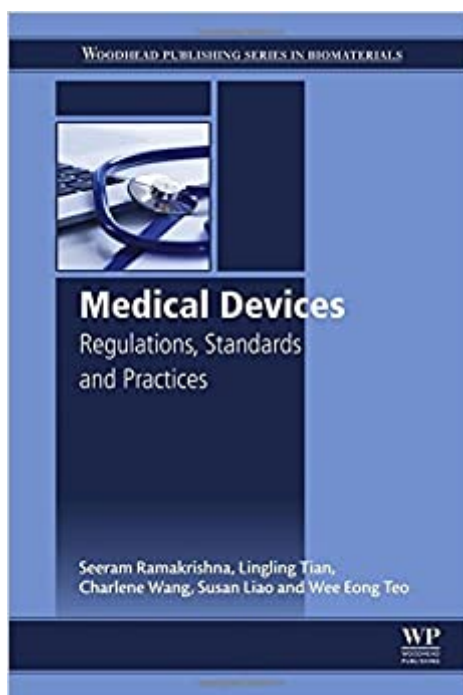


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# Medical Devices: Regulations, Standards And Practices



## 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

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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 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.

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](http://www.highlycited.com)). He is among the Worldâ™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 IFEEES 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.

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