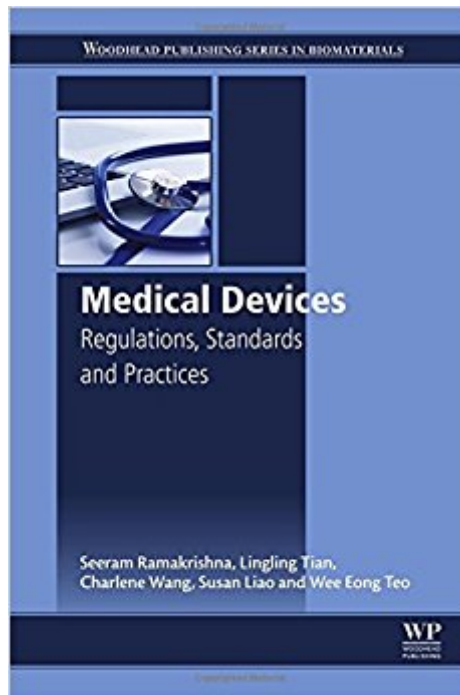




The book was found

Medical Devices: Regulations, Standards And Practices



Synopsis

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

Book Information

Hardcover: 256 pages

Publisher: Woodhead Publishing; 1 edition (December 24, 2015)

Language: English

ISBN-10: 0081002890

ISBN-13: 978-0081002896

Product Dimensions: 6 x 0.7 x 9.1 inches

Shipping Weight: 1.6 pounds (View shipping rates and policies)

Average Customer Review: Be the first to review this item

Best Sellers Rank: #2,652,595 in Books (See Top 100 in Books) #73 in Books > Textbooks > Medicine & Health Sciences > Reference > Instruments & Supplies #116 in Books > Medical Books > Medicine > Reference > Instruments & Supplies #874 in Books > Engineering & Transportation > Engineering > Bioengineering > Biomedical Engineering

Customer Reviews

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. 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. Part One, covers the worldwide regulation of medical devices, management systems, standards for medical device manufacture, and the process of gaining approval for new medical devices. In addition, including recent changes to the regulations and standards. In Part Two, we provide guidance on risk assessment procedures for new medical devices and safety and clinical testing

based on 3 main ISO standards. Based on the latest version of those standards, we illustrate current standards and guidance documents. In Part Three, we discuss the practices: product design overview, case studies and highlight the role of the international medical device regulator forum in the pursuit of global harmonization. Professor Dr PE Seeram Ramakrishna, FREng, is the Director of Center for Nanofibers & Nanotechnology at the National University of Singapore and an Elected fellow Royal Academy of Engineering, UK; Institution of Engineers Singapore; and American Institute for Medical & Biological Engineering. Dr. Tian Lingling is a Research Fellow at National University of Singapore, Singapore. Ms. Charlene Wang has five years' experience in biomedical research laboratory management. Dr. Susan Liao is Programme manager and Senior Research Fellow at Nanyang Technological University, Singapore. Mr Teo Wee Eong has over a decade of academic and industrial experience in medical devices ranging from single component implantable to electrical medical device. He is currently a senior product engineer responsible for ensuring compliance of medical devices.

Professor Seeram Ramakrishna, FREng, FBSE is the Director of Center for Nanofibers & Nanotechnology, and a leader of Future of Manufacturing at the National University of Singapore (NUS). He is a Highly Cited Researcher in Materials Science (www.highlycited.com). He is among the World's Most Influential Scientific Minds (Thomson Reuters). He authored 1,000 articles which attracted ~ 57,000 citations and ~110 H-index. His innovations have been translated into products. He is an editor of Current Opinion in Biomedical Engineering. He delivered over 200 plenary and keynote lectures around the world including a special lecture at the Kavli Symposium on Nanosciences and Nanotechnologies, Norway. He is a Fellow of UK Royal Academy of Engineering (FREng); Biomaterials Science and Engineering (FBSE); American Association of the Advancement of Science (AAAS) and American Institute for Medical & Biological Engineering (AIMBE) He is a recipient of IFEES President award- Global Visionary; Chandra P Sharma Biomaterials Award; Nehru Fellowship; LKY Fellowship; NUS Outstanding Researcher Award; IES and ASEAN Outstanding Engineer Award. He received PhD from the University of Cambridge, UK, and the General Management Training from Harvard University, USA. Dr. Tian Lingling is a Research Fellow at National University of Singapore, Singapore. She obtained her Ph.D in Textile Engineering from College of Textiles, Donghua University, Shanghai, China in March of 2014. Her research interests include fabrication of electrospun nanofibers and electrosprayed nano/micro-particles, and the application in cardiac, bone and nerve tissue engineering. She has around 10 peer-reviewed journal/conference paper/book chapter publications and one patent. Dr.

Susan Liao is Programme manager and Senior Research Fellow at Nanyang Technological University, Singapore. She was Lee Kuan Yew Research Fellow in the Division of Bioengineering and Department of Orthopaedic Surgery, National University of Singapore. She obtained her Ph.D in Biomaterials from the Department of Materials Science and Engineering, Tsinghua University, Beijing, China. Her research interests include Tissue Engineering, Biomimetic nanomaterials, Biomineralization and Cell-biomimetic matrix reactions. She has around 80 peer-reviewed journal/book chapter publications and over 40 international conference presentations. She has also served as an editorial board member for four professional journals and as a reviewer for over forty professional journals.

[Download to continue reading...](#)

Medical Devices: Regulations, Standards and Practices ISO 14971:2007, Medical devices - Application of risk management to medical devices ISO 14971:2000, Medical devices -- Application of risk management to medical devices 2017 Little League Softball® Official Regulations Playing Rules, and Operating Policies: Official Regulations, Playing Rules, and Policies For All Divisions Of Play 2016 Little League® Softball Official Regulations Playing Rules, and Operating Policies: Official Regulations, Playing Rules, and Policies For All Divisions Of Play FCC Rules and Regulations (Fcc Rules and Regulations for the Amateur Radio Service) Federal Firearms Regulations Reference Guide: Firearm laws and ATF Rules and Regulations (updated through 2017) Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology) Medical Terminology: Medical Terminology Made Easy: Breakdown the Language of Medicine and Quickly Build Your Medical Vocabulary (Medical Terminology, Nursing School, Medical Books) Prostheses: Design, Types, and Complications (Biomedical Devices and Their Applications; Medical Devices and Equipment) FBA: Private Label Product Sourcing: Finding Manufacturers and Understanding Product Regulations, Standards, Customs and Import Tax Rates. (Mastermind Roadmap to Selling on with FBA Book 2) Codes, Regulations, and Standards in Interior Design Cost Accounting Standards Board Regulations, as of January 1, 2017 Cost Accounting Standards Board Regulations as of January 1, 2016 (CASB) Soap and Cosmetic Packaging & Labeling Rules and Regulations Handbook: How to Implement Good Manufacturing Practices The Patient's Medical Journal: Record Your Personal Medical History, Your Family Medical History, Your Medical Visits & Treatment Plans American Medical Association Complete Medical Encyclopedia (American Medical Association (Ama) Complete Medical Encyclopedia) Integrated circuit devices and components (Integrated-circuit technology, analog and logic circuit

design, memory and display devices) Silica Optical Fiber Technology for Devices and Components: Design, Fabrication, and International Standards Private Pilot Airman Certification Standards - Airplane: FAA-S-ACS-6, for Airplane Single- and Multi-Engine Land and Sea (Practical Test Standards series)

[Contact Us](#)

[DMCA](#)

[Privacy](#)

[FAQ & Help](#)