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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 ...

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 autoclav

Biomedical Engineering Design presents the design processes and practices used in academic and industry medical device design projects. The first two chapters are an overview of the design process, project management and working on technical teams. Further chapters follow the general order of a design sequence in biomedical engineering, from problem identification to validation and verification testing. The first seven chapters, or parts of them, can be used for first-year and sophomore design classes. The next six chapters are primarily for upper-level students and include in-depth discussions of detailed design, testing, standards, regulatory requirements and ethics. The last two chapters summarize the various activities that industry engineers might be involved in to commercialize a medical device. Covers subject matter rarely addressed in other BME design texts, such as packaging design, testing in living systems and sterilization methods Provides instructive examples of how technical, marketing, regulatory, legal, and ethical requirements inform the design process Includes numerous examples from both industry and academic design projects that highlight different ways to navigate the stages of design as well as document and communicate design decisions Provides comprehensive coverage of the design process, including methods for identifying unmet needs, applying Design for 'X', and incorporating standards and design controls Discusses topics that prepare students for careers in medical device design or other related medical fields

A guide to help manufacturers, engineers, designers, and suppliers of medical products evaluate the design, materials, and technology of their packaging. Highlights recent developments in the field, and presents information on current industry standards and practices, and regulation. Provides details of materials and specifications, sterilization methods, distribution test cycles, labeling criteria, bar coding, autoclave systems, and other topics. Annotation(c) 2003 Book News, Inc., Portland, OR (booknews.com)

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.

Reference text on validation processes for manufacturing medical devices.

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?

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 scalpelsstents 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

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.

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.

UHMWPE Biomaterials Handbook describes the science, development, properties and application of of ultra-high molecular weight polyethylene (UHMWPE) used in artificial joints. This material is currently used in 1.4 million patients around the world every year for use in the hip, knee, upper extremities, and spine. Since the publication of the 1st edition there have been major advances in the development and clinical adoption of highly crosslinked UHMWPE for hip and knee replacement. There has also been a major international effort to introduce Vitamin E stabilized UHMWPE for patients. The accumulated knowledge on these two classes of materials are a key feature of the 2nd edition, along with an additional 19 additional chapters providing coverage of the key engineering aspects (biomechanical and materials science) and clinical/biological performance of UHMWPE, providing a more complete reference for industrial and academic materials specialists, and for surgeons and clinicians who require an understanding of the biomaterials properties of UHMWPE to work successfully on patient applications. The UHMWPE Handbook is the comprehensive reference for professionals, researchers, and clinicians working with biomaterials technologies for joint replacement New to this edition: 19 new chapters keep readers up to date with this fast moving topic, including a new section on UHMWPE biomaterials; highly crosslinked UHMWPE for hip and knee replacement; Vitamin E stabilized UHMWPE for patients; clinical performance, tribology an biologic interaction of UHMWPE State-of-the-art coverage of UHMWPE technology, orthopedic applications, biomaterial characterisation and engineering aspects from recognised leaders in the field