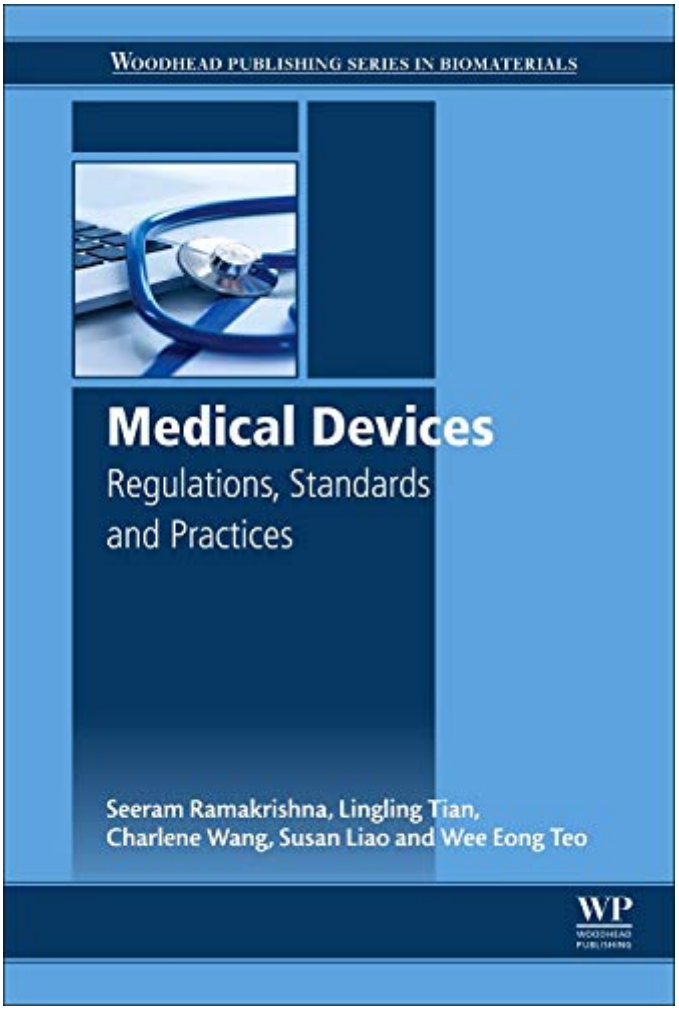

[Book] Medical Devices: Regulations, Standards And Practices (Woodhead Publishing Series In Biomaterials)

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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

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.

Medical Device Regulations-Michael Cheng 2003-09-16 The term 'medical devices' covers a wide range of equipment essential for patient care at every level of the health service, whether at the bedside, at a health clinic or in a large specialised hospital. Yet many countries lack access to high-quality devices, particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices. This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices, based on best practice experience in other countries. Issues highlighted include: the need for harmonised regulations; and the adoption, where appropriate, of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources. These approaches allow emphasis to be placed on locally-assessed needs, including vendor and device registration, training and surveillance and information exchange systems.

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.

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.

Public Health Effectiveness of the FDA 510(k) Clearance Process-Institute of Medicine 2010-10-04 The Food and Drug Administration (FDA) is responsible for assuring that medical devices are safe and effective before they go on the market. As part of its assessment of FDA's premarket clearance process for medical devices, the IOM held a workshop June 14-15 to discuss how to best balance patient safety and technological innovation. This document summarizes the workshop.

Medical Devices and the Public's Health-Institute of Medicine 2011-10-25 Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.

Medical Device Quality Assurance and Regulatory Compliance-Richard C. Fries 1998-08-11 "Acquaints developers of medical devices with the basic concepts and major issues of medical quality assurance and regulatory documents, describes the requirements listed in these documents, and provides strategies for compliance with these requirements."

Medical Device Design and Regulation-Carl T. DeMarco 2011-01-01

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.

Medical Device Design-Peter J Ogrodnik 2012-12-17 This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products’ commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelsstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

Handbook of Medical Device Design-Richard C. Fries 2000-09-14 The Handbook of Medical Device Design provides a review of regulatory and standards issues in medical device design, including FDA regulations, types of 510 (k), the ISO 9000 series, and medical device directives. It identifies how to determine and document customer needs and device requirements. It also establishes reliability and quality metrics for the duration of the product development cycle. Topics include

Toxicological Aspects of Medical Device Implants-Prakash Srinivasan Timiri Shanmugam 2020-06-10 Toxicological Aspects of Medical Device Implants provides comprehensive information on the use of medical implant and devices and the balance between the application of the devices in relation to any potential adverse effects. In order to ensure the safety and effectiveness of medical devices, many international policies, regulations, and standards have been established, and the book also discusses medical devices within this regulatory framework. The book covers a broad range of disease topics and disease-specific implants and an interdisciplinary team of experts brings a wealth of information on implants used in various disease models and associated risk factors. Toxicological Aspects of Medical Device Implants is a comprehensive resource for toxicologists, biomedical engineers, immunologists, medical staff, regulators, and manufacturers working in the field who need to be aware of the potential toxicity and device management of such a wide variety of implants and devices and their health risks. Discusses the adverse toxicological effects of medical devices Covers a broad range of disease topics and disease specific implants Offers contributions from experts from across several disciplines

Sensor Technologies-Michael J. McGrath 2014-01-23 Sensor Technologies: Healthcare, Wellness and Environmental Applications explores the key aspects of sensor technologies, covering wired, wireless, and discrete sensors for the specific application domains of healthcare,

wellness and environmental sensing. It discusses the social, regulatory, and design considerations specific to these domains. The book provides an application-based approach using real-world examples to illustrate the application of sensor technologies in a practical and experiential manner. The book guides the reader from the formulation of the research question, through the design and validation process, to the deployment and management phase of sensor applications. The processes and examples used in the book are primarily based on research carried out by Intel or joint academic research programs. “Sensor Technologies: Healthcare, Wellness and Environmental Applications provides an extensive overview of sensing technologies and their applications in healthcare, wellness, and environmental monitoring. From sensor hardware to system applications and case studies, this book gives readers an in-depth understanding of the technologies and how they can be applied. I would highly recommend it to students or researchers who are interested in wireless sensing technologies and the associated applications.” Dr. Benny Lo Lecturer, The Hamlyn Centre, Imperial College of London “This timely addition to the literature on sensors covers the broad complexity of sensing, sensor types, and the vast range of existing and emerging applications in a very clearly written and accessible manner. It is particularly good at capturing the exciting possibilities that will occur as sensor networks merge with cloud-based ‘big data’ analytics to provide a host of new applications that will impact directly on the individual in ways we cannot fully predict at present. It really brings this home through the use of carefully chosen case studies that bring the overwhelming concept of 'big data' down to the personal level of individual life and health.” Dermot Diamond Director, National Centre for Sensor Research, Principal Investigator, CLARITY Centre for Sensor Web Technologies, Dublin City University "Sensor Technologies: Healthcare, Wellness and Environmental Applications takes the reader on an end-to-end journey of sensor technologies, covering the fundamentals from an engineering perspective, introducing how the data gleaned can be both processed and visualized, in addition to offering exemplar case studies in a number of application domains. It is a must-read for those studying any undergraduate course that involves sensor technologies. It also provides a thorough foundation for those involved in the research and development of applied sensor systems. I highly recommend it to any engineer who wishes to broaden their knowledge in this area!" Chris Nugent Professor of Biomedical Engineering, University of Ulster

Trends in Development of Medical Devices-Prakash Srinivasan Timiri Shanmugam 2020-01-25 Trends in Development of Medical Devices covers the basics of medical devices and their development, regulations and toxicological effects, risk assessment and mitigation. It also discusses the maintenance of a medical device portfolio during product lifecycle. This book provides up-to-date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare. Researchers and industry professionals from the fields of medical devices, surgery, medical toxicology, pharmacy and medical devices manufacture will find this book useful. The book's editors and contributors form a global, interdisciplinary base of knowledge which they bring to this book. Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, government regulations Presents new strategies that readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce imperfections in production and develop products that enable completely new treatment possibilities

Medical Device Technologies-Gail Baura 2011-09-28 Medical Device Technologies introduces undergraduate engineering students to commonly manufactured medical devices. It is the first textbook that discusses both electrical and mechanical medical devices. The first 20 chapters are medical device technology chapters; the remaining eight chapters focus on medical device laboratory experiments. Each medical device chapter begins with an exposition of appropriate physiology, mathematical modeling or biocompatibility issues, and clinical need. A device system description and system diagram provide details on technology function and administration of diagnosis and/or therapy. The systems approach lets students quickly identify the relationships between devices. Device key features are based on five applicable consensus

standard requirements from organizations such as ISO and the Association for the Advancement of Medical Instrumentation (AAMI). The medical devices discussed are Nobel Prize or Lasker Clinical Prize winners, vital signs devices, and devices in high industry growth areas Three significant Food and Drug Administration (FDA) recall case studies which have impacted FDA medical device regulation are included in appropriate device chapters Exercises at the end of each chapter include traditional homework problems, analysis exercises, and four questions from assigned primary literature Eight laboratory experiments are detailed that provide hands-on reinforcement of device concepts

Handbook of Medical Device Regulatory Affairs in Asia-Jack Wong 2018-03-28 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. 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. Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs.

Engineering High Quality Medical Software-Antonio Coronato 2018 This book focuses on high-confidence medical software in the growing field of e-health, telecare services and health technology. It covers the development of methodologies and engineering tasks together with standards and regulations for medical software.

Safety Risk Management for Medical Devices-Bijan Elahi 2018-06-29 Safety Risk Management for Medical Devices demystifies risk management, providing clarity of thought and confidence to the practitioners of risk management as they do their work. Written with practicing engineers, safety management professionals, and students in mind, this book will help readers tackle the difficult questions, such as how to define risk acceptance criteria and how to determine when to stop risk reduction. This book delivers not only theory, but also practical guidance for applying the theory in daily risk management work. The reader is familiarized with the vocabulary of risk management and guided through a process to ensure compliance with the international standard ISO 14971—a requirement for all medical devices. This book outlines sensible, easily comprehensible, and state-of the-art methodologies that are rooted in current industry best practices. Opening chapters introduce the concept of risk, the legal basis for risk management, and the requirements for a compliant risk-management process. The next group of chapters discusses the connection between risk management and quality systems, usability engineering and biocompatibility. This book delves into the techniques of risk management, such as fault tree analysis and failure modes and effects analysis, and continues with risk estimation, risk control, and risk evaluation. Special topics such as software risk management, clinical investigations, and security are also discussed. The latter chapters address benefit-risk analysis, and production and postproduction monitoring. This book concludes with advice and wisdom for sensible, efficient, and successful safety risk management of medical devices. Teaches industry best practices on medical-device risk management in compliance with ISO 14971 Provides practical, easy-to-understand, and step-by-step instructions on how to perform hazard analysis and manage the risks of medical devices Offers a worked-out example applying the risk management process on a hypothetical device

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.

Biological Safety & European Medical Device Regulations-

Managing Medical Devices within a Regulatory Framework-Beth Ann Fiedler 2016-09-10 Managing Medical Devices within a Regulatory Framework helps administrators, designers, manufacturers, clinical engineers, and biomedical support staff to navigate worldwide regulation, carefully consider the parameters for medical equipment patient safety, anticipate problems with equipment, and efficiently manage medical device acquisition budgets throughout the total product life cycle. This contributed book contains perspectives from industry professionals and academics providing a comprehensive look at health technology management (HTM) best practices for medical records management, interoperability between and among devices outside of healthcare, and the dynamics of implementation of new devices. Various chapters advise on how to achieve patient confidentiality compliance for medical devices and their software, discuss legal issues surrounding device use in the hospital environment of care, the impact of device failures on patient safety, methods to advance skillsets for HTM professionals, and resources to assess digital technology. The authors bring forth relevant challenges and demonstrate how management can foster increased clinical and non-clinical collaboration to enhance patient outcomes and the bottom line by translating the regulatory impact on operational requirements. Covers compliance with FDA and CE regulations, plus EU directives for service and maintenance of medical devices Provides operational and clinical practice recommendations in regard to regulatory changes for risk management Discusses best practices for equipment procurement and maintenance Provides guidance on dealing with the challenge of medical records management and compliance with patient confidentiality using information from medical devices

Design Controls for the Medical Device Industry-Marie Teixeira 2002-09-20 This reference provides real-world examples, strategies, and templates for the implementation of effective design control programs that meet current ISO 9000 and FDA QSR standards and regulations-offering product development models for the production of safe, durable, and cost-efficient medical devices and systems. Details procedures utilize

The Design and Manufacture of Medical Devices-J Paulo Davim 2012-10-16 Medical devices play an important role in the field of medical and health technology, and encompass a wide range of health care products. Directive 2007/47/EC defines a medical device as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. The design and manufacture of medical devices brings together a range of articles and case studies dealing with medical device R&D. Chapters in the book cover materials used in medical implants, such as Titanium Oxide, polyurethane, and advanced polymers; devices for specific applications such as spinal and craniofacial implants, and other issues related to medical devices, such as precision machining and integrated telemedicine systems. Contains articles on a diverse range of subjects within the field, with internationally renowned specialists discussing each medical device Offers a practical approach to recent developments in the design and manufacture of medical devices Presents a topic that is the focus of research in many important universities and centres of research worldwide

Metallic Biomaterials Processing and Medical Device Manufacturing-Cuie Wen 2020-08-20 Metallic Biomaterials Processing and Medical Device Manufacturing details the principles and practices of the technologies used in biomaterials processing and medical device manufacturing. The book reviews the main categories of metallic biomaterials and the essential considerations in design and manufacturing of medical devices. It bridges the gap between the designing of biomaterials and manufacturing of medical devices including requirements and standards. Main themes of the book include, manufacturing, coatings and

surface modifications of medical devices, metallic biomaterials and their mechanical behaviour, degradation, testing and characterization, and quality controls, standards and FDA regulations of medical devices. The leading experts in the filed discuss the requirements, challenges, recent progresses and future research directions in the processing of materials and manufacturing of medical devices. Metallic Biomaterials Processing and Medical Device Manufacturing is ideal for those working in the disciplines of materials science, manufacturing, biomedical engineering, and mechanical engineering. Reviews key topics of biomaterials processing for medical device applications including metallic biomaterials and their mechanical behavior, degradation, testing and characterization Bridges the gap between biomaterials design and medical device manufacturing Discusses the quality controls, standards, and FDA requirements for biomaterials and medical devices

FDA Regulatory Affairs-David Mantus 2014-02-28 FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that’s broadly useful to both business and academia.

Medical Device Quality Management Systems-Susanne Manz 2018-10 Medical Devices Quality Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness is written for the needs of quality, compliance, and regulatory professionals in medical device companies. It includes secrets for developing an effective, yet efficient, Quality Management System (QMS) and explains how to create a vision, strategy, and tactical plans. Author Manz shares lessons on leadership, key roles and responsibilities within a medical device company, while also exploring the concepts of process ownership, individual accountability, and how to cultivate a culture of quality and compliance. This book is useful for all executive, functional leaders, and organizations in the highly regulated medical device industry. Provides practical, real-world guidance on developing an effective and efficient Quality Management System Presents a roadmap for QMS development Covers techniques to assess current state Includes discussions on tools, such as CAPA and Six Sigma that help define vision, strategy and quality plans

Safe Medical Devices for Children-Institute of Medicine 2006-01-20 Innovative medical devices have helped reduce the burden of illness and injury and improve the quality of life for countless children. Mechanical ventilators and other respiratory support devices rescue thousands of fragile newborns every year. Children who once would have died of congenital heart conditions survive with the aid of implanted pacemakers, mechanical heart valves, and devices that close holes in the heart. Responding to a Congressional request, the Institute of Medicine assesses the system for postmarket surveillance of medical devices used with children. The book specifically examines: The Food and Drug Administrationâ€™s monitoring and use of adverse event reports The agency's monitoring of manufacturersâ€™ fulfillment of commitments for postmarket studies ordered at the time of a deviceâ€™s approval for marketing The adequacy of postmarket studies of implanted devices to

evaluate the effects of childrenâ€™s active lifestyles and their growth and development on device performance Postmarket surveillance of medical devices used with children is a little investigated topic, in part because the market for most medical products is concentrated among older adults. Yet children differ from adults, and their special characteristics have implications for evaluation and monitoring of the short- and long-term safety and effectiveness of medical devices used with young patients.

Applied Human Factors in Medical Device Design-Mary Beth Privitera 2019-06-15 Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process, integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact, when it's ideal to use, and related challenges. Also discussed are other barriers, such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing and regulation. Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU) Explains technology development and the application of human factors throughout the development process Covers FDA and MHRA regulations Includes case examples with each method

Usability Testing of Medical Devices-Michael E. Wiklund P.E. 2015-12-23 Usability Testing of Medical Devices covers the nitty-gritty of usability test planning, conducting, and results reporting. The book also discusses the government regulations and industry standards that motivate many medical device manufacturers to conduct usability tests.Since publication of the first edition, the FDA and other regulatory groups h

Registries for Evaluating Patient Outcomes-Agency for Healthcare Research and Quality/AHRQ 2014-04-01 This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Pharmaceutical and Medical Devices Manufacturing Computer Systems Validation-Orlando Lopez 2018-10-02 Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards, and applicable regulatory authority’s requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book,

which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.

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.

Guidelines for Failure Modes and Effects Analysis for Medical Devices-Dyadem Press 2018-06-28 Challenged by stringent regulations, vigorous competition, and liability lawsuits, medical device manufactures must develop safe, reliable, and cost-effective products, and managing and reducing risk is a vital element of reaching that goal. A practical guide to achieving corporate consistency while dramatically cutting the time required for studies, Guidelines for Failure Modes and Effects Analysis for Medical Devices focuses on Failure Modes and Effects Analysis (FMEA) and its application throughout the life cycle of a medical device. It outlines the major U.S. and E.U. standards and regulations and provides a detailed yet easy-to-read overview of risk management and risk analysis methodologies, common FMEA pitfalls, and FMECA-Failure Mode, Effects, and Criticality Analysis. Discover how the FMEA methodology can help your company achieve a more cost-effective manufacturing process by improving the quality and reliability of your products. This new FMEA manual from the experts at Dyadem is the ultimate resource for you and your colleagues to learn more about Failure Modes and Effects Analysis and then teach others at your facility. This comprehensive manual is sure to become a standard reference for engineering professionals.

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices-World Health Organization 2017-05-09 The Model recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient regulation to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. It foresees that such countries will progress from basic regulatory controls towards an expanded level to the extent that their resources allow. The Model is written for the legislative, executive, and regulatory branches of government as they develop and establish a system of medical devices regulation. It describes the role and responsibilities of a country's regulatory authority for implementing and enforcing the regulations. Also, it describes circumstances in which a regulatory authority may either "rely on" or "recognize" the work products from trusted regulatory sources (such as scientific assessments, audit, and inspection reports) or from the WHO Prequalification Team. Section 2 of this document recommends definitions of the terms "medical devices" and IVDs. It describes how they may be grouped according to their potential for harm to the patient or user and specifies principles of safety

and performance that the device manufacturer must adhere to. It explains how the manufacturer must demonstrate to a regulatory authority that its medical device has been designed and manufactured to be safe and to perform as intended during its lifetime. Section 3 presents the principles of good regulatory practice and enabling conditions for effectively regulating medical devices. It then introduces essential tools for regulation, explaining the function of the regulatory entity and the resources required. Section 4 presents a stepwise approach to implementing and enforcing regulatory controls for medical devices as the regulation progresses from a basic to an expanded level. It describes elements from which a country may choose according to national priorities and challenges. Also, it provides information on when the techniques of reliance and recognition may be considered and on the importance of international convergence of regulatory practice.Section 5 provides a list of additional topics to be considered when developing and implementing regulations for medical devices. It explains the relevance of these topics and provides guidance for regulatory authorities to ensure that they are addressed appropriately. The Model outlines a general approach but cannot provide country-specific guidance on implementation. While it does not offer detailed guidance on regulatory topics, it contains references to relevant documents where further information may be found. It does not detail the responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies, and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of medical devices.

Good Design Practice for Medical Devices and Equipment-Sandra Shefelbine 2002 Due to the direct health and safety effects they have on users, medical devices are subject to many regulations and must undergo extensive validation procedures before they are allowed on the market. Requirements formulation is one of the most important aspects of the design process because it lays the foundation for the rest of the design.

Biocompatibility and Performance of Medical Devices-Jean-Pierre Boutrand 2012-10-26 Implant and device manufacturers are increasingly facing the challenge of proving that their products are safe and biocompatible, and that they will perform as expected. Biocompatibility and performance of medical devices provides an essential guide to the performance analysis of these vital devices. Part one introduces the key concepts and challenges faced in relation to biocompatibility in medical devices, with consideration of biological safety evaluation planning and biomechanical and biochemical compatibility in innovative biomaterials. Part two goes on to discuss the evaluation and characterisation of biocompatibility in medical devices. Topics covered include material and chemical characterisation, allowable limits for toxic leachables, in vivo and in vitro testing and blood compatibility assessment. Testing and interpreting medical device performance is the focus of part three, with chapters describing preclinical performance studies for bone, dental and soft tissue implants, and mechanical testing of soft and hard tissue implants. Part four provides information on the regulation of medical devices in the European Union, Japan and China, and the book concludes with part five, a review of histopathology principles for biocompatibility and performance studies. With its distinguished editor and international team of expert contributors, Biocompatibility and performance of medical devices is a vital tool for all those involved in the research, design, production and application of medical devices, including research directors, production companies and medical regulatory agencies, as well as industry professionals and academics. Examines the key concepts and challenges faced in relation to biocompatibility in medical devices Discusses evaluation and characterisation issues, including material and chemical characterization, allowable limits for toxic leachables, in vivo and in vitro testing, and blood compatibility assessment Delivers a comprehensive overview of testing and interpreting medical device performance

Medical Device Regulation-ELIJAH N. WREH 2021-08 This book sheds light on the importance of regulations and standards for manufacturers' development of medical devices. Based on the author's practical experience with the US Food and Drug Administration (FDA) and industry, it provides a concise, practical guide on key issues and processes in developing new medical devices to meet the FDA regulatory requirements and standards. The book is designed to help medical

device manufacturers navigate FDA regulation, carefully consider the parameters for medical device patient safety, anticipate problems with medical device, and efficiently manage medical device throughout the total product life cycle. The book contains perspectives from industry and FDA professionals and academics providing a comprehensive look of FDA regulation of medical devices in the United States, best practices for medical device product development, FDA current thinking on medical device regulation, and the dynamics of implementation of new product introduction. Various chapters advise manufacturers on how to achieve marketing approval and clearance for all types of medical device classification, including Class 1 (low to moderate risk), Class 2 (moderate to high risk), and Class 3 (high risk). In addition, the book describes compliance for medical device and their software and discusses legal issues and case studies surrounding medical devices, the impact of medical device failures on patient safety, mobile medical applications, cybersecurity, and wireless coexistence. It brings forth relevant challenges and demonstrates how medical device manufacturers can foster increased clinical and non-clinical data to support their marketing application to the FDA and the bottom line by translating the regulatory impact on operational requirements.

Hearing Health Care for Adults-National Academies of Sciences, Engineering, and Medicine 2016-10-06 The loss of hearing - be it gradual or acute, mild or severe, present since birth or acquired in older age - can have significant effects on one's communication abilities, quality of life, social participation, and health. Despite this, many people with hearing loss do not seek or receive hearing health care. The reasons are numerous, complex, and often interconnected. For some, hearing health care is not affordable. For others, the appropriate services are difficult to access, or individuals do not know how or where to access them. Others may not want to deal with the stigma that they and society may associate with needing hearing health care and obtaining that care. Still others do not recognize they need hearing health care, as hearing loss is an invisible health condition that often worsens gradually over time. In the United States, an estimated 30 million individuals (12.7 percent of Americans ages 12 years or older) have hearing loss. Globally, hearing loss has been identified as the fifth leading cause of years lived with disability. Successful hearing health care enables individuals with hearing loss to have the freedom to communicate in their environments in ways that are culturally appropriate and that preserve their dignity and function. Hearing Health Care for Adults focuses on improving the accessibility and affordability of hearing health care for adults of all ages. This study examines the hearing health care system, with a focus on non-surgical technologies and services, and offers recommendations for improving access to, the affordability of, and the quality of hearing health care for adults of all ages.

New Medical Devices-Institute of Medicine 1988-01-01 In the past 50 years the development of a wide range of medical devices has improved the quality of people's lives and revolutionized the prevention and treatment of disease, but it also has contributed to the high cost of health care. Issues that shape the invention of new medical devices and affect their introduction and use are explored in this volume. The authors examine the role of federal support, the decision-making process behind private funding, the need for reforms in regulation and product liability, the effects of the medical payment system, and other critical topics relevant to the development of new devices.