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Routledge Handbook of Risk Management and the Law - Virginia A. Suveiu 2022-12-14
In today's highly globalized and regulated economy, private and public organizations face myriad complex laws and regulations. A process designed to detect and prevent regulatory compliance failures is vital. However, such an effective process cannot succeed without development and maintenance of a strong compliance and legal risk management culture. This wide-ranging handbook pulls together work from experts across universities and industries around the world in a variety of key disciplines such as law, management, and business ethics. It provides an all-inclusive resource, specifying what needs to be known and what needs to be further pursued in these developing areas. With no such single text currently available, the book fills a gap in our current understanding of legal risk management, regulatory compliance, and ethics, offering the potential to advance research efforts and enhance our approaches to effective legal risk management practices. Edited by an expert on legal risk management, this book is an essential reference for students, researchers, and professionals with an interest in business law, risk management, strategic management, and business ethics.
Springer Handbook of Medical Technology - Rüdiger Kramme 2011-10-02
This concise, user-oriented and up-to-date desk reference offers a broad introduction to the fascinating world of medical technology, fully considering today's progress and further development in all relevant fields. The Springer Handbook of Medical Technology is a systemized and well-structured guideline which distinguishes itself through simplification and condensation of complex facts. This book is an indispensable resource for professionals working directly or indirectly with medical systems and appliances every day. It is also meant for graduate and post graduate students in hospital management, medical engineering, and medical physics.
Nuclear Science Abstracts - 1967-05

Factors Affecting International Brand Equity and Brand Image - Akihiro Yoshikawa 1995

The ASQ Certified Medical Device Auditor Handbook - Scott A. Laman 2021-02-05
The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include: • A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP) • Current information about federal and international regulations • New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations • A thorough explanation of quality tools and techniques

The Biomedical Quality Auditor Handbook, Third Edition - Heather Crawford 2017-09-08
The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge (BoK) and reference list for ASQ's Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably it has been re-organized to align more closely with the BoK.
Restaurant Chains in China - Guojun Zeng 2018-10-12
This book explores the paradox of the hospitality industry: customers demand not only personal and innovative tourism products and services, but also cost-effective ones. Enterprises have the option to meet the former demand by offering authentic products and services while the latter could be achieved through standardization. Although it seems ideal to combine both concepts, they seemingly contradict each other leading to suppliers facing an authenticity-standardization paradox. The authors identify, analyze, and provide solutions for this authenticity-standardization paradox based on a series of case studies of restaurants in China. This book will be of interest to scholars, business owners, and consultants.
ISO 13485 for Engineers - Priscilla Browne 2021-12
This book is written to provide Quality engineers, medical engineers, device engineers with a practical and insightful companion to understand ISO 13485, Quality Management system for medical devices. It provides a straight-to-the-point perspective which should assist in the interpretation of the standard and provide a benchmark for what is expected in the application of the standard and compliance for industry. ISO 13485:2016 is an international standard for the quality management of medical devices. It is of value and applicable to a number of business areas that are involved in the various stages of a medical device and its product lifecycle. It may be applied by a design company, manufacturer, raw material supplier, calibration service, sterilization services or distributer. The scope of the standard covers: design and development production, storage and distribution installation servicing (if required) decommissioning and disposal In particular, manufacturers of medical devices and typically mandated by regulatory bodies to comply with ISO 13484, and must demonstrate compliance and application of the standard subject to certification and an audit process. FDA, 21 CFR Part 820 is another example of a Quality Management system. While its official designation is a Quality System (QS) it serves a similar purpose to ISO 13485-Quality management system for medical devices. However, there is an important distinction. 21 CFR Part 820 has a regulatory standing in the United states. While many competent authorities require the application of ISO 13485, the framework of ISO 13485 is a standard opposed to a regulation. Revised in 2016, ISO 13485:2016 "specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements." The scope of the standard can apply to any organisation or company involved throughout the life-cycle of a product, including design and/or development, production, storage and distribution, installation, or servicing of a medical device and design and

development or provision of technical or professional services. The 2016 revision is designed to address recent developments in quality management and other updated regulations that relate to the industry. Improvements in the new version of the standard include broadening its applicability to include all organisations involved in the life cycle of the product, from the concept stage to end of life along with greater alignment with regulatory requirements and post-market surveillance including complaint handling. Overview of Content: Introduction to ISO 13485, Directives and Standards, Competent Authorities, Notified Bodies, How ISO 13485 differs to ISO 900I ISO/TR 14969, Terms /Definitions, Process Approach, Plan-Do-Check-Act (PDCA) Quality Management System, Introduction, Regulatory Requirements, Risk Based Approach, Changes within the QMS, Documentation, Quality Manual, Control of Records Management Responsibility, Management Commitment, Customer Focus, Quality Policy, Planning, Management Review, Resource Management, Provision of resources, Human resources, Infrastructure, Work environment & contamination control, Product realization, Planning of Product Realization, Design and Development, Production and service provision, Ctrl of monitoring & measuring equipment Measurement Analysis PART 2 Good Documentation Practices, Introduction, Quality Management Systems PART 3 Validation Introduction, Equipment and Software Validation, Software Validation, Process Validation, Packaging Validation

Medical Error and Patient Safety - George A. Peters 2007-11-01

A difficult and recalcitrant phenomenon, medical error causes pervasive and expensive problems in terms of patient injury, ineffective treatment, and rising healthcare costs. Simple heightened awareness can help, but it requires organized, effective remedies and countermeasures that are reasonable, acceptable, and adaptable to see a truly significant drop in the intolerable rate of medical mistakes. Only with better understanding, knowledge, and directed techniques can there be rapid and marked improvement in medical error management discipline. Since medical error is situation specific and involves diverse variables in equipment, environment, and human performance, the correct choice of preventive and corrective techniques is critical. Providing a wealth of useful ideas, concepts, and techniques, Medical Error and Patient Safety: Human Factors in Medicine uses abroad perspective to present more than 500 remedies that can be applied and tailored to your unique circumstances. This detailed review of so many measures enables you to correctly identify needs and undertake appropriate actions to achieve a success that can be measured in avoided injuries, improved healthcare, and reduced cost. Thought provoking and useful, this book considers the potential for error and the possibility for improvement in every aspect of healthcare. After an introduction to general concepts and approaches, it examines vulnerabilities in medical services, including emergency services, healthcare facilities, and infection control. It covers risks in medical devices and product design; human factors such as fatigue and stress; management errors; errors in communication at all levels of the healthcare hierarchy; as well as mistakes in drug delivery including faulty labels and warnings. The authors also compare and contrast several analytical methods, their interpretation, and their translation into a plan of action.

Titanium in Medicine - D.M. Brunette 2012-12-06

Providing scientific and technical in-depth information in a clear format with a homogeneous structure, this text is suited for educational and self-teaching purposes as well as a reference on titanium for biomedical applications. It covers the whole area relevant to the use of titanium for implants, devices and instruments in medicine: material and surface science, physics, chemistry, biology, medicine, quality and regulatory aspects.

Medical Devices [electronic Resource] : Quality Management Systems : Requirements for Regulatory Purposes - Canadian Standards Association 2003

PCR for Clinical Microbiology - Ian W.J. Carter 2010-07-03

Not another textbook, but a valuable tool for doctors and microbiologists wanting to know how to set up a PCR diagnostic microbiology laboratory according to current regulatory standards and perform assays supplied with patient clinical diagnostic criteria and easy to follow protocols. Whether laboratories are using commercial kits or in-house methods developed in their own laboratories or adopted from published methods, all clinical microbiology laboratories need to be able to understand, critically evaluate, perform and interpret these tests according to rigorous and clinically appropriate standards and international guidelines. The cost and effort of development and evaluation of in-house tests is considerable and many laboratories do not have the resources to do so. This compendium is a vehicle to improve and maintain the clinical relevance and high quality of diagnostic PCR. It is a unique collection of; guidelines for PCR laboratory set up and quality control, test selection criteria, methods and detailed step by step protocols for a diagnostic assays in the field of molecular microbiology. The structure of the book provides the PCR fundamentals and describes the clinical aspects and diagnosis of infectious disease. This is followed by protocols divided into; bacteria, virus, fungi and parasites, and susceptibility screens. The inclusion of medical criteria and interpretation adds value to the compendium and benefits clinicians, scientists, researchers and students of clinical diagnostic microbiology

Medical Regulatory Affairs - Jack Wong 2022-01-27

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

Quality Systems Update - 1997

Health Information Systems - Adrian Stavert-Dobson 2015-12-21

This is a practical book for health and IT professionals who need to ensure that patient safety is prioritized in the design and implementation of clinical information technology. Healthcare professionals are increasingly reliant on information technology to deliver care and inform their clinical decision making. Health IT provides enormous benefits in efficiency, communication and decision making. However a number of high-profile UK and US studies have concluded that when Health IT is poorly designed or sub-optimally implemented then patient safety can be compromised. Manufacturers and healthcare organizations are increasingly required to demonstrate that their Health IT solutions are proactively assured. Surprisingly the majority of systems are not subject to regulation so there is little in the way of practical guidance as to how risk management can be achieved. The book fills that gap. The author, a doctor and IT professional, harnesses his two decades of experience to characterize the hazards that health technology can introduce. Risk can never be eliminated but by drawing on lessons from other safety-critical industries the book systematically sets out how clinical risk can be strategically controlled. The book proposes the employment of a Safety Case to articulate and justify residual risk so that not only is risk proactively managed but it is seen to be managed. These simple techniques drive product quality and allow a technology's benefits to be realized without compromising patient safety.

Proceedings of the XIVth Triennial Congress of the International Ergonomics Association and 44th Annual Meeting of the Human Factors and Ergonomics Society - Human Factors and Ergonomics Society. Annual meeting 2000

The Objective is Quality - Michel Jaccard 2013-04-23

Quality is a form of management that is composed of the double approach of driving

an organization towards excellence, while conforming to established standards and laws. The objective of quality confers advantages to companies: it makes them more resilient to change that can be unexpected or even chaotic; it makes them more competitive by identifying those steps in processes that do not offer added value. No longer the concern of a small community of experts, even scientists and engineers working in the private sector will find that they will have to con-front questions related to quality management in their day-to-day professional lives. This volume offers such people an unique entry into the universe of quality management, providing not only a cartography of quality standards and their modes of application - with particular attention to the ISO standards - but also a broader cultural context, with chapters on the history, prizes, deontology and moral implications of systems of quality management. This book thus opens the door to all those eager to take the first steps to learning how the principles of quality are organized today, and how they can be applied to his or her own activity.

Characterization of Biomaterials - Imran Khan 2013-03-12

Preclinical testing is a critical part of the orthopaedic device design process and is required to demonstrate efficacy, safety and adherence to the requirements of essential regulations. The following chapter provides an overview of the key regulatory and technical requirements associated with mechanical and tribological testing of orthopaedic devices and the characterization of metallic coatings applied to such devices for improved biological fixation. Mechanical testing is typically carried out according to regional or international standards that define the type of device to be tested, its laboratory-based performance requirements and reference criteria that a product must meet. The most widely used tests for orthopaedic devices are static or fatigue tests. These may be conducted under compression, bending, shear or torsion, depending on the in vivo loading conditions that they are trying to replicate. Bearing wear simulator test methods have evolved over several decades from simpler tests such as pin-on-plate to more realistic tests that replicate the forces and motions experienced during walking or other gait cycles and, importantly, allow the testing of actual components. Current wear simulator test standards for hip and knee joints are reviewed and methods of characterizing wear debris and measuring friction are discussed. Metallic coatings on orthopaedic devices can be employed to improve the fixation of the implant to the host bone. This chapter discusses methods to characterize critical properties of metallic coatings for orthopaedic devices and also identifies the acceptance standards set by regulatory bodies for these kinds of coatings.

ASQC ... Annual Quality Congress Proceedings - 2002

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices - Amiram Daniel 2008-01-01

How have recent changes in domestic and international regulations affected quality management in the development and marketing of medical devices in the US and abroad? Consultants Daniel and Kimmelman take a close look at the Quality System Regulation (QsReg), the ISO 13485: 2003 standard and the ISO/TR 14969: 2004 guidance document as well as a number of US Food and Drug Administration (FDA) and Global Harmonization Task Force (GHTF) guidance documents. The authors provide extensive commentary and notes an update their material to include such topics as the incorporation of principles of risk management into the medical device organizations' quality management systems (QMSs) and considerations of combination products. Daniel and Kimmelman include full coverage of the QSReg requirements, descriptions of comparable requirements in the ISO documents, excerpts of the FDA's responses to the QSReg preamble and excerpts from FDA guidance documents related to QMSs.

Yearbook of International Organizations 2014-2015 (Volume 2) - Union of International Associations 2014-07-16

The Yearbook of International Organizations provides the most extensive coverage of non-profit international organizations currently available. Detailed profiles of international non-governmental and intergovernmental organizations (IGO), collected and documented by the Union of International Associations, can be found here. In addition to the history, aims and acitvities of international organizations, with their events, publications and contact details, the volumes of the Yearbook include networks between associations, biographies of key people involved and extensive statistical data. Volume 2 allows users to locate organizations by the country in which secretariats or members are located.

World Intellectual Property Indicators 2021 - World Intellectual Property Organization 2021-11-03

This authoritative report analyzes IP activity around the globe. Drawing on 2020 filing, registration and renewals statistics from national and regional IP offices and WIPO, it covers patents, utility models, trademarks, industrial designs, microorganisms, plant variety protection and geographical indications. The report also draws on survey data and industry sources to give a picture of activity in the publishing industry.

Best's Insurance Reports - 2008

Proactive Supplier Management in the Medical Device Industry - James B. Shore 2016-05-06

In order for organizations to have high confidence in the reliability of their medical devices, they must ensure that each and every component or service meets requirements, including quality requirements. In that light, supplier management is not only a regulatory requirement but also a business aspect. The intent of this book is to show readers a process of effectively selecting, evaluating, and implementing applicable controls based on the evaluation and ongoing proactive management of suppliers, consultants, and contractors in a state of compliance. These processes can be applied to all suppliers, consultants, and contractors. In writing this book, the authors made sure that readers could immediately apply its content. They provide best practices based on a combined 50+ years of quality and engineering experience, having worked with some of the best medical device companies and contract manufacturers in the world. Four icons use throughout the book help readers navigate and understand the content. The FDA and toolbox icons assist in determining whether it's a requirement or a tool to help achieve compliance. The "Lessons from the Road" icon indicates real-life stories and what the authors have learned throughout their careers. Lastly, the check mark icon is used to highlight key thoughts, what they feel are unique takeaways or deserve a special focus.

Medical Device Regulatory Practices - Val Theisz 2015-08-03

This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case studies. Medical devices, like pharmaceuticals, are highly regulated, and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in their pursuit of commercial success. Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes practical solutions for a coherent, one-size-fits-all (or most) set of systems and processes in compliance with regulations in all key markets, throughout the life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets; important terminology needed to understand the regulators' language; and examples, case studies, and practical recommendations that bridge the gap between regulatory theory and practice.

Mobile Health - Sasan Adibi 2015-02-18

This book offers a comprehensive report on the technological aspects of Mobile Health (mHealth) and discusses the main challenges and future directions in the field. It is divided into eight parts: (1) preventive and curative medicine; (2) remote health monitoring; (3) interoperability; (4) framework, architecture, and software/hardware systems; (5) cloud applications; (6) radio technologies and

applications; (7) communication networks and systems; and (8) security and privacy mechanisms. The first two parts cover sensor-based and bedside systems for remotely monitoring patients' health condition, which aim at preventing the development of health problems and managing the prognosis of acute and chronic diseases. The related chapters discuss how new sensing and wireless technologies can offer accurate and cost-effective means for monitoring and evaluating behavior of individuals with dementia and psychiatric disorders, such as wandering behavior and sleep impairments. The following two parts focus on architectures and higher level systems, and on the challenges associated with their interoperability and scalability, two important aspects that stand in the way of the widespread deployment of mHealth systems. The remaining parts focus on telecommunication support systems for mHealth, including radio technologies, communication and cloud networks, and secure health-related applications and systems. All in all, the book offers a snapshot of the state-of-art in mHealth systems, and addresses the needs of a multidisciplinary audience, including engineers, computer scientists, healthcare providers, and medical professionals, working in both academia and the industry, as well as stakeholders at government agencies and non-profit organizations.

Catalogue - International Organization for Standardization 2008

Monthly Catalog of United States Government Publications - 2002

Medical Devices - Seeram Ramakrishna 2015-08-18

Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

Objectif qualité - Michel Jaccard 2010

Longtemps confinée au monde de la production et de ses ingénieurs, l'aire de la Qualité s'est progressivement étendue par le biais de diverses initiatives comme le prix Deming, le prix Baldridge, la perspective EFQM, la norme ISO 9001 ou l'approche Six Sigma. Divers systèmes de management ont alors émergé, appliqués notamment à l'environnement (ISO 14000), à la gestion des risques (ISO 31000) ou à la responsabilité sociétale (AFNOR SD 21000, annonciatrice de la norme ISO 26000 à venir). Peu d'auteurs se sont risqués à proposer à leurs lecteurs un panorama complet du monde de la Qualité, de la Qualité totale, de la performance, de la responsabilité sociétale ; c'est précisément le défi relevé par Michel Jaccard dans cet ouvrage, qui présente l'ensemble des outils essentiels des systèmes de management les plus largement utilisés dans le monde de l'économie publique et privée d'aujourd'hui. Clair et didactique, ce manuel expose les concepts de base dont la maîtrise est indispensable, comme les huit principes d'ISO 9001, accompagnés d'un panorama historique permettant de situer chacune de ces approches dans leur contexte et de comprendre les relations existant entre ces différents modèles. L'auteur établit des liens inédits entre la morale, la déontologie et les systèmes de management, et valorise tout particulièrement l'apport de l'économie privée japonaise, encore au bénéfice d'un leadership conséquent dans le domaine. Cette vision synthétique fait appel à de nombreux exemples procurant une base solide pour l'application de ces principes en entreprise.

Ward's Auto World - 2001

Handbook of Digital Homecare - Kanagasingam Yogesan 2009-10-01

Digital Homecare is a collection of services to deliver, maintain and improve care in the home environment using the latest ICT technology and devices. It is important to recognize the wide range of issues that are covered by digital homecare. This book shows a good selection of related issues, be it experience, technologies, managerial issues or standardization. A very diverse "audience"; elderly, people with chronic conditions, disabled, to name the most important groups, benefits from digital homecare, within the comfort and protection of their own homes.

Biodesign - Stefanos Zenios 2010

Recognize market opportunities, master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. Outlining a systematic, proven approach for innovation - identify, invent, implement - and integrating medical, engineering, and business challenges with real-world case studies, this book provides a practical guide for students and professionals.

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices - Amiram Daniel 2008-02-21

This new and expanded second edition maintains the organizational approach of the first and includes the requirements and guidance contained in the Quality System Regulation (QSReg), the ISO 13485:2003 standard, the ISO/TR 14969:2004 guidance document, and, as appropriate, a number of the FDA and Global Harmonization Task Force (GHTF) guidance documents.This second edition also addresses a number of additional topics, such as the incorporation of risk management into the medical device organization's QMS, QMS issues related to combination products, the key process interactions within a QMS, effective presentation of and advocacy for a QMS during FDA inspections and third-party assessments, and future FDA compliance and standards activities. The organization of the guidebook is based on the order of the requirements in the QSReg. For each substantive requirement section there is: A verbatim statement of the QSReg requirement. A description of the comparable requirement in ISO 13485:2003, focusing on any additions to or differences from the requirements contained in the QSReg.Excerpts of the FDA responses to relevant comment groups contained in the Preamble to the QSReg. Excerpts from various FDA guidance documents related to quality management systems. A description of the relevant guidance contained in ISO/TR 14969:2004, focusing on any additions to or differences from the guidance in the Preamble and other FDA guidance documents, and, if useful, excerpts from relevant GHTF guidances. Authors' notes giving guidance derived from the authors' sixty years of regulatory compliance experience. This guidance book is meant as a resource to manufacturers of medical devices, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves and texts on the specific processes and activities contained within the QMS.

Handbook of Medical Device Regulatory Affairs in Asia - Jack Wong 2013-03-27

Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the medical device industry, and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects.

Scientific and Technical Aerospace Reports - 1976

Lists citations with abstracts for aerospace related reports obtained from world wide sources and announces documents that have recently been entered into the NASA Scientific and Technical Information Database.

Handbook of Investigation and Effective CAPA Systems, Second Edition - José Rodríguez-Pérez 2016-04-04

Understanding and improving the CAPA system as a whole is the focal point of this

book, the only of its kind dealing exclusively with this critical system within highly regulated industries. Features include: Information about the importance of the CAPA system within the quality system for the medical products regulated industry. Fully updated with current versions of regulations (U.S. FDA, EU, ISO 13485, and so on), and a new section covers the regulatory expectation of customer complaint investigations. Investigation and CAPA elements of the 2015 revision of the ISO 9001 standard. New coverage on the investigation plan and the new U.S. FDA quality metric guidance, as well as a section discussing the tight relationship between CAPAs and FMEA. A new chapter fully devoted to human errors and human factors, and their impact in the investigation and CAPA system. Discussion of a dozen of the most common pitfalls commonly encountered in the investigation and CAPA world of regulated companies. An example of an investigation and CAPA expert certification program being used for many companies. Forms and examples of the different elements (investigation report, root causes checklist, human error investigation, CAPA plan, and so on) covered in the book. Fully usable forms are also included in the companion CD in Microsoft Word format. While the first edition of this book was aimed solely at the FDA-regulated industry, the title of this second edition reflects the importance of the investigation/root cause analysis stage as the necessary preceding step of any effective corrective and preventive action system. Investigation and CAPA are concepts used in many sectors besides the FDA-regulated industry, such as: automotive, electronics, aerospace, telecommunications, process industry, and many more. This book will become an essential reference for those in these other industries.

International Aerospace Abstracts - 1991

Medical Device Safety - G.R Higson 2001-10-29

Medical Device Safety: The Regulation of Medical Devices for Public Health and Safety examines the prospects for achieving global harmonization in medical device regulation and describes a possible future global system. Unresolved difficulties are discussed while solutions are proposed. An essential book for all those involved in health physics, engineering, and medical regulatory affairs.

ISO Catalogue - International Organization for Standardization 2007