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"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 'one-stop' 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 company?from start-up to ...

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This volume details current developments in industry practices and standards relating to medical device packaging. This edition offers entirely new as well as revised chapters on packaging materials, package validation and methods and integrity testing, bar-coding technology, environmentally sound packaging and disposal procedures, storage autoclave systems, international standards, customer needs, regulatory aspects, and more.

The second edition of this bestselling title examines how sterilization methods affect the properties of plastics and elastomers. It provides the comprehensive detail necessary to make first evaluations, materials comparisons, and final decisions in applications pursuits.

Developed to promote the design of safe, effective, and usable medical devices, Handbook of Human Factors in Medical Device Design provides a single convenient source of authoritative information to support evidence-based design and evaluation of medical device user interfaces using rigorous human factors engineering principles. It offers guidance

No book has been published that gives a detailed description of all the types of plastic materials used in medical devices, the unique requirements that the materials need to comply with and the ways standard plastics can be modified to meet such needs. This book will start with an introduction to medical devices, their classification and some of the regulations (both US and global) that affect their design, production and sale. A couple of chapters will focus on all the requirements that plastics need to meet for medical device applications. The subsequent chapters describe the various types of plastic materials, their properties profiles, the advantages and disadvantages for medical device applications, the techniques by which their properties can be enhanced, and real-world examples of their use. Comparative tables will allow readers to find the right classes of materials suitable for their applications or new product development needs.

This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial

prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpels to stents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

Pharmaceutical Packaging Handbook provides a complete overview of the role that packaging plays in the development and delivery of pharmaceuticals and medical devices. Supplying a thorough examination of the industry in size and scope, the book covers drug dosage forms, vaccines, biologically produced products, and medical foods. Features: Discusses how packaging is designed and integrated into the product development cycle Provides an overview of the regulatory environment procedures Describes the materials used to package pharmaceuticals, including glass, metal, plastics, flexible films, rubber, and elastomers Examines new hybrids used for packaging Explores the processing techniques used with the materials to produce pharmaceutical containers Discusses some of the strengths and weaknesses of the processes used for container fabrication Explains retort, aseptic, gas, and radiation sterilization of product Reviews labeling and design for pharmaceuticals, including how labels are produced, materials used, and production techniques Complete and straightforward, the book lists information in an easy to follow fashion, making it a complete standalone reference for anyone working in the pharmaceutical industry.

With more international contributors than ever before, Block's Disinfection, Sterilization, and Preservation, 6th Edition, is the first new edition in nearly 20 years of the definitive technical manual for anyone involved in physical and chemical disinfection and sterilization methods. The book focuses on disease prevention—rather than eradication—and has been thoroughly updated with new information based on recent advances in the field and understanding of the risks, the technologies available, and the regulatory environments.

The collection of topics in the second volume of this book challenges the reader to think beyond standard methods and question why certain current procedures remain static while technological advances abound in other aspects of sterilisation technology. By small means, better practices may come to pass to help answer some of the residual healthcare sterilisation and nosocomial infection queries: What are some of the current challenges in healthcare sterilisation, and how can they be handled? What are some of the acceptable current non-traditional sterilisation methods, challenging alternatives, and novel modalities? What are some of the packaging, validation and statistical considerations of sterilisation practices? How does design-of-product and packaging interrelate with sterilisation processing? Are the current sterility media and practices optimal for recovery of more modified and more resistant viable organism entities and product? Are there increased sterility and product quality needs with new types of implantables and technological advances within the three dimensional combinations of diagnostics, drug release and challenging medical devices?