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Maria Cristina Galli



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Safety Concerns for Herbal Drugs Divya Vohora, S. B. Vohora, 2015-12-01 Are herbal drugs totally devoid of adverse effects when used alone as herbal formulations or in concurrent use with modern medicines Safety Concerns for Herbal Drugs examines that question and others like it to give you the information you need to judge for yourself the balance between the risks and benefits associated with the therapeutic use of

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection World Health Organization, 2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry

Quality Assurance of Pharmaceuticals World Health Organization, 2007 Quality assurance of pharmaceutical products is a continuing concern of WHO Despite efforts made around the world to ensure a supply of quality and effective medicines substandard spurious and counterfeit products still compromise health care delivery in many countries To respond to the global need for adequate quality assurance of pharmaceuticals WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices GMP Important texts on inspection are also included Most of the material has been published separately in the Expert Committee's reports This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy in medicines regulation and control and in the pharmaceutical industry This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series

The Combination Products Handbook Susan Neadle, 2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs devices and or biological products According to the US Food and Drug Administration FDA a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product Examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products This handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market The authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices This

handbook Brings clarity of understanding for global combination products guidance and regulations Reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors Endorsed by AAMI Association for the Advancement of Medical Instrumentation

Regulatory Aspects of Gene Therapy and Cell Therapy Products Maria Cristina Galli, 2023-08-01 This book discusses the different regulatory pathways for Advanced Therapy Medicinal Products implemented by national agencies in North and South America Europe and Asia and by international bodies in the effort of international harmonization This book represents an update of the first edition as it covers regulatory novelties and accumulated experience in the regions already addressed In addition this new edition offers a wider international perspective new chapters are included covering Advanced Therapy Medicinal Products regulations in India Malaysia Spain and Thailand the European Pharmacopoeia texts for gene therapy medicinal products as well as international harmonization programs Each chapter authored by experts from various regulatory bodies throughout the international community walks the reader through the applications of nonclinical research to translational clinical research to licensure and therapeutic use of these innovative products More specifically each chapter offers insights into fundamental considerations that are essential for developers of Advanced Therapy Medicinal Products in the areas of product quality pharmacology and toxicology clinical trial design and HTA pathways as well as pertinent must know guidelines and regulations Regulatory Aspects of Gene Therapy and Cell Therapy Products a Global Perspective is part of the American Society of Gene Cell Therapy sub series of the highly successful Advances in Experimental Medicine and Biology series It is essential reading for graduate students clinicians and researchers interested in gene and cell therapy and the regulation of pharmaceuticals

Understanding Drugs Markets Carine Baxerres, Maurice Cassier, 2021-07-23 Drawing on anthropology historical sociology and social epidemiology this multidisciplinary book investigates how pharmaceuticals are produced distributed prescribed and consumed and regulated in order to construct a comprehensive understanding of the issues that drive medicine pharmaceutical markets in the Global South today Based on primary research conducted in Benin and Ghana and additional data collected in Cambodia and the Ivory Coast this volume uses artemisinin based combination therapies ACTs against malaria as a central case study It highlights the influence of the countries colonial and post colonial history on their models for state regulation production and distribution explores the determining role transnational actors as well as industries from the North but also and increasingly from the South play in influencing local pharmaceutical markets and looks at the behaviour of health care professionals and individuals Stepping back the authors then unpick the pharmaceuticalization process and the multiple regulations at stake by looking at the workings of and linkages between biomedical health pharmaceutical systems representatives of companies industries actors in private

distribution and consumer practices Providing a thorough comparative analysis of the advantages and disadvantages of different pharmaceutical systems it is an important contribution to the literature on pharmaceuticalization and the governance of medication It is of interest to students researchers and policy makers interested in medical anthropology the sociology of health and illness global health healthcare management and pharmacy *Legal Reforms in China and Vietnam* John Gillespie, Albert Chen, 2010-09-13 Although the adoption of market reforms has been a key factor leading to China's recent economic growth China continues to be governed by a communist party and has a socialist influenced legal system Vietnam starting later also with a socialist influenced legal system has followed a similar reform path and other countries too are now looking towards China and Vietnam as models for development This book provides a comprehensive comparative assessment of legal developments in China and Vietnam examining similarities and differences and raising important questions such as Is there a distinctive Chinese model and or a more general East Asian Model If so can it be flexibly applied to social and economic conditions in different countries If it cannot be applied to a culturally and politically similar country like Vietnam is the model transportable elsewhere in the world Combining micro or interpretive methods with macro or structural traditions the book provides a nuanced account of legal reforms in China and Vietnam highlighting the factors likely to promote change or resist the spread of the Chinese model WHO Global Report on Traditional and Complementary Medicine 2019 World Health Organization, 2019-05-16 This report is structured in five parts national framework for traditional and complementary medicine T product regulation practices and practitioners the challenges faced by countries and finally the country profiles Apart from the section on practices and practitioners the report is consistent with the format of the report of the first global survey in order to provide a useful comparison The section on practices and practitioners which covers providers education and health insurance is a new section incorporated to reflect the emerging trends in T that is before and after the first WHO Traditional Medicine Strategy 1999 2005 from the first global survey to the second global survey 2005 2012 and from the second survey to the most recent timeline 2012 2018 **OECD Review of Fisheries: Policies and Summary Statistics 2013** OECD, 2013-12-23 This Review contains a General Survey of Policy Developments based on material submitted by OECD member countries information gathered on observer and enhanced engagement countries and an overview of recent activities of the Committee of Fisheries *WHO Expert Committee on Specifications for Pharmaceutical Preparations* WHO Expert Committee on Specifications for Pharmaceutical Preparations, 1992 Pemastian Mutu Obat , *Cumulated Index Medicus* , 1996 *Translating Foreign Ideas Into Domestic Practices* Kristina Jönsson, 2002 **Bowker's Law Books and Serials in Print 1993** Bowker Editorial Staff, 1993-02 **Regulations For Agricultural Products Derived From Biotechnology - Proceedings Of The Asean Workshop** Primary Production Department, 1998-08-06 The agricultural industry in Asia is a primary market for the growing number of biotechnology derived products and genetically modified organisms which are useful in agriculture Faced with growing populations limited resources and the promise of better and

sustainable yields using biotechnology agricultural producers are welcoming this new technology On the other hand there has been some concern about the safety of agricultural products derived from biotechnology To address public concern many ASEAN countries have developed individual biosafety guidelines to regulate the use of such agricultural products The ASEAN Workshop on Regulations for Agricultural Products Derived from Biotechnology served as a forum for the exchange of ideas and knowledge among ASEAN countries international regulatory agencies and agri industry representatives involved in agriculture biotechnology Eminent agribiotechnologists and regulators from Europe the USA the Peoples Republic of China Taiwan Canada Australia the United Nations Environment Programme UNEP Information Systems for Biotechnology ISB International Service for the Acquisition of Agri Biotech Applications ISAAA Monsanto Novartis AgrEvo Rhone Poulenc and Nestl presented papers on various aspects of biotechnology regulation In addition each ASEAN country presented country papers outlining the status of existing regulations on GMOs

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