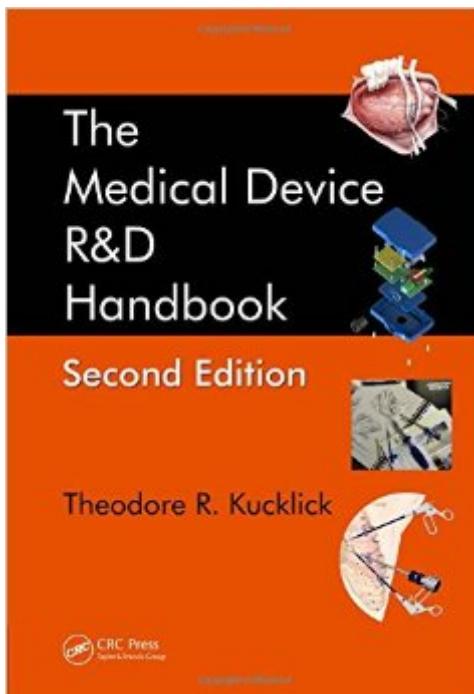


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# The Medical Device R&D Handbook, Second Edition



## 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 companies—both what works and what doesn'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

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## Customer Reviews

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 low 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 orthopedic 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.

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

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