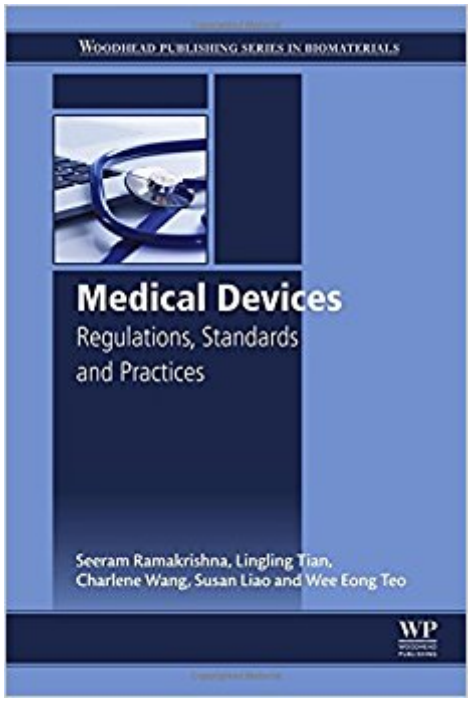
Medical Devices: Regulations, Standards And Practices



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 authorsâ ™ 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 regulationsConcise and comprehensive information on how to design medical devices to ensure they meet regulations and standardsIncludes 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)

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Based on the authorsâ ™ 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 yearsâ ™ 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.

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