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Pharmacopoeia of the People's Republic of China - Chinese Pharmacopoeia Commission 2011-08-01
Chinese Pharmacopoeia 2010 is an official and authoritative compendium of drugs. It covers most traditional Chinese medicines, most western medicines and preparations, giving information on the standards of purity, description, test, dosage, precaution, storage, and the strength for each drug. It is published in three volumes, and contains up to 4567 monographs with 1386 new admissions. In Volume I, it contains monographs of Chinese crude drugs and the prepared slices. Vegetable oil/fat and its extract, the patented Chinese traditional medicines, single ingredient of Chinese crude drug preparations etc. it has 2165 monographs with 1019 new admissions (439 articles of the prepared slice) and 634 revised; Volume II deals with monographs of chemical drugs, antibiotics, biochemical preparations, radiopharmaceuticals and excipients for pharmaceutical use, contains 2271 monographs with 330 new admissions and 1500 revised; Volume III contains biological products, has 131 monographs with 37 new admissions and 94 revised

Probiotics in The Prevention and Management of Human Diseases - Mitesh Kumar Dwivedi 2021-12-02
Probiotics in The Prevention and Management of Human Diseases: A Scientific Perspective addresses the use of probiotics and their mechanistic aspects in diverse human diseases. In particular, the mechanistic aspects of how these probiotics are involved in mitigating disease symptoms (novel approaches and immune-mechanisms induced by Probiotics), clinical trials of certain probiotics, and animal model studies will be presented through this book. In addition, the book covers the role of probiotics in prevention and management aspects of crucial human diseases, including multidrug resistant infections, hospital acquired infections, allergic conditions, autoimmune diseases, metabolic disorders, gastrointestinal diseases, neurological disorders, and cancers. Finally, the book addresses the use of probiotics as vaccine adjuvants and as a solution for nutritional health problems and describes the challenges of using probiotics in management of human disease

conditions as well as their biosafety concerns. Intended for nutrition researchers, microbiologists, physiologists, and researchers in related disciplines as well as students studying these topics require a resource that addresses the specific role of probiotics in the prevention and management of human disease. Contains information on the use of probiotics in significant human diseases, including antibiotic resistant microbial infections Presents novel applications of probiotics, including their use in vaccine adjuvants and concept of pharmabiotics Includes case studies and human clinical trials for probiotics in diverse disease conditions and explores the role of probiotics in mitigation of the symptoms of disease

WHO Expert Committee on Biological Standardization - WHO Expert Committee on Biological Standardization. Meeting 2005

The Committee reports on general issues discussed and provides information on the status and development of reference materials for various antibodies, antigens, blood products and related substances, cytokines, growth factors and endocrinological substances. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains guidelines on the production and quality control of candidate tetravalent dengue virus vaccines and recommendations for the preparation, characterisation and establishment of international and other biological reference standards.

Countering the Problem of Falsified and Substandard Drugs - Institute of Medicine 2013-06-20

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

WHO Expert Committee on Biological Standardization - 2021-03-10

Pharmacology for Health Professionals - Bronwen Jean Bryant 2011

"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.

Chemistry and Biology of Heparin and Heparan Sulfate - Hari G. Garg 2011-10-10
The chemistry, biochemistry and pharmacology of heparin and heparan sulfate have been and continue to be a major scientific undertaking - heparin and its derivative remain important drugs in clinical practice. Chemistry and Biology of Heparin and Heparan Sulfate provides readers with an insight into the chemistry, biology and clinical applications of heparin and heparan sulfate and examines their function in various physiological and pathological conditions. Providing a wealth of useful information, no other tome covers the diversity of topics in the field. Students, doctors, chemists, biochemists, and research scientists will find this book an invaluable source for updating their current knowledge of developments in this area. Comprehensively reviews all aspects of heparin and heparan sulfate research Uniquely describes the chemistry, biology and clinical application of heparins and heparan sulfates in one work Provides an invaluable source of knowledge of current developments for chemists, biochemists, medical doctors, researchers, students and practitioners
An Overview of FDA Regulated Products - Eunjoo Pacifici 2018-06-13
Today’s challenge, especially for many newcomers to the regulated industry, is not necessarily to gather regulatory information, but to know how to interpret and apply it. The ability to discern what is important from what is not, and to interpret regulatory documents correctly, provides a valuable competitive advantage to any newcomer or established professional in this field. An Overview of FDA Regulated Products: From Drugs and Medical Devices to Food and Tobacco provides a valuable summary of the key information to unveil the meaning of critical, and often complex, regulatory concepts. Concise and easy to read with practical explanations, key points, summaries and case studies, this book highlights the regulatory processes involved in bringing an FDA regulated product from research and development to approval and market. Although the primary focus will be on the US system, this book also features global perspectives where appropriate. A valuable resource for students, professors and professionals, An Overview of FDA Regulated Products illustrates the most important elements and concepts so that the reader can focus on the critical issues and make the necessary connections to be successful. Provides an overview of key regulatory requirements using a practical approach that features detailed discussions of hypothetical and real-world case studies in order to highlight the concepts and applications of regulations Covers all FDA regulated products, including drugs, biologics, medical devices, cosmetics, foods, dietary supplements, cosmetics, veterinary products, tobacco and more in one single reference Illustrates complex topics in a clear, succinct and engaging manner by breaking down technical terms and offering straightforward and easy to understand explanations
WHO Expert Committee on Biological Standardization - World Health Organization 2017
This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The

next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and revision of WHO Guidelines for a number of vaccines, blood products and related substances. Specific discussion areas included WHO guidance on the production and evaluation of the quality, safety and efficacy of monoclonal antibodies as similar biotherapeutic products (SBPs); blood and blood components as essential medicines; estimation of residual risk of HIV, HBV or HCV infections via cellular blood components and plasma; snake antivenom immunoglobulins; human pandemic influenza vaccines in non-vaccine-producing countries; and clinical evaluation of vaccines: regulatory expectations. In addition, the following WHO guidance documents were also adopted: WHO manual for the preparation of secondary reference materials for in vitro diagnostic assays designed for infectious disease nucleic acid or antigen detection: calibration to WHO International Standards; and Human challenge trials for vaccine development: regulatory considerations. One WHO addendum document "Labeling information of inactivated influenza vaccines for use in pregnant women" was also adopted. Subsequent sections of the report provide information on the current status, proposed development and establishment of international reference materials in the areas of: biotherapeutics other than blood products; blood products and related substances; cellular and gene therapies; in vitro diagnostics; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1). The above nine WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-10). Finally, all additions and discontinuations made during the 2016 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 11. The updated full catalog of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2013

WHO's international guidelines written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States international organizations United Nations agencies regional and interregional harmonization efforts and underpin important initiatives including the prequalification of medicines the Roll Back Malaria Programme Stop TB essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The In.

Herbal Medicinal Products - Frauke Gaedcke 2003

Herbal medicinal products are becoming more widely accepted as alternatives to medical prescriptions. Many physicians believe that herbal medicinal products are able to beneficially complement or even replace chemical medicines. Recognizing this, European institutions are pushing the harmonization of assessment criteria for herbal medicinal products. However, this kind of reevaluation of herbal medicinal products is combined with increased expectations of physicians, pharmacists, and patients with regard to quality, safety and

efficacy. There are often uncertainties about the interpretation of basic terms related to the manufacture and quality of herbal medicinal products. Herbal Medicinal Products clarifies these uncertainties, increasing transparency in the herbal medicinal products market and supporting an adequate scientific discussion related to herbal medicinal products. It offers a complete survey on current scientific knowledge, as well as on legal basic requirements for the development, standardization, and licensing of herbal medicinal products.

WHO Expert Committee on Biological Standardization - World Health Organization. Expert Committee on Biological Standardization 2016

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines and guidance documents. Following these discussions, a WHO guidance document on Regulatory assessment of approved rDNA-derived biotherapeutics was adopted along with WHO Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions and on WHO good manufacturing practices for biological products. In addition, revised WHO Recommendations to assure the quality, safety and efficacy of recombinant human papillomavirus virus-like particle vaccines were also adopted by the Committee. Subsequent sections of the report provide information on the current status and proposed development of international reference materials in the areas of antibiotics; biotherapeutics other than blood products; blood products and related substances; in vitro diagnostic device reagents; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally, all additions and discontinuations made during the 2015 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalog of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

Heparin - A Century of Progress - Rebecca Lever 2012-05-08

Heparins remain amongst the most commonly used drugs in clinical practice. Almost 100 years have passed since the initial discovery of this complex substance and, during this time, understanding of the nature and uses of heparin and related molecules has grown dramatically. The aim of this volume is to summarise the developments that have led to the current status of both heparins as drugs and the field of heparin research, with a focus on the particularly rapid progress that has been made over the past three decades. Individual sections are dedicated to the nature of heparin as a biological

molecule, the current approaches and techniques that are used to ensure the safety and reliability of heparin as a medicine, the clinical pharmacology of heparin as an anticoagulant drug, effects and potential applications of heparin aside of those involving haemostasis and, finally, the nature and potential uses of heparin-like materials from both natural and synthetic sources.

Practical Pharmaceutics - Yvonne Bouwman-Boer 2015-08-24

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.

The International Pharmacopoeia - World Health Organization 2006

The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances, excipients and products. This new edition consolidates the texts of the five separate volumes of the third edition and includes new monographs for antiretroviral substances (didanosine, indinavir sulfate, nelfinavir mesilate, nevirapine, ritonavir, saquinovir, and saquinovir mesilate) adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2004. It includes some additions and amendments to the general notices of the Pharmacopoeia, as well as some changes to its layout and format. Volume one contains monographs for pharmaceutical substances A to O and the General Notices; and volume two contains monographs for pharmaceutical substances P to Z, together with those for dosage forms and radiopharmaceutical preparations, the methods of analysis and reagents.

Development and Validation of Analytical Methods - Christopher M. Riley 1996-05-29

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the

critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Guide to the Quality and Safety of Tissues and Cells for Human Application - European Directorate for the Quality of Medicines & Healthcare 2013-10-11

This guide provides state-of-the-art information in order to maximise the quality and minimise the risks during donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells. As with all transplanted material of human origin, tissues and cells carry risks of disease transmission, which must be controlled by the application of scrupulous donor selection criteria (including testing) and comprehensive quality systems. The idea behind this guide is to help professionals on a practical level by providing generic guidance that will help improve the rate of successful clinical application of tissues and cells. The guide makes reference to EU mandatory requirements where appropriate and describes generally-accepted good practice. It has been divided into two parts. Part A contains general requirements applicable to all establishments involved in the

donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells. Part B contains specific guidelines and requirements for the different tissue and/or cell types

European Pharmacopoeia - Council of Europe 2010

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.

Development and Formulation of Veterinary Dosage Forms - Gregory E Hardee 2021-04-30

Although the United States (U.S.) and the more developed nations of the remainder of the world are blessed with a variety of pharmaceuticals, feed additives, and biological products to treat, prevent, and control animal diseases, there is a healthy desire among persons involved in animal health issues to increase our animal medicine chest. The interest stems from the desire to efficiently produce food that is safe and plentiful and from the desire to have more and better government-approved products available for the prevention and treatment of diseases of dogs, cats, and horses and for an increasing variety of minor animal species. For the animal health industry, increased drug availability means broader markets, increased revenues, and an opportunity to better serve their customers. For the veterinarian, more animal health products means that he or she is better able to treat the usual and the unusual conditions, and to prevent animal disease and suffering. No doubt, we are all winners when new technology and industrial and regulatory initiatives hasten the availability of safe and effective animal health products.

WHO Expert Committee on Biological Standardization - 2022-04-12

The Science and Regulations of Naturally Derived Complex Drugs - Ram Sasisekharan 2019-04-23

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.

Indian Pharmacopoeia 2010 - Government of India. Ministry of Health & Family Welfare 2010

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2016

The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project.

WHO Expert Committee on Biological Standardization - World Health Organization 2018-07-18

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances and the establishment of international biological reference materials. Following a brief introduction the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report of particular relevance to manufacturers and national regulatory authorities outlines the discussions held on the development and

adoption of new and revised WHO Recommendations Guidelines and guidance documents. Following these discussions WHO Guidelines on the quality safety and efficacy of Ebola vaccines and WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products were adopted on the recommendation of the Committee. In addition the following two WHO guidance documents on the WHO prequalification of in vitro diagnostic medical devices were also adopted: (a) Technical Specifications Series (TSS) for WHO Prequalification - Diagnostic Assessment: Human immunodeficiency virus (HIV) rapid diagnostic tests for professional use and/or self-testing; and (b) Technical Guidance Series (TGS) for WHO Prequalification - Diagnostic Assessment: Establishing stability of in vitro diagnostic medical devices. Subsequent sections of the report provide information on the current status proposed development and establishment of international reference materials in the areas of: antibiotics biotherapeutics other than blood products; blood products and related substances; in vitro diagnostics; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations Guidelines and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally all additions and discontinuations made during the 2017 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalogue of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2019-05-29

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 consensusbuilding 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.

The Textbook of Pharmaceutical Medicine - John P. Griffin 2008-04-15

New edition of succesful standard reference book for thepharmaceutical industry and pharmaceutical physicians! The Textbook of Pharmaceutical Medicine is the coursebookfor the Diploma in Pharmaceutical

Medicine, and is used as astandard reference throughout the pharmaceutical industry. The newedition includes greater coverage of good clinical practice, acompletely revised statistics chapter, and more on safety. Coversthe course information for the Diploma in PharmaceuticalMedicine Fully updated, with new authors Greater coverage of good clinical practice and safety New chapters on regulation of medical devices in Europe andregulation of therapeutic products in Australia

Handbook of Pharmaceutical Salts Properties, Selection, and Use - P. Heinrich Stahl 2008-08-04

This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products.

European Pharmacopoeia - Consejo de Europa. Dirección para la Calidad en los Medicamentos 2013

Dictionary of Pharmaceutical Medicine - Gerhard Nahler 2013-06-29

This dictionary is aimed primarily at the beginners entering the new discipline of Pharmaceutical Medicine, an area comprising aspects of toxicology, pharmacology, pharmaceutics, epidemiology, statistics, drug regulatory and legal affairs, medicine and marketing. But also more experienced colleagues in departments engaged in clinical development as well as researchers and marketing experts in the pharmaceutical industry will find concise and up-to-date information. The book is completed by a list of a about 1000 abbreviations encountered in pharmaceutical medicine and a compilation of important addresses of national and international health authorities.

NMR in Glycoscience and Glycotechnology - Koichi Kato 2017-05-15

This volume focuses on solution and solid-state NMR of carbohydrates, glycoproteins, glyco-technologies, biomass and related topics. It is estimated that at least 80% of all proteins are glycoproteins. Because of the complexity, heterogeneity and flexibility of the sugar chains, the structural biology approaches for glycoconjugates have been generally avoided. NMR techniques although well established for structural analyses of proteins and nucleic acids, cannot be simply applied to this complex class of biomolecules. Nonetheless, recently developed NMR techniques for carbohydrates open the door to conformational studies of a variety of sugar chains of biological interest. NMR studies on glycans will have significant impact on the development of vaccines, adjuvants, therapeutics, biomarkers and on biomass regeneration. In this volume, the Editors have collected the most up-to-date NMR applications from experts in the field of carbohydrate NMR spectroscopy. Timely and useful, not only for NMR specialists, it will appeal to researchers in the general field of structural biology, biochemistry and biophysics, molecular and cellular biology and material science.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization

2020-04-21

The EDQM, a leading organisation that protects public health - Council of Europe 2014-11-04
The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe traces its origins and statutes to the Convention on the Elaboration of a European Pharmacopoeia (an international treaty adopted by the Council of Europe in 1964). The 37 member states and European Union (EU) that have signed the Convention are committed to achieving harmonisation of the quality of medicines throughout the European continent and beyond. This brochure presents the activities of the EDQM.
Biosimilars - Hiten J. Gutka 2018-12-13
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.
Pharmaceutical Biotechnology - Oliver Kayser 2012-05-21
This second edition of a very successful book is thoroughly updated with existing chapters completely rewritten while the content has more than doubled from 16 to 36 chapters. As with the first edition, the focus is on industrial pharmaceutical research, written by a team of industry experts from around the world, while quality and safety management, drug approval and regulation, patenting issues, and biotechnology fundamentals are also covered. In addition, this new edition now not only includes biotech drug development but also the use of biopharmaceuticals in diagnostics and vaccinations. With a foreword by Robert Langer, Kenneth J Germeshausen Professor of Chemical and Biomedical Engineering at MIT and member of the National Academy of Engineering and the National Academy of Sciences.
Non-Biological Complex Drugs - Daan J.A. Crommelin 2015-06-24
The rise of bio- and nano-technology in the last decades has led to the emergence of a new and unique type of medicine known as non-biological complex drugs (NBCDs).

This book illustrates the challenges associated with NBCD development, as well as the complexity of assessing the effects of manufacturing changes on innovator and follow-on batches of NBCDs. It also touches upon proven marketing authorization requirements for biosimilars that could be effective in evaluating follow-on NBCDs, including a demonstration of control over the manufacturing process and a need for detailed physico-chemical characterization and (pre)clinical tests. This book is meant to be used for years to come as a standard reference work for the development of NBCDs. Moreover, this book aims to stimulate discussions and further our thinking to ensure that decisions regarding the approval of complex drugs are made with relevant scientific data on the table.

Medical Product Regulatory Affairs - John J. Tobin 2011-08-24

Written in a clear and concise style by an experienced author, this attractively-priced book covers regulatory affairs in all major global markets for pharmaceuticals and medical devices, making it the most comprehensive in its field. Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices. Everything pharmacologists, bioengineers, pharma engineers, students in pharmacy and those working in the pharmaceutical industry need to know about medical regulatory affairs.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2018

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: - WHO guidelines on good herbal processing practices for herbal medicines; - Guidelines on good manufacturing practices for the manufacture of herbal medicines; - Considerations for requesting analysis of medicine samples; - WHO model certificate of analysis; - WHO guidance on testing of "suspect" falsified medicines; - Good pharmacopoeial practices - Chapter on monographs for compounded preparations; - Good pharmacopoeial practices - Chapter on monographs on herbal medicines; - Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products; - Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions; - Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and - Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.

WHO Expert Committee on Biological Standardization - WHO Expert Committee on Biological Standardization. Meeting 2014

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading

to the adoption of international recommendations for the production and control of vaccines and other biologicals, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development of revised WHO Recommendations and Guidelines for a number of vaccines, blood products and related substances. Specific discussion areas included the development of WHO guidance on the quality, safety and efficacy of poliomyelitis vaccines (oral, live, attenuated); recombinant malaria vaccines; diphtheria vaccines (adsorbed); tetanus vaccines (adsorbed); combined vaccines based on diphtheria and tetanus vaccines; and Japanese encephalitis vaccines (live, attenuated). Subsequent sections of the report then provide information on the current status and proposed development of international reference materials in the areas of vaccines and related substances; blood products and related substances; in vitro diagnostic device reagents; biotherapeutics other than blood products; and antibiotics. A series of annexes are then presented which include an updated list of WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1), followed by a series of WHO Recommendations and Guidelines adopted on the advice of the Committee (Annexes 2-7). All additions made during the meeting to the list of International Standards and Reference Reagents for biological substances maintained by WHO are then summarized in Annex 8.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals - John Geigert 2019-05-08

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.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - 2021-04-26

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations; Points to consider when including Health Based Exposure Limits (HBELs) in cleaning validation; Good manufacturing practices: water for pharmaceutical use; Guideline on data integrity; WHO/United Nations Population Fund recommendations for condom storage and shipping temperatures; WHO/United Nations Population Fund guidance on testing of male latex condoms; WHO/United Nations Population Fund guidance on conducting post-market surveillance of condoms; WHO “Biowaiver List”: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce; Good reliance practices in the regulation of medical products: high-level principles and considerations; and Good regulatory practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.