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WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2008-05-05
The Expert Committee on Specifications for Pharmaceutical Preparations works towards standards and guidelines for medicines' quality assurance. The forty-second meeting adopted 11 new monographs for inclusion in The International Pharmacopoeia (Ph.Int.) and seven related new International Chemical Reference Standards (ICRS). The specifications currently developed are internationally applicable test methodologies for antimalarial, antituberculosis, antiretroviral and specifically also medicines for children. The main principles for selection of INNs for biologicals were endorsed. In order to serve the WHO-managed Prequalification Program, two new procedures were adopted, namely on prequalification of intrauterine devices (IUDs) and of male latex condoms, together with a new guidance on the assessment of active pharmaceutical ingredients for use in medicines.--Publisher's description.
WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting 2015-05-11
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 5 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further received a concept paper on the benefits of good pharmacopoeial practices (GPhP) and was informed of progress achieved with developing a comprehensive document on GPhP through discussions at 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 eight guidelines and 16 technical supplements as listed below including a new guidance text on good review practice prepared under the leadership of the Asian-Pacific Economic Cooperation Regulatory Harmonization Steering Committee. 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. The report includes the following annexes which are recommended as new WHO guidelines: . Annex 1. Procedure of the development of monographs for inclusion in The International Pharmacopoeia (revision); . Annex 2. Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia (revision); . Annex 3. Supplementary guidelines on good manufacturing practices: validation; Appendix 7: non-sterile process validation (revision); . Annex 4. General guidance for inspectors on hold-time studies (new); . Annex 6. Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients (revision); . Annex 7. Guidelines on registration requirements to establish interchangeability (revision); . Annex 8. Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products (revision); . Annex 9: Good review practices guidelines for regulatory authorities (new). In addition 16 technical supplements to the WHO model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance (Annex 5). The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia. Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs. The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM. The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia.
Navy Civil Engineer - 1964

A Practical Approach to Pharmaceutical Policy - Andreas Seiter 2010-06-17
This book offers policy makers a hands-on approach, tested in the World Bank’s field work in many countries, for developing policies that improve access to safe, effective medicines in health systems of low- and middle-income economies.
Hospital Administration in Canada - 1971

Philippines: Doing Business and Investing in Philippines Guide Volume 1 Strategic, Practical Information and Contacts - IBP, Inc. 2012-03-27
Philippines: Doing Business and Investing in ... Guide Volume 1 Strategic, Practical Information, Regulations, Contacts
Computers in the Water Environment - 1993

Report to Congress - 1978

WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Expert Committee on Specifications for Pharmaceutical Preparations 2014
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, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles;

Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.

Rapid Excavation and Tunneling Conference 2021 Proceedings - Jarrett E. Carlson 2021-06-06

Every two years, industry leaders and practitioners from around the world gather at the Rapid Excavation and Tunneling Conference (RETC), the authoritative program for the tunneling profession, to learn about the most recent advances and breakthroughs in this unique field. The information presented helps professionals keep pace with the ever-changing and growing tunneling industry. This book includes the full text of 106 papers presented at the 2021 conference. Though the tunneling industry continues to develop both technically and contractually, one notable adaptation of the last two years has been the onset and management of COVID-19. The hallmarks of tunneling professionals include adaptability, resiliency, optimism, and management of change. These are traits that have been recently put to an entirely new challenge over the last year or so. We have truly witnessed why what we do is deemed “essential” infrastructure. The COVID-19 pandemic has impacted each of us, personally and professionally, and while times have been hard, we are fortunate to work in a field that is able to meet the challenge and thrive thereafter. Congratulations are in order to everyone in our industry for keeping the planning and development of projects moving forward and for maintaining safe and productive worksites in these challenging times.

Guidelines for the international packaging and shipping of vaccines - 2020-12-22

International shipping of vaccines is the first leg of the complex journey that vaccines undertake to reach the end users in a country. Particular challenges include the size and weight of packages, implementation of quality control checks at reception, ensuring environmental sustainability, and maintaining required temperatures during the journey. Although there are many possibilities of transport e.g. sea freight and terrestrial transportation, air freight currently remains the most widely used means of transport for vaccines. In recognition of this fact, these guidelines apply predominantly to the air freighting of vaccines. Transportation of vaccines from the manufacturing facility to the airport facility require the use of ground transportation, and reference is also made to the qualification of refrigerated road vehicles as well. The objective of these guidelines is to provide technical guidance to help ensure the quality of vaccines during all stages of the international air transportation process. These guidelines are applicable to all persons and institutions involved in international air shipment of vaccines from the premises of the product manufacturer to the recipient country. This includes all parties involved in shipment, vaccine manufacturers, logistics service providers (LSPs), freight forwarders, carriers and their employees. The relevant sections of these guidelines should also be considered for implementation by UN procurement agencies and other international procurement organizations, countries, donor agencies and certifying bodies.

Commerce Business Daily - 1998-03

Report of the Paediatric Regulatory Network meeting, 14-15 April 2021 - 2022-05-30

State of the World's Vaccines and Immunization - J. M. Maurice 2009-07-20

This casebook collects 64 case studies each of which raises an important and difficult ethical issue connected with planning, reviewing or conducting health-related research. The book's purpose is to contribute to thoughtful analysis of these issues by researchers and members of research ethics committees (REC's known in some places as ethical review committees or institutional review boards) particularly those involved with studies that are conducted or sponsored internationally. . This collection is envisioned principally as a tool to aid educational programs from short workshops on research.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Expert Committee on Specifications for Pharmaceutical Preparations 2006

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. The report is complemented by a number of annexes. These include: a list of available international chemical reference substances and international infrared spectra; supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms; updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines; supplementary guidelines on good manufacturing practices for validation; good distribution practices for pharmaceutical products; a model quality assurance system for procurement agencies (recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products); multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability; a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; and additional guidance for organizations performing in vivo bioequivalence studies. ...This is an excellent book with a misleading title... a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients (API) and finished pharmaceutical products. Annex 5 on Good distribution practices (GDP) for pharmaceutical products is an excellent Annex that splits the task of GDP into 20, small, easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products. It contains a comprehensive glossary of terms used in GDP... a useful reference book for anyone involved in Quality Assurance, Manufacturing of marketed products, Clinical Manufacturing and Development. - Industrial Pharmacy

Technical Report Series - 2006

Commerce Today - 1975

HIV/AIDS in Europe - World Health Organization. Regional Office for Europe 2006

Tells the story of HIV/AIDS in Europe from a broad variety of perspectives: bio-medical, social, cultural, economic and political. The authors are leading experts from across the region and include both the infected and the affected, be they doctors or former drug users, United Nations employees or gay men, public health researchers or community activits. They describe how, from the first documented cases in 1981 to the present era of antiretroviral management, controlling the human inmmunodeficiency virus in Europe has provided elusive.

Disease Control Priorities in Developing Countries - Dean T. Jamison 2006-04-02

Based on careful analysis of burden of disease and the costs ofinterventions, this second edition of 'Disease Control Priorities in Developing Countries, 2nd edition' highlights achievable priorities; measures progresstoward providing efficient, equitable care; promotes cost-effectiveinterventions to targeted populations; and encourages integrated effortsto optimize health. Nearly 500 experts - scientists, epidemiologists, health economists,academicians, and public health practitioners - from around the worldcontributed to the data sources and methodologies, and identifiedchallenges and priorities, resulting in this integrated, comprehensivereference volume on the state of health in developing countries.

Development and Evaluation of an Active Warning Device for School Bus Loading and Unloading Points in Areas of Limited Visibility - 2005

The primary objectives of this research project were: (1) to develop an active advance warning device (AAWD) comprised of an actuated flashing beacon supplement to a conventional SCHOOL BUS STOP AHEAD sign (S3-1) and (2) to evaluate its effect on driver performance and safety through school bus loading and unloading zones. Secondary objectives were to summarize system components and costs, develop an activation strategy, review the liability risk, review national experience related to safety, and provide guidance regarding specifications and use in Texas. With respect to safety, 37 of 46 studies reported a positive effect resulting from AAWDs. Findings from field studies conducted in Texas also suggest favorable results with confirmed reductions in vehicle approach speeds when the flashing beacon was activated. Costs for the final AAWD are estimated to be 2,000 dollars for the S3-1 sign and flashing

beacons and 2,600 dollars for the flashing beacon activation system, not including sign installation or ongoing maintenance and operations costs. A review of published literature and historic case law suggests minimal additional liability risk above what is already experienced by transportation departments. Unique areas of risk relate to "jurisdictional responsibility" for establishing, operating, and maintaining school bus loading and unloading zones and the hazard expectation tied to the flashing beacon activation (i.e., motorists may not exercise the same degree of caution when the bus is not present and the beacons are not flashing despite children being present at the bus stop). Given the favorable safety impacts, the low system cost, and the minimal additional liability risk incurred, the AA WD is recommended for further implementation.

Handbook of Humanitarian Health Care Logistics - George Mc Guire 2015-10-31

The Political Economy of HIV/AIDS in Developing Countries - Benjamin Coriat 2008-01-01

The issue of universal and free access to treatment is now a fundamental goal of the international community. Based on original data and field studies from Brazil, Thailand, India and Sub-Saharan Africa under the aegis of ANRS (the French nationalagency for research on Aids and viral hepatitis, this timely and significant book both assesses the progress made in achieving this objective and presents a rigorous diagnosis of the obstacles that remain. Placing particular emphasis on the constraints imposed by TRIPS as well as the poor state of most public health systems in Southern countries, the contributing authors provide a comprehensive analysis of the huge barriers that have yet to be overcome in order to attain free access to care and offer innovative suggestions of how they might be confronted. In doing this, the book renews our understanding of the political economy of HIV/AIDS in these vast regions, where the disease continues to spread with devastating social and economic consequences. This volume will be a valuable addition to the current literature on HIV/AIDS in developing countries and will find widespread appeal amongst students and academics studying economics, sociology and public health. It will also be of interest to international organizations and professional associations involved in the fight against pandemics.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2020-04-21

Capital Project Delivery - Shawn LaBonde 2010

Printbegrænsninger: Der kan printes 10 sider ad gangen og max. 40 sider pr. session

Moving Mountains - Anne-Christine D'Adesky 2006-07-17

Collects field reports from numerous countries to chart the global effort to provide life-saving medicines and care to some forty million people living with HIV and AIDS in resource-poor nations, in a paperback edition that includes a new foreword that considers global AIDS and public policy since 2004. Reprint.

The Economist - 2002

Saudi Arabia Export-Import, Trade and Business Directory - IBP, Inc. 2009-03-30

2011 Updated Reprint. Updated Annually. Saudi Arabia Export-Import Trade and Business Directory

The Wiley Project Engineer's Desk Reference - Sanford I. Heisler 1994-02-08

A companion volume and sequel to The Wiley Engineer's Desk Reference. Covers major areas regarding the technology of engineering and its operational methodology, accentuating questions of schedule and schedule maintenance. Describes professional practice skills and engineering aspects essential to success. Includes a slew of examples, checklists, sample forms and documents to facilitate understanding.

Oregon Administrative Rules - 2001

Capital Project Delivery, 2nd Ed. (M47) - AWWA Staff 2011-01-12

Printbegrænsninger: Der kan printes 10 sider ad gangen og max. 40 sider pr. session

Stronger Food and Drug Regulatory Systems Abroad - National Academies of Sciences, Engineering, and Medicine 2020-04-09

Ensuring the safety of food and the quality and safety of medicines in a country is an important role of government, made more complicated by global manufacturing and international trade. By recent estimates, unsafe food kills over 400,000 people a year, a third of them children under 5, mostly in low- and middle-income countries; every year poor quality medicines cause about 70,000 excess deaths from childhood pneumonia and roughly 8,500 to 20,000 malaria deaths in sub-Saharan Africa alone. The Federal Drug Administration (FDA) Office of Global Policy and Strategy is charged with improving capacity of the agency's foreign counterpart offices and increasing understanding of the importance of regulatory systems for public health, development, and trade. At the request of the FDA, this study sets out a strategy to support good quality, wholesome food and safe, effective medical products around the world. Its goal is to build on the momentum for strengthening regulatory systems and to set a course for sustainability and continued progress. The 2012 report Ensuring Safe Food and Medical Products Through Stronger Regulatory Systems Abroad outlined strategies to secure international supply chains, emphasized capacity building and support for surveillance in low- and middle-income countries, and explored ways to facilitate work sharing among food and medical product regulatory agencies. This new study assess progress made and the current regulatory landscape.

Clinical Dilemmas in Viral Liver Disease - Graham R. Foster 2020-03-20

The only evidence-based book to approach viral liver disease by focusing exclusively on the clinical dilemmas encountered by hepatologists and their medical teams Although viral hepatitis is a growing public health risk around the world, the World Health Organization (WHO) views the elimination of hepatitis infection over the next several as an achievable goal. Effective pharmaceutical therapies are now available, yet medical teams caring for patients with viral hepatitis are challenged when looking for answers to specific questions in the current medical literature. The second edition of Clinical Dilemmas in Viral Liver Disease provides evidence-based guidance for medical teams involved in diagnosing, treating, and managing patients with viral liver disease. This fully updated book explores developments in new treatments and new diagnostic approaches that are contributing to WHO goals of viral elimination. Brief, easily referenced chapters examine clearly defined topics, addressing the clinical questions and difficulties encountered by medical teams in day-to-day practice. Contributions by an international team of investigators and clinicians address clinical questions and issues which are seldom found in standard textbooks and online repositories. Offering practical guidance on the specific challenges and dilemmas of treating viral liver disease, this unique volume: Provides practical, evidence-based guidance on topical and controversial issues Addresses understudied questions that arise in day-to-day clinical practice Discusses the challenges surrounding global elimination programs Presents focused approach that is supported by current literature and expert opinion The second edition of Clinical Dilemmas in Viral Liver Disease is required reading for practicing and trainee hepatologists, gastroenterologists, transplant surgeons, virologists, and other practitioners involved in caring for patients with liver disease.

Vaccines E-Book - Stanley A. Plotkin 2012-09-22

Apply the latest vaccination knowledge with a reference that Bill Gates calls "an indispensable guide to the enhancement of the well-being of our world." Inside Vaccines, you'll find comprehensive and current coverage of every aspect of vaccination, from the development of each vaccine to its use in reducing disease. This medical reference book offers the expert information you need to apply the very latest techniques and information in your practice! Consult this title on your favorite e-reader, conduct rapid searches, and adjust font sizes for optimal readability. Gain a complete understanding of each disease, including clinical characteristics, microbiology, pathogenesis, diagnosis, and treatment, as well as epidemiology and public health and regulatory issues. Update your knowledge of both existing vaccines and vaccines currently in the research and development stage. Get complete answers on each vaccine, including its stability, immunogenicity, efficacy, duration of immunity, adverse events, indications, contraindications, precautions, administration with other vaccines, and disease-control strategies. Analyze the cost-benefit and cost-effectiveness of different vaccine options. Clearly visualize concepts and objective data through an abundance of tables and figures. Make optimal use of the latest vaccines for pneumococcal disease, rotavirus, human papillomavirus, herpes zoster, meningococcal disease, and much more. Stay at the forefront of new developments with completely updated chapters on malaria and HIV vaccines, a new chapter on vaccine regulations across the world, and many other revisions throughout.

Board of Contract Appeals Decisions - United States. Armed Services Board of Contract Appeals 1998

Procurement of Health Sector Goods - 2001-01-01
These Standard Bidding Documents (SBD) and its companion Technical Note (TN) have been prepared by the World Bank for use by borrowers and their implementing agencies in the procurement of pharmaceuticals, vaccines, and condoms through international competitive bidding (ICB). For the purpose of these documents, pharmaceuticals also include nutritional supplements and oral and injectable hormonal forms of contraception. The procedures and practices presented in these SBD have been developed through broad international experience and are mandatory for use in projects that are financed in whole or in part by the World Bank in accordance with the provisions of the latest edition of Guidelines: Procurement under IBRD Loans and IDA Credits. The purpose of the TN is to provide background information to the Bank's project staff and borrowers, about the complex issues in the procurement of health sector goods and to help them make well-informed decisions in each special situation.
WHO Expert Committee on Biological Standardization - World Health Organization 2019-08-13
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 Recommendations to assure the quality safety and efficacy of recombinant hepatitis E vaccines; WHO Guidelines for the safe development and production of vaccines to human pandemic influenza viruses and influenza viruses with pandemic potential; and WHO Guidelines for the safe production and quality control of poliomyelitis vaccines were adopted on the recommendation of the Committee. In addition a WHO questions-and-answers guidance document on the evaluation of similar biotherapeutic product (SBPs) was also adopted with the Committee recommending that it be posted on the WHO website. Subsequent sections of the report provide information on the current status proposed development and establishment of international reference materials in the areas of: antibiotics; blood products and related substances; cellular and gene therapies; in vitro diagnostics; standards for use in public health emergencies; 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 three WHO documents adopted for publication on the advice of the Committee are then presented as part of this report (Annexes 2-4). Finally all additions and discontinuations made during the 2018 meeting to the list of International Standards Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 5. The updated full catalogue of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.
International Commerce - 1968-07

International Commerce - 1970

The selection and use of essential medicines - 2022-01-26
The 23rd meeting of the WHO Expert Committee on Selection and Use of Essential Medicines was coordinated from Geneva, Switzerland, and held virtually from 21 June to 2 July 2021. The Committee considered 88 applications proposing additions, changes and deletions of medicines, medicine classes and formulation on the Model Lists of Essential Medicines. The Committee evaluated the scientific evidence for comparative effectiveness, safety and cost-effectiveness of the medicines in question. The Committee also considered a review of the therapeutic alternatives for medicines on the Model Lists, and update to the AWaRe classification of antibiotics, and reviews and reports relevant to the selection and use of essential medicines.
Business America - 1987