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Orlando Lopez

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Orlando Lopez,2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.

Health Policy and European Union Enlargement Mckee,2004-04-01 While there may be consensus on the broader issues of the core objectives of the health care system, expectations differ between EU countries, and European national policy-makers. This book seeks firstly to assess the impact of the enlargement process and then to analyse the challenges that lie ahead in the field of health and health policy.

Medical Devices World Health Organization,2010 Background papers 1 to 9 published as technical documents. Available in separate records from WHO/HSS/EHT/DIM/10.1 to WHO/HSS/EHT/DIM/10.9

Ensuring Quality to Gain Access to Global Markets Martin Kellermann,2019-04-09 In a modern world with rapidly growing international trade, countries compete less based on the availability of natural resources, geographical advantages, and lower labor costs and more on factors related to firms' ability to enter and compete in new markets. One such factor is the ability to demonstrate the quality and safety of goods and services expected by consumers and confirm compliance with international standards. To assure such compliance, a sound quality infrastructure (QI) ecosystem is essential. Jointly developed by the World Bank Group and the National Metrology Institute of Germany, this guide is designed to help development partners and governments analyze a country's quality infrastructure ecosystems and provide recommendations to design and implement reforms and enhance the capacity of their QI institutions.

Bridging the Gulf: EU-GCC Relations at a Crossroads Silvia Colombo ,2014-05-27 Relations between the European Union (EU) and the Gulf Cooperation Council (GCC) are at a crossroads. After the derailment of the negotiations for the Free Trade Agreement (FTA) in 2008, the cooperation between the two regional blocs has remained low-key in a number of different areas, while the unprecedented changes that have taken place in North Africa and the Middle East, the common

neighbourhood of the EU and the GCC, have not led to a renewed, structured cooperation on foreign and security policy issues. This volume addresses the shortcomings and potential of EU-GCC relations by taking stock of their past evolution and by advancing policy recommendations as to how to revamp this strategic cooperation. In this light, it highlights the areas where greater room for manoeuvre exists in order to enhance EU-GCC relations, discusses the instruments available and sheds light on the features of the regional and international context that are likely to significantly influence the new phase in the mutual relation between the two blocs. The book is the result of the research conducted in the framework of the project 'Sharaka - Enhancing Understanding and Cooperation in EU-GCC Relations' co-funded by the European Commission.

Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use Therapeutic Goods Administration (Australia), 1991

Harnessing Quality for Global Competitiveness in Eastern Europe and Central Asia Jean-Louis Racine, 2011-05-05
Standards are everywhere, yet go mostly unnoticed. They define how products, processes, and people interact, assessing these entities' features and performance and signaling their level of quality and reliability. They can convey important benefits to trade, productivity, and technological progress and play an important role in the health and safety of individual consumers and the environment. Firms' ability to produce competitive products depends on the availability of adequate quality-support services. A "national quality infrastructure" denotes the chain of public and private services (standardization, metrology, inspection, testing, certification, and accreditation) needed to ascertain that products and services introduced in the marketplace meet defined requirements, whether demanded by authorities or by consumers. In much of Eastern Europe and Central Asia, national quality infrastructure systems are underdeveloped and not harmonized with those of their trading partners. This imbalance increases trade costs, hinders local firms' competitiveness, and weakens overall export performance. The objective of *Harnessing Quality for Global Competitiveness in Eastern Europe and Central Asia* is to highlight the need to reform and modernize the institutions in the region toward better quality and standards. The book ties in with much of the work done in the World Bank on the business environment, trade facilitation, economic diversification, and enterprise innovation. The countries in the region can improve this situation, revising mandatory standards, streamlining technical regulations, and harmonizing their national quality infrastructure with those of regional and international trade partners. Most governments will need to invest strategically in their national quality infrastructure, including pooling services with neighboring countries and stimulating local awareness and demand for quality. Specifically for the countries of the former Soviet Union, the restructuring process will need to improve governance, thus eliminating conflicts of interest and providing technically credible services to the economy.

Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade World Intellectual Property Organization, 2013 This study has emerged from an ongoing program of trilateral

cooperation between WHO, WTO and WIPO. It responds to an increasing demand, particularly in developing countries, for strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies.

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.

Data Integrity and Data Governance R. D. McDowall, 2018-11-09 This book provides practical and detailed advice on how to implement data governance and data integrity for regulated analytical laboratories working in the pharmaceutical and allied industries.

Quality Assurance of Aseptic Preparation Services Alison M. Beaney, 2016 *Quality Assurance of Aseptic Preparation Services Standards Handbook* (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of

unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

Rigged Rules and Double Standards Kevin Watkins,Penny Fowler,2002 A critical and detailed analysis of inequalities of world trade systems.

Countering the Problem of Falsified and Substandard Drugs Institute of Medicine,Board on Global Health,Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products,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.

The Urban Rail Development Handbook Daniel Pulido,Georges Darido,Ramon Munoz-Raskin,Joanna Moody,2018-09-11 Cities across the globe are looking to develop affordable, environmentally friendly, and socially responsible transportation solutions that can meet the accessibility needs of expanding metropolitan populations and support future economic and urban development. When appropriately planned and properly implemented as part of a larger public transportation network, urban rail systems can provide rapid mobility and vital access to city centers from surrounding districts. High-performing urban rail services, when carefully approached as development projects, can help enhance quality of life by giving citizens access to employment opportunities, essential services, urban amenities, and neighboring communities. The purpose of this Handbook is to synthesize and disseminate knowledge to inform the planning, implementation, and operations of urban rail projects with a view towards: -- Emphasizing the need for early studies and project planning; -- Making projects more sustainable (economically, socially, and environmentally); -- Improving socioeconomic returns and access to opportunities for users; -- Maximizing the value of private participation, where appropriate; and -- Building capacity within project implementing and managing institutions This Handbook provides experiential advice to tackle the technical, institutional, and financial challenges faced by decision makers considering urban rail projects. It brings together the expertise of World Bank

staff and the input of numerous specialists to synthesize international 'good practices' and recommendations that are independent of commercial, financial political, or other interests. The material presented is intended as an honest-broker guide to maximize the impact and manage the challenges of urban rail systems in cities in both developed and developing countries. Rather than identify a single approach, this Handbook acknowledges the complexities and context necessary when approaching an urban rail development by helping to prepare decision makers to ask the right questions, consider the key issues, perform the necessary studies, apply adequate tools, and learn from international good practice all at the right time in the project development process.

Understanding ICT Standardization Nizar Abdelkafi, Raffaele Bolla, 2019-05-23 To advance education about ICT standardization, comprehensive and up-to-date teaching materials must be available. With the support of the European Commission, ETSI has developed this textbook to facilitate education on ICT standardization, and to raise the knowledge level of ICT standardization-related topics among lecturers and students in higher education, in particular in the fields of engineering, business administration and law. Readers of this book are not required to have any previous knowledge about standardization. They are introduced firstly to the key concepts of standards and standardization, different elements of the ecosystem and how they interact, as well as the procedures required for the production of standardization documents. Then, readers are taken to the next level by addressing aspects related to standardization such as innovation, strategy, business, and economics. This textbook is an attempt to make ICT standardization accessible and understandable to students. It covers the essentials that are required to get a good overview of the field. The book is organized in chapters that are self-contained, although it would be advantageous to read the book from cover to cover. Each chapter begins with a list of learning objectives and key messages. The text is enriched with examples and case studies from real standardization practice to illustrate the key theoretical concepts. Each chapter also includes a quiz to be used as a self-assessment learning activity. Furthermore, each book chapter includes a glossary and lists of abbreviations and references. Alongside the textbook, we have produced a set of slides that are intended to serve as complementary teaching materials in face-to-face teaching sessions. For all interested parties there is also an electronic version of the textbook as well as the accompanying slides that can be downloaded for free from the ETSI website (www.etsi.org/standardization-education).

Global Value Chains in a Postcrisis World Olivier Cattaneo, Gary Gereffi, Cornelia Staritz, 2010 The book looks to address the following questions in a post-crisis world: How have lead firms responded to the crisis? Have they changed their traditional supply chain strategy and relocated and/or outsourced part of their production? How will those changes affect developing countries? What should be the policy responses to these changes?

Agglomeration Economics Edward L. Glaeser, 2010-04-15 When firms and people are located near each other in cities and in industrial clusters, they benefit in various ways, including by reducing the costs of exchanging goods and ideas. One might

assume that these benefits would become less important as transportation and communication costs fall. Paradoxically, however, cities have become increasingly important, and even within cities industrial clusters remain vital. Agglomeration Economics brings together a group of essays that examine the reasons why economic activity continues to cluster together despite the falling costs of moving goods and transmitting information. The studies cover a wide range of topics and approach the economics of agglomeration from different angles. Together they advance our understanding of agglomeration and its implications for a globalized world.

Tourism in Africa Iain Christie, Eneida Fernandes, Hannah Messerli, Louise Twining-Ward, 2014-06-19 This book presents how tourism initiates economic development and how constraints to the growth of tourism in Sub-Saharan Africa can be addressed. With 24 case studies that illustrate tourism development, it reveals that despite destination challenges, the basic elements needed to initialize or intensify success are applicable across the region.

Rising Concentration in Asia-Latin American Value Chains Osvaldo Rosales, Keiji Inoue, Nanno Mulder, 2015 Dynamic Asia has overtaken the European Union as Latin America and the Caribbean's second largest export market, after the United States. However, the region's exports to Asia remain concentrated in few commodities involved a small number of large firms. This book explores the present and future scope for the participation of small and medium-sized enterprises (SMEs) in biregional trade and value chains and the measures that can be taken to make those chains more inclusive and sustainable. It encourages governments in Latin America to improve the business environment in order to encourage multinational firms to invest, upgrade and innovate in the region.

A World of Regions Peter J. Katzenstein, 2015-11-16 Observing the dramatic shift in world politics since the end of the Cold War, Peter J. Katzenstein argues that regions have become critical to contemporary world politics. This view is in stark contrast to those who focus on the purportedly stubborn persistence of the nation-state or the inevitable march of globalization. In detailed studies of technology and foreign investment, domestic and international security, and cultural diplomacy and popular culture, Katzenstein examines the changing regional dynamics of Europe and Asia, which are linked to the United States through Germany and Japan. Regions, Katzenstein contends, are interacting closely with an American imperium that combines territorial and non-territorial powers. Katzenstein argues that globalization and internationalization create open or porous regions. Regions may provide solutions to the contradictions between states and markets, security and insecurity, nationalism and cosmopolitanism. Embedded in the American imperium, regions are now central to world politics.

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