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Morten Bøås

Excellence Beyond Compliance William I. White,2018-05-16 Many companies limp along from day-to-day treating the quality side of the business as a necessary evil, and doing only what is minimally necessary for compliance to regulations. This kind of approach to compliance almost always results in inefficiencies and sometimes can result in a curious kind of noncompliance. Documentation created with compliance as the sole consideration often ends up confusing the employees who must use the documentation. This book looks beyond what is necessary for compliance alone to address what makes a quality management system (QMS) both effective and efficient. This book also never forgets that real people must make any QMS work; the book provides a blueprint for creating a QMS that real people will find useful. After a review of the challenges that any medical device company faces in the world of today—the multiple sources of QMS requirements—the book poses a question: are we satisfied with the QMS we have now, or could we do better? If we want to do better, this book can help. This book offers: Advice that will lead to an effective and efficient QMS. Detailed guidance on the key decisions to be made regarding the quality system being established. Detailed ideas on how to execute those decisions. Up-to-date information on compliance to current regulations and standards and guidance on staying up to date. Specific examples of procedures. Information regarding requirements for combination products, such as a drug + device combination. Advice on incorporating risk management in the QMS.

Doing Business 2020 World Bank,2019-11-21 Seventeen in a series of annual reports comparing business regulation in 190 economies, Doing Business 2020 measures aspects of regulation affecting 10 areas of everyday business activity.

Bioequivalence Requirements in Various Global Jurisdictions Isadore Kanfer,2017-12-05 Although the Bioequivalence (BE) requirements in many global jurisdictions have much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada,

China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

Specification of Drug Substances and Products Christopher M. Riley,K. Lien Nguyen,2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals. There have been several recent developments in the ICH Guidelines, which were not captured in previous editions, notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines, and the specification guidelines. This edition contains chapters discussing the unique requirements for the universal critical quality attributes, as well as the specific tests required to characterize and control different types of products, ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug-antibody conjugates and mRNA-based products. This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists, managers, educators, and consultants involved in the development and regulation of pharmaceutical products - Presents critical assessment, potential impact, and application of the recent revisions to ICH guidelines on method validation (Q2) (as well as the latest guideline on Analytical Method Development (Q14), and the special regional requirements in non-ICH regions. - Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis, control, and specification of a variety of different types of dosage forms, ranging from traditional oral solid dosage forms to proteins, nRNA-based drugs, vaccines, and gene therapy. This book will also address drug–device combination products such as digital drug delivery systems, transdermal systems, and inhalation products. - Presents detailed treatment of latest statistical approaches, including new approaches to the treatment of validation data method, specification setting, and shelf-life prediction (based on stability data).

Small Arms Survey 2015 Keith Krause,2015-07-30 Highlights emerging trends and concerns regarding armed violence and small arms proliferation as well as related policies and programming.

Development of Medical Device Policies World Health Organization,2012-10-25 WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas: * policy framework for health technology * medical device regulations * health technology assessment * health technology management * needs assessment of medical devices * medical device procurement * medical equipment donations * medical equipment inventory management * medical equipment maintenance * computerized maintenance management systems * medical device data * medical device nomenclature * medical devices by health-care setting * medical devices by clinical procedures * medical device innovation, research and development. These documents

are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. The number of countries with existing health technology policies and with units to implement those policies shows that there is forward movement in the development and implementation of health technology policies. However, because medical devices are complex to select, manage and use, it is important to ensure that new policies are developed appropriately and existing ones are modified as necessary to make them as effective as possible. Proper integration of health technology policies and strategies within the framework of a national health plan has the potential to harness the political support to ensure improved access, quality and use of medical devices, enhance the best use of the resources in a framework of universal coverage, respond to the needs of the population, and ultimately achieve better health outcomes.

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

World Inequality Report 2022 Lucas Chancel,Thomas Piketty,Emmanuel Saez,Gabriel Zucman,2022-11 World Inequality Report 2022 is the most authoritative and comprehensive account of global trends in inequality, providing cutting-edge information about income and wealth inequality and also pioneering data about the history of inequality, gender inequality, environmental inequalities, and trends in international tax reform and redistribution.

Halsbury's Laws of England ,1990

Doing Business 2013 World Bank,2012-10-23 Tenth in a series of annual reports comparing business regulation in 185 economies, Doing Business 2013 measures regulations affecting 11 areas of everyday business activity: starting a business, dealing with construction permits, getting electricity, registering property, getting credit, protecting investors, paying taxes, trading across borders, enforcing contracts, closing a business, and employing workers. The report updates all indicators as of June 1, 2012, ranks economies on their overall "ease of doing business", and analyzes reforms to business regulation – identifying which economies are strengthening their business environment the most. The Doing Business reports illustrate how reforms in business regulations are being used to analyze economic outcomes for domestic entrepreneurs and for the wider economy. This year marks the tenth anniversary of the global Doing Business report. Doing Business is a flagship product by the World Bank and IFC that garners worldwide attention on regulatory barriers to entrepreneurship. More than 60 economies use the Doing Business indicators to shape reform agendas and monitor improvements on the ground. In addition, the Doing Business data has generated over 870 articles in peer-reviewed academic journals since its inception.

The United Nations and Security Sector Reform Adedeji Ebo,Heiner Haenggi,2019-12-16 Multilateral organizations - the United Nations (UN) in particular - have played, and continue to play, an important role in shaping the security sector reform (SSR) agenda, both in terms of policy development and the provision of support to a wide range of national SSR

processes. This volume presents a variety of perspectives on UN support to SSR, past and present, with attention to policy and operational practice. Drawing from the experience of UN practitioners combined with external experts on SSR, this volume offers an in-depth exploration of the UN approach to SSR from a global perspective.

Trade Policy Review - Brazil World Trade Organization,Wto,2014-04-04 Monitoring the trade policies and practices of members is a fundamentally important activity of the World Trade Organization. All WTO members are reviewed at regular intervals, according to their share of world trade. Each Trade Policy Review consists of three parts: a report by the government under review, a report written independentlyby the WTO Secretariat, and the concluding remarks by the chair of the Trade Policy Review Body. A highlights section provides an overview of key trade facts.

Generic Drug Product Development Isadore Kanfer,Leon Shargel,2016-04-19 Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutica

Global Corruption Report: Sport Transparency International,2016-02-05 Sport is a global phenomenon engaging billions of people and generating annual revenues of more than US$ 145 billion. Problems in the governance of sports organisations, fixing of matches and staging of major sporting events have spurred action on many fronts. Yet attempts to stop corruption in sport are still at an early stage. The Global Corruption Report (GCR) on sport is the most comprehensive analysis of sports corruption to date. It consists of more than 60 contributions from leading experts in the fields of corruption and sport, from sports organisations, governments, multilateral institutions, sponsors, athletes, supporters, academia and the wider anti-corruption movement. This GCR provides essential analysis for understanding the corruption risks in sport, focusing on sports governance, the business of sport, planning of major events, and match-fixing. It highlights the significant work that has already been done and presents new approaches to strengthening integrity in sport. In addition to measuring transparency and accountability, the GCR gives priority to participation, from sponsors to athletes to supporters an essential to restoring trust in sport.

Working with Markets Wei Neng Wu,Jean Chia,Ningzhen Ruan,2017 It examines the four aspects of working with markets for land and infrastructure development in Singapore since the 1960s.

The Effectiveness of Environmental Law Sandrine Maljean-Dubois (juriste)),2017 This book is the third volume in the European Environmental Law Forum (EELF) book series. The EELF is a non-profit initiative of environmental law scholars and practitioners from across Europe aiming to support intellectual exchange on the development and implementation of international, European and national environmental law in Europe. One of the activities of the EELF is an annual conference. This book is comprised of fifteen contributions presented at the Third EELF Conference in Aix-en-Provence, hosted by the

Central European Research Infrastructure Consortium, at Aix-Marseille University, September 2015. The central topic of the book is the effectiveness of environmental law. The impressive development in environmental law has not always been matched by corresponding improvements in environmental quality. The threats to our environment and, by extension, to our health have never been so numerous or serious. But paradoxically, the effectiveness of environmental law has been a long-neglected issue. This book offers a fruitful and stimulating dialogue between practitioners and academics, from varied countries and varied fields, combining empirical and theoretical approaches. The contributions go from classical-but still necessary-tools (control, criminal, administrative, civil sanctions, liability rules, strengthening of the regulatory structure, and the role of judges), to more innovative ones (public participation, effectiveness of instrument mixes, collaborative governance, hybrid governance, and private environmental enforcement). (Series: European Environmental Law Forum, Vol. 3) Subject: Environmental Law, European Law]

Rethinking National Action Plans on Women, Peace and Security S. Aroussi,2017-05-30 At the time of its adoption in October 2000, United Nations Security Council resolution 1325 on Women, Peace and Security (WPS) was hailed as a turning point for women involved in conflicts, peacemaking, peacekeeping and post-conflict reconstruction. Resolution 1325 required all efforts aimed at resolving conflicts and building peace to be inclusive, gender-sensitive and transformative for women. In recent years, National Action Plans (NAPs) on WPS have become one of the most commonly used tools by states to channel, assess and monitor the implementation of resolution 1325 and other UN WPS resolutions. This book presents an edited version of the proceedings of the NATO Advanced Research Workshop (ARW) on 'National Action Plans on Women, Peace and Security', held in Dublin, Ireland, in May 2016. The workshop brought together representatives from various states, as well as academics, and members of civil society and international organizations, to discuss their experiences with NAPs and to critically reflect on the role of NAPs in supporting the implementation by states of the WPS framework. The aim of this book is to disseminate the key arguments, findings, and recommendations which emerged from the discussions held at the ARW. It includes a summary report which sets out key arguments and recommendations and offers a number of key papers from the ARW, with the intention of contributing to academic and policy debates concerning gender and armed conflict and, more particularly, the WPS framework.

World Heritage Sites and Indigenous Peoples' Rights Stefan Disko,Helen Tugendhat,2014 This book includes twenty case studies of World Heritage sites from around the world that explore, from a human rights perspective, indigenous peoples' experiences with World Heritage sites and with the processes of the World Heritage Convention. The book will serve as a resource for indigenous peoples, World Heritage site managers, and UNESCO, as well as academics, and it will contribute to discussions about what changes or actions are needed to ensure that World Heritage sites can play a consistently positive role for indigenous peoples, in line with the spirit of the United Nations Declaration on the Rights of Indigenous Peoples.

The Sahel Crisis and the Need for International Support Morten Bøås,2019-10-30 The crisis in the Sahel is serious and multidimensional, and if it continues unabated it could have consequences far beyond the region. As the states of the region are too poor and weak to deal with this on their own, international support is needed. the current international emphasis on the G5 Sahel should change from a focus on more 'boots on the ground' to support for the development agenda of this embryonic international organisation. The Sahel needs a functioning regional framework and the G5 Sahel has some potential; but the only way to harvest this potential is to help fine-tune it to address the underlying causes of conflict. Improving security conditions in the Sahel is absolutely essential; but neither the inhabitants of the region nor the external stakeholders will find security exclusively through military means. The correct priorities must be set. And at the heart of this there must be an improvement in living conditions and a new system of governance that makes it much less possible for jihadist insurgents to appropriate local land-rights conflicts.

Herbal Medicine in Andrology Ralf Henkel,Ashok Agarwal,2020-11-13 Herbal Medicine in Andrology: An Evidence-Based Update provides a comprehensive overview of ethnomedical approaches in andrology, including ethnopharmacology of plant extracts and relevant bioactive compounds. It highlights information on the availability of medicinal plants and the legal and procedural processes involved in developing a marketable product. This reference helps clinicians and scientists develop an understanding on how herbal medicine can be used to treat andrological patients in practice. Only a limited number of journal articles are available on this topic, making this reference a valuable source of information for a large audience, including urologists, andrologists, gynecologists, reproductive endocrinologists and basic scientists. Provides essential evidence-based information about herbal medicine Offers an ethnopharmacological background on bioactive compounds in certain plant extracts Educates the basic scientist and clinician on the use of herbal medicines in andrology Provides an update to recent advances on herbal medicine in andrology from world experts

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