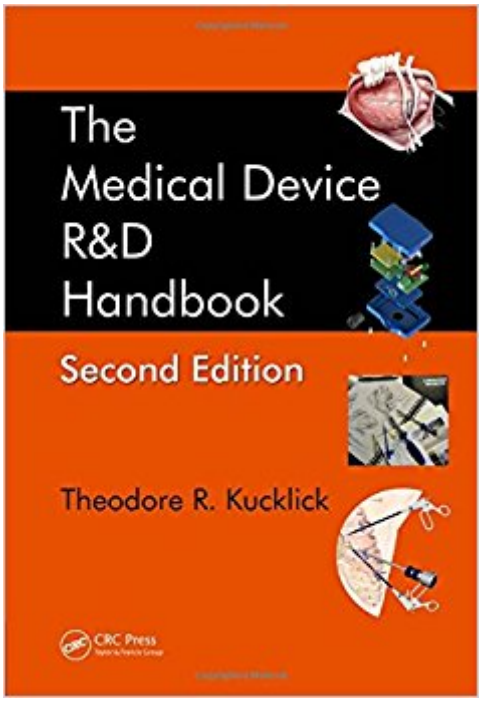
The Medical Device R&D Handbook, Second Edition



Synopsis

Exploring the practical, entrepreneurial, and historical aspects of medical device development, this second edition of The Medical Device R&D Handbook provides a how-to guide for medical device product development. The book offers knowledge of practical skills such as prototyping, plastics selection, and catheter construction, allowing designers to apply these specialized techniques for greater innovation and time saving.The author discusses the historical background of various technologies, helping readers understand how and why certain devices were developed. The text also contains interviews with leaders in the industry who offer their vast experience and insights on how to start and grow successful companiesÃ¢â ¬â ¢both what works and what doesnÃ¢â ¬â„¢t work. This updated and expanded edition adds new information to help meet the challenges of the medical device industry, including strategic intellectual property management, operating room observation protocol, and the use of new technologies and new materials in device development.

Book Information

Hardcover: 510 pages

Publisher: CRC Press; 2 edition (December 5, 2012)

Language: English

ISBN-10: 143981189X

ISBN-13: 978-1439811894

Product Dimensions: 9.3 x 6.2 x 1.1 inches

Shipping Weight: 2 pounds (View shipping rates and policies)

Average Customer Review: 5.0 out of 5 stars 4 customer reviews

Best Sellers Rank: #472,699 in Books (See Top 100 in Books) #17 inÃ Â Books > Textbooks > Medicine & Health Sciences > Reference > Instruments & Supplies #25 inÃ Â Books > Medical Books > Medicine > Reference > Instruments & Supplies #78 inÃ Â Books > Textbooks > Medicine & Health Sciences > Medicine > Biotechnology

Customer Reviews

"This is a handbook in the classic sense of the word. It is a concise guide that is directed for those who want to develop products for the marketplace. Ã¢â ¬Â¦ I would say this would serve any professional well, and also be an excellent guide for senior design projects by those students studying biomedical engineering. The information in this book is priceless and represents an immense accumulation of practical knowledge. There is no other text like it.This is a must read for anyone entering the medical device industry. If you want to make a productÃ¢â ¬â ¢ particularly a

therapeutic deviceÃ¢â ¬â ¢you will find no better resource than this text. It should be on the bookshelf of each and every biomedical engineer"Ã¢â ¬â ¢Brian Wong M.D., Ph.D., University of CaliforniaÃ¢â ¬â œIrvine, USA"I think this book is a must-have for any engineer involved in medical device design, but also for medical doctors focused on inventing innovative devices to address their needs. A book like this is inspiring for an undergraduate or a graduate student that is planning a career in medical device design. It can be an invaluable source for answers for the full lifecycle of a medical device. It covers the conception and nurturing of a new idea, how to develop a reliable prototype, how to bring it into production, and, last but not least, addresses the fundamental issues of intellectual property protection. Interviews of big names in medical device design are the grand finale of the book. It is so inspiring to read about success stories in the field of medical devices. There is such a need for innovation in healthcare and this book is a perfect how-to manual to guide inventors of all ages through the full process of medical device design."Ã¢â ¬â ¢Pietro Valdastri, Vanderbilt University, Nashville, Tennessee, USA"With all your academic training in biomedical engineering, I hope you will agree you have not been taught how to develop a practical medical device. Ted Kucklick wrote this book just for you. He assumes that you are well schooled in the basic concepts, and he recognizes that what you need is a tutorial on how to apply your knowledge to develop medical devices. He covers broad areas of design and early prototyping of disposable medical devices, with how-to instructions for many fabrications, and links to helpful outside industrial resources. This is a book you will want to keep handy on your bookshelf and find a valuable reference."Ã¢â ¬â ¢Frank Ingle, Ph.D., PE, CEO, and CTO, Instruments for Science and Medicine, Inc., Palo Alto, California, USA"The Medical Device Handbook is a must for any company engaged in the increasingly complex world of medical device development. Author Kucklick has updated his Ã¢â ¬Ëœone-stopÃ¢â ¬â„¢ handbook, covering the essentials of medical device development from design to manufacturing scale-up. This is a practical reference book that will have a broad audience in any medical device companyÃ¢â ¬â ¢from start-up to multinational."Ã¢â ¬â ¢Thomas Loarie, Mercator MedSystems, Inc., Danville, California Praise for the First Edition: "This is the first in its class of multidisciplinary books for medical device innovators, reaching across several disciplines to capture what innovators need."Ã¢â ¬â ¢Michael Gertner, MD, Co-Director, Surgical Innovation Program at Stanford University "This is a resource that will help medical device innovators develop better products, and more focused companies, more quickly."Ã¢â ¬â ¢Randy Williams, Founder, The Keiretsu Forum"Finally, a real manual that for the first time supports efficient medical device development."Ã¢â ¬â ¢Peter H. Muller, President, Interform Product Development

Theodore R. Kucklick has extensive experience in the hands-on design and commercial development of medical devices, including radio frequency ablation devices, microwave catheters for minimally invasive therapy, in-home diagnostics devices, surgical closure devices, battery-powered devices, disposables, and general surgery tools. Ted is currently the cofounder, CEO, and CTO for Cannuflow, Inc., an arthroscopic instrument start-up company, and design director for TRKD Medical Device R&D, a medical device design and development company. Ted is the inventor of more than 40 U.S. and international patents, and he is a member of the IEEE/Engineering in Medicine and Biology Society, the Industrial Designers Society of America, and the Association of Medical Illustrators.

Plenty of Information for people interested in R&D of medical devices. Covers everything from FDA approved materials to 3D printing and rapid prototyping.

I read other medical device related books before but they were more about piling up standards and regulations, which for a freshman of the industry, is boring and not that useful. The book, however, brings in the life experience of medical device development. The language is easy to understand and the author used many daily life examples to illustrate scientific and engineering concepts. The book is written from an entrepreneur’s perspective. It listed related companies’ and institutes’ names, which a reader who is planning on create a startup would really appreciate. I cannot say that I agree with all the political views mentioned in this book but the technical part is awesome. I recommend this book to anyone who wants to enter the medical device R&D world.

The Medical Devices R&D Handbook series by author Theodore "Ted" Kucklick fills a very important gap for engineers, managers, and students interested in developing innovative medical devices and/or creating a medical device start-up. Kucklick is a seasoned medical device professional with years of experience in the hands-on design and commercial development of medical devices across multiple engineering and medical specialties. He is also the author of more than 40 US and foreign patents and is a co-founder of a medical start-up.Kucklick was inspired to write "The R&D Handbook" after he realized that the "tribal knowledge" that existed in the trenches of medical device development was not being effectively communicated within the industry, particularly to younger entrants. If the US is to continue being the world’s leader in medical technology, this information needed to be shared more broadly so we can develop medical devices more effectively and quickly. Sharing what is known and what works as well as what does not work provides the

starting point for effective development."The Handbook" is tied together by three threads - the practical side of medical device engineering, valuable historical knowledge that gets lost in the shadows of development, and insights provided by innovation thought leaders, successful entrepreneurs and venture investors. These include: Tom Fogerty MD, Paul Yock MD, Dane Miller PhD, Rich Ferrari, Casey McGlynn Esq, Kucklick, and more. This last section is exceptional and will be the most valued for those wanting to learn more about entrepreneurship and the creation of a new medical device company.The book is organized in three sections: Materials; Processes; Methods: and Insights. The section on materials covers everything from an introduction to medical plastics to assessing biocompatibility; the section on processes offers insights on catheter production, rapid-prototyping, reverse engineering, injection molding, and make/buy decisions; the section on methods includes how to observe in an OR (operating room), NDAs, preclinical research, medical illustrations, and more.We have witnessed the globalization of medical technology development and manufacturing over the past forty years. US device regulation and reimbursement, the need for lost cost manufacturing, and new emerging markets have all contributed to this phenomenon. We must step up our innovation effort or the US will lose its leadership role. Kucklick has made a significant contribution to this need with his "The Medical Device R&D Handbook (2nd Edition)" and it is my hope that he continues to build on this foundation with many more editions. They are needed and welcomed.

I am an orthopeadic surgeon of China. I love to develop new devices, but could find no related book in China. I am lucky to find this book. It is really a good guide to beginner, especially to some physicians, who have little experience in this area.

American Medical Association Complete Medical Encyclopedia (American Medical Association (Ama) Complete Medical Encyclopedia) Medical Device Technologies: A Systems Based Overview Using Engineering Standards (Academic Press Series in Biomedical Engineering) IEC 62304 Ed. 1.0 b:2006, Medical device software - Software life cycle processes Design Controls for the Medical Device Industry Medical Device Software Verification, Validation and Compliance ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry Medical Device Design: Innovation from Concept to Market Design, Execution, and Management of Medical Device Clinical Trials Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness Mastering and Managing the FDA Maze: Medical Device Overview: A Training and Management Desk Reference for Manufacturers Regulated by the Food and Drug Administration