory authorities to understand the nature and extent of oxytocin quality issues and to provide key technical information and quality requirements for oxytocin products in dossier assessments. This guidance is addressed to National Medicines Regulators. It provides the parameters that they need to consider when assessing an oxytocin product. The implementation of this guidance will contribute to the improvement of the quality of oxytocin available in the market.**

ORAL DRUG ABSORPTION

PREDICTION AND ASSESSMENT, SECOND EDITION

CRC Press **Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an**

REGULATORY TOXICOLOGY IN THE EUROPEAN UNION

Royal Society of Chemistry **Consumer and environmental protection depend on the careful regulation of all classes of chemicals. Toxicology is the key science used to evaluate safety and so underpins regulatory decisions on chemicals. With the growing body of EU legislation involved in chemical regulation, there is a concomitant need to understand the toxicological principles underlying safety assessments. Regulatory Toxicology in the European Union is the first book to cover regulatory toxicology specifically in Europe. It addresses the need for a wider understanding of the principles of regulatory toxicology and their application and presents the relationship between toxicology and legislative processes in regulating chemical commodities across Europe. This title has a broad scope, covering historical and current chemical regulation in Europe, the role of European agencies and institutions, and also the use of toxicology data for important classes of chemicals, including human and veterinary medicines, animal feed and food additives, biocides, pesticides and nanomaterials. This book is therefore extremely pertinent and timely in the toxicology field at present. This book is an essential reference for regulatory authorities, industrialists, academics, undergraduates and postgraduates working within safety and hazards, toxicology, the biological sciences, and the medicinal and pharmaceutical sciences across the European Union.**

NUCLEAR MEDICINE TEXTBOOK

METHODOLOGY AND CLINICAL APPLICATIONS

Springer **Building on the traditional concept of nuclear medicine, this textbook presents cutting-edge concepts of hybrid imaging and discusses the close interactions between nuclear medicine and other clinical specialties, in order to achieve the best possible outcomes for patients. Today the diagnostic applications of nuclear medicine are no longer stand-alone procedures, separate from other diagnostic imaging modalities. This is especially true for hybrid imaging guided interventional radiology or surgical procedures. Accordingly, today's nuclear medicine specialists are actually specialists in multimodality imaging (in addition to their expertise in the diagnostic and therapeutic uses of radionuclides). This new role requires a new core curriculum for training nuclear medicine specialists. This textbook is designed to meet these new educational needs, and to prepare nuclear physicians and technologists for careers in this exciting specialty.**

THE CHALLENGE OF CMC REGULATORY COMPLIANCE FOR BIOPHARMACEUTICALS

Springer **Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies**

(both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.

GUIDE TO THE QUALITY AND SAFETY OF ORGANS FOR TRANSPLANTATION

KUCERS' THE USE OF ANTIBIOTICS

A CLINICAL REVIEW OF ANTIBACTERIAL, ANTIFUNGAL, ANTIPARASITIC, AND ANTIVIRAL DRUGS, SEVENTH EDITION - THREE VOLUME SET

CRC Press **Kucers’ The Use of Antibiotics is the definitive, internationally-authored reference, providing everything that the infectious diseases specialist and prescriber needs to know about antimicrobials in this vast and rapidly developing field. The much-expanded Seventh Edition comprises 4800 pages in 3 volumes in order to cover all new and existing therapies, and emerging drugs not yet fully licensed. Concentrating on the treatment of infectious diseases, the content is divided into four sections - antibiotics, anti-fungal drugs, anti-parasitic drugs, and anti-viral drugs -**

and is highly structured for ease of reference. Each chapter is organized in a consistent format, covering susceptibility, formulations and dosing (adult and pediatric), pharmacokinetics and pharmacodynamics, toxicity, and drug distribution, with detailed discussion regarding clinical uses - a feature unique to this title. Compiled by an expanded team of internationally renowned and respected editors, with expert contributors representing Europe, Africa, Asia, Australia, South America, the US, and Canada, the Seventh Edition adopts a truly global approach. It remains invaluable for anyone using antimicrobial agents in their clinical practice and provides, in a systematic and concise manner, all the information required when prescribing an antimicrobial to treat infection.

PRIONS IN HUMANS AND ANIMALS

Walter de Gruyter **This comprehensive work, aimed at both students and researchers alike, systematically covers all aspects of prion diseases (transmissible spongiform encephalopathies), from their history, microbiology and pathology to their transmissibility and prevention. The book describes diseases such as Creutzfeldt-Jakob disease, kuru, mad cow disease (BSE), chronic wasting disease and scrapie, highlighting their biochemical, molecular biological, genetic, and clinical aspects. A renowned editorial team brought together 80 internationally respected authors for this translation and new edition of the successful German publication. The book includes chapters by, among many other notable scientists, William J. Hadlow, who discovered the relationship between the human and animal forms of prion diseases and Michael P. Alpers, with 45 years of experience in Papua New Guinea investigating the first known human epidemic form, kuru, transmitted by endocannibalism. Carefully edited with numerous illustrations, this work offers a systematic approach committed to a clear presentation of the current knowledge of prion diseases. It aims to inspire and stimulate interdisciplinary cooperation, innovative research ideas and effective prevention.**

IMMUNOGLOBULIN THERAPY IN THE 21ST CENTURY: THE DARK SIDE OF THE MOON

Frontiers Media SA **In the early decades since the introduction in the early '80s of immunoglobulin therapy many studies tried to identify which clinical indications might benefit from the therapy, which treatment's schedules are effective and safe. It is universally accepted that immunoglobulin therapy is a life-saving treatment in patients with PID. The rise of new indications for further different clinical conditions resulted in a steady increase in demand for immunoglobulins. Currently the consumption of immunoglobulin for PID represents a small fraction of the market. In the recent past we have been observing: 1) An increase in the demand for plasma and in the consequent need to increase the number of donors; 2) Changes in methods to improve IgG recovery and to increase**

productivity as a response to growing clinical demand; 3) Introduction of immunoglobulin treatments with higher concentration; 4) Changes in the timing of administration with an increase in the rate of infusion; 5) Introduction of immunoglobulin treatment administered subcutaneously mainly confined initially to patients with PID and later extended to other clinical indications which often require higher volumes of infusion. Doctors following patients with PID were initially alarmed only to a possible risk of shortage. More relevant and less discussed appear the possible consequences of: 1) the risk of an improper transfer of information on treatments from a clinical indication to another. In particular, the idea of a mere replacement function in patients with PID might possibly be borrowed from the model of other clinical conditions requiring a replacement such as haemophilia. In PID, immunoglobulin treatment instead is obviously replacing a missing feature. However, other immune alterations are responsible for the large number of PID-associated diseases including inflammatory manifestations and tumors, common causes of morbidity and mortality. The immunomodulatory effects of immunoglobulin administered at replacement dosages on multiple cells and immune system functions are still largely to be checked in in vitro studies and in vivo. 2) the changes in the immunoglobulin production and schedules of administration. These should have been assessed in studies of drug surveillance, necessary in order to evaluate on large numbers of what it is initially reported on patients enrolled in the pivotal clinical trials, usually in the absence of most of the main disease-associated clinical conditions affecting pharmacokinetics, efficacy and tolerability. Severe side effects are now more frequently reported. This requires surveillance studies in order to verify the tolerability. Nowadays, personalized health research presents methodologic challenges, since emphasis is placed on the individual response rather than on the population. Even within a universally accepted indication, such as in PID, the identification of prognostic markers should guide the therapeutic intervention. 3) the risk of a decrease in the surveillance and monitoring of PID-associated clinical conditions. In fact, self- administration of immunoglobulins administered subcutaneously increased the independence of a number of patients. On the other hand, it led to the reduction in the number of contacts between specialized centers and patients who often require a close monitoring of disease-associated conditions. A wide debate between experts is necessary to afford the new challenge on immunoglobulin usage.

INTEGRATED PHARMACEUTICS

APPLIED PREFORMULATION, PRODUCT DESIGN, AND REGULATORY SCIENCE

John Wiley & Sons **Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a**

comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

THE STATIONERY OFFICE ANNUAL CATALOGUE 2011

Stationery Office/Tso **The Stationery Office annual catalogue 2011 provides a comprehensive source of bibliographic information on over 4900 Parliamentary, statutory and official publications - from the UK Parliament, the Northern Ireland Assembly, and many government departments and agencies - which were issued in 2011.**

BRITISH PHARMACOPOEIA 2021 [PRINT EDITION]

Updated annually, the British Pharmacopoeia (BP) is the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products. It includes approximately 4,000 monographs which are legally enforced by the Human Medicines Regulations 2012. Where a BP monograph exists, medicinal products or active pharmaceutical ingredients sold or supplied in the UK must comply with the relevant monograph.All monographs and requirements of the European Pharmacopoeia (Ph. Eur.) are reproduced in the BP, making the BP a convenient and fully comprehensive set of standards that can be used across Europe and beyond.

CMBEBIH 2017

PROCEEDINGS OF THE INTERNATIONAL CONFERENCE ON MEDICAL AND BIOLOGICAL ENGINEERING 2017

Springer **This volume presents the proceedings of the International Conference on Medical and Biological Engineering held from 16 to 18 March 2017 in Sarajevo, Bosnia and Herzegovina. Focusing on the theme of 'Pursuing innovation. Shaping the future', it highlights the latest advancements in Biomedical Engineering and also presents the latest findings, innovative solutions and emerging challenges in this field. Topics include: - Biomedical Signal Processing - Biomedical Imaging and Image Processing - Biosensors and Bioinstrumentation - Bio-Micro/Nano Technologies - Biomaterials - Biomechanics, Robotics and Minimally Invasive Surgery - Cardiovascular, Respiratory and Endocrine Systems Engineering - Neural and Rehabilitation Engineering - Molecular, Cellular and Tissue Engineering - Bioinformatics and Computational Biology - Clinical Engineering and Health Technology Assessment - Health Informatics, E-Health and Telemedicine - Biomedical Engineering Education**

- Pharmaceutical Engineering

WHO DRUG INFORMATION

VOLUME 34

World Health Organization

SPECIFICATION OF DRUG SUBSTANCES AND PRODUCTS

DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS

Elsevier **Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction**

POULTRY SCIENCE, CHICKEN CULTURE

A PARTIAL ALPHABET

Rutgers University Press **Poultry Science, Chicken Culture is a collection of engrossing, witty, and thought-provoking essays about the chicken-the familiar domestic bird that has played an intimate part in our cultural, scientific, social, economic, legal, and medical practices and concerns since ancient Egypt, Greece, and Rome. Organized as a primer, the book reaches beyond narrow disciplines to discover why individuals are so fascinated with the humble, funny, overlooked, and omnipresent chicken. Spanning fascinating and diverse fields, Susan Merrill Squier assesses the chicken as the focus of film, photography, and visual art in many media; details some of the roles played by chickens and eggs in the development of**

embryology, biology, and regenerative medici≠ traces the iconic figure of the chicken (and the chicken thief) in political discourse during the 2008 presidential election; demonstrates the types of knowledge that have been lost as food production moved from small-scale farming to industrial agriculture; investigates the connection between women and chickens; analyzes the fears and risks behind the panic around avian flu; and scrutinizes the role of chicken farming in international development. A combination of personal passion and surprising scholarly information, Poultry Science, Chicken Culture will change forever the way you think about chickens.

PARENTERAL MEDICATIONS, FOURTH EDITION

CRC Press **Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements**

ENCYCLOPEDIA OF DIETARY SUPPLEMENTS

CRC Press **Encyclopedia of Dietary Supplements presents peer-reviewed, objective entries that rigorously examine the most significant scientific research on basic chemical, preclinical, and clinical data. Designed for healthcare professionals, researchers, and health-conscious consumers, it presents evidence-based information on the major vitamin and mineral micronutrients, herbs, botanicals, phytochemicals, and other bioactive preparations. Supplements covered include: Vitamins, beta-carotene, niacin, and folate Omega-3 and omega-6 fatty acids, isoflavones, and**

quercetin Calcium, copper, iron, and phosphorus 5-hydroxytryptophan, glutamine, and L-arginine St. John's Wort, ginkgo biloba, green tea, kava, and noni Androstenedione, DHEA, and melatonin Coenzyme Q10 and S-adenosylmethionine Shiitake, maitake, reishi, and cordiceps With nearly 100 entries contributed by renowned subject-specific experts, the book serves as a scientific checkpoint for the many OTC supplements carried in today's nutritional products marketplace. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

DRYING ATLAS

DRYING KINETICS AND QUALITY OF AGRICULTURAL PRODUCTS

Woodhead Publishing **Drying Atlas: Drying Kinetics and Quality of Agricultural Products provides, in a condensed and systematic way, specific insights on the drying-relevant properties and coefficients of over 40 agricultural products. It also presents information about the production methods that influence the drying process, the quality of the dried product, the official quality standards of the products, and the design principles and operating characteristics of drying systems that are widely used in the postharvest processing and food industry. Available books on drying technology mainly focus on drying theory and simulation of drying processes. This book offers systematic information on the impact of other important parameters, such as relative humidity, air flow rate, mechanical, thermal and chemical pre-treatment, and drying mode for specific products. It is a unique and valuable reference for scientists and engineers who want to focus on industrial drying applications and dryers, as well as graduate and post-graduate students in postharvest technology and drying. Explores the production methods that influence the drying process and quality of the dried product Outlines the official quality standards of the products, the design principles, and the operating characteristics of drying systems that are used in postharvest processing Features 41 chapters that are (each for an agricultural product) presented in a condensed and systematic way**

MODERN PHARMACEUTICAL INDUSTRY

A PRIMER

Jones & Bartlett Learning **With its expansion into the global marketplace, the pharmaceutical industry of today is uniquely positioned to improve the global health standards of society by saving lives and improving the**

quality of lives around the world. Modern Pharmaceutical Industry: A Primer comprehensively explains the broad range of divisions in this complex industry. Experts actively involved in each division discuss their own contribution to a pharmaceutical company's work and success. Divisions include regulatory affairs, research and development, intellectual property, pricing, marketing, generics, OTC, and more

HANDBOOK OF PHARMACEUTICAL EXCIPIENTS

Amer Pharmacists Assn **An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.**

HANDBOOK OF IMMUNOLOGICAL PROPERTIES OF ENGINEERED NANOMATERIALS (SECOND EDITION) (IN 3 VOLUMES)

World Scientific **This unique book provides comprehensive overview of the field of immunology related to engineered nanomaterials used for biomedical applications. It contains literature review, case studies and protocols. The book can serve as a source of information about nanoimmunotoxicology for both junior scientists and experts in the field. The authors have more than 10 years of experience with preclinical characterization of engineered nanomaterials used for medical applications, and they share their experience with the readers. In addition, the international team of experts in the field provides the opinion and share the expertise on individual topics related to nanoparticle physicochemical characterization, hematocompatibility, and effects on the immune cell function . The second edition contains updated chapters from the first edition plus new chapters covering areas of tumor immunology, nanoparticle interaction with lymphatic system, mathematical modeling of protein corona, utilization of nanoparticles for the delivery of antiviral drugs, extensive analysis of nanoparticle anti-inflammatory and immunosuppressive properties, novel ways of protecting therapeutic nanoparticles from the immune recognition, as well as case studies regarding nanoparticle sterilization, complement activation, protein binding and immunotherapy of cancer. The second edition comes in 3 volumes. Volume 1 is focused on nanoparticle characterization, sterility and sterilization, pyrogen contamination and depyrigenation. It also**

contains overview of regulatory guidelines, protocols for in vitro and in vivo immunotoxicity studies, and correlation between in vitro and in vivo immunoassays. Volume 2 is focused on hematocompatibility of nanomaterials. It provides comprehensive review and protocols for investigating nanoparticle interaction with erythrocytes, platelets, endothelial cells, plasma coagulation factors and plasma proteins forming so called 'corona' around nanoparticles. Volume 3 is dedicated to nanoparticle interaction with and effects on the immune cell function. It also contains examples of nanoparticle use for delivery of antiviral and anti-inflammatory drugs.

BIOSIMILARS

REGULATORY, CLINICAL, AND BIOPHARMACEUTICAL DEVELOPMENT

Springer **This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.**

VACCINE CELL SUBSTRATES 2004

NATIONAL INSTITUTES OF HEALTH (NIH), DOUBLETREE HOTEL, ROCKVILLE, MD., USA, JUNE 29-JULY 1, 2004

S Karger Ag **This publication comprises the proceedings of the Vaccine Cell Substrates 2004 conference. The purpose of this conference was to review current data and progress in the field of cell substrates, discuss the continued use of existing tests and the appropriateness of new ones at this**

time, and develop consensus recommendations on how to address these issues, by either recommending implementation or identifying research gaps that preclude decision-making. Scientific topics covered oncogenicity of cellular components, both latent viruses and cellular DNA, viral adventitious agent test methods, level of assurance provided by the current tests, bovine (and porcine) viruses in (primarily) bovine-derived raw materials, and bovine spongiform encephalopathy agents as potential contaminants of cell substrates. Also presented were tests that ensure the safety and quality of novel vaccine cell substrates for investigational vaccine production. Academia, regulators, the vaccine industry and the testing industry developing, regulating or testing viral vaccines will greatly benefit from the wealth of new findings.