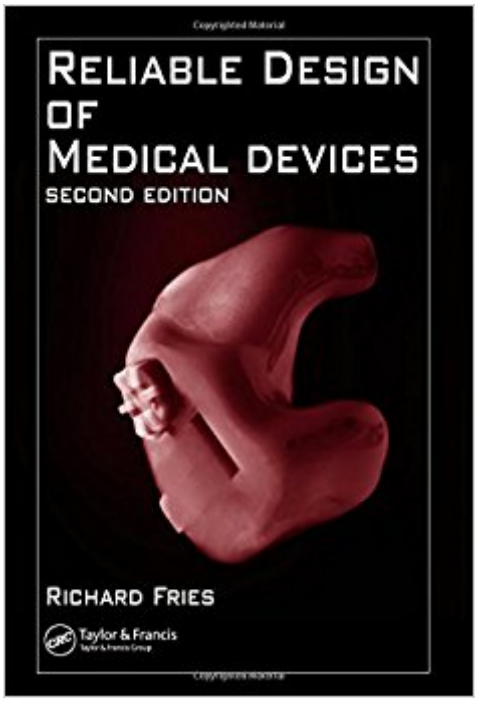
Reliable Design Of Medical Devices, Second Edition



Synopsis

As medical devices increase in complexity, concerns about efficacy, safety, quality, and longevity increase in stride. Introduced nearly a decade ago, Reliable Design of Medical Devices illuminated the path to increased reliability in the hands-on design of advanced medical devices. With fully updated coverage in its Second Edition, this practical guide continues to be the benchmark for incorporating reliability engineering as a fundamental design philosophy.The book begins by rigorously defining reliability, differentiating it from quality, and exploring various aspects of failure in detail. It examines domestic and international regulations and standards in similar depth, including updated information on the regulatory and standards organizations as well as a new chapter on quality system regulation. The author builds on this background to explain product specification, liability and intellectual property, safety and risk management, design, testing, human factors, and manufacturing. New topics include design of experiments, CAD/CAM, industrial design, material selection and biocompatibility, system engineering, rapid prototyping, quick-response manufacturing, and maintainability as well as a new chapter on Six Sigma for design.Supplying valuable insight based on years of successful experience, Reliable Design of Medical Devices, Second Edition leads the way to implementing an effective reliability assurance program and navigating the regulatory minefield with confidence.

Book Information

Hardcover: 504 pages

Publisher: CRC Press; 2 edition (November 21, 2005)

Language: English

ISBN-10: 0824723759

ISBN-13: 978-0824723750

Product Dimensions: 9.2 x 6.4 x 1.3 inches

Shipping Weight: 1.8 pounds

Average Customer Review: 3.8 out of 5 stars 2 customer reviews

Best Sellers Rank: #2,460,368 in Books (See Top 100 in Books) #71 inÃ Â Books > Textbooks > Medicine & Health Sciences > Reference > Instruments & Supplies #101 inÃ Â Books > Medical Books > Medicine > Prosthesis #109 inÃ Â Books > Medical Books > Medicine > Reference > Instruments & Supplies

Customer Reviews

"This book is an absolute must for anybody who is just overwhelmed by the prospect of having to go

through the various standards that are becoming increasingly important to manufacturers and users alike. . ..It not only explains every aspect of the science of reliable design but provides clear definitions of the jargon and good practical examples of the paperwork required from the various certifying bodies. . . .it is unlikely that most of us will ever need to refer to any other book than this one." ---Proceedings of the Institution of Mechanical Engineers --This text refers to an out of print or unavailable edition of this title.

Fries; Richard Baxter Healthcare, Round Lake, Illinois, USA, --This text refers to an out of print or unavailable edition of this title.

Worked Reliability for Lockheed Martin for many years. Did not teach me anything I didn't already know. However, I was a Corporate Fellow when I retired so I was pretty knowledgeable.

This book provides a solid reference for the Systems Engineer who is working on a medical device, including for IVD devices. The book is specifically structured to cover the design process and important documentation requirements in order to meet FDA 510(k) submissions. It also introduces the more typical reliability design process approach used in other industries such as telecommunications, to the design of medical devices.The chapters of the book develop many areas of the engineering design process specific to biotechnology. The book covers the important area of 14971 Risk Assessment requirements and how this standard impacts the engineering design process. The book provides good ideas for incorporating 14971 into the standard engineering design process.The book is useful for both medical devices (60601 requirements) as well as providing guidance for IVD devices. It lists many references for the medical systems engineer. I highly recommend it as a reference book.

School, Medical Books) Plastics in Medical Devices, Second Edition: Properties, Requirements, and Applications (Plastics Design Library) Integrated circuit devices and components (Integrated-circuit technology, analog and logic circuit design, memory and display devices) Process Design for Reliable Operations The Patient's Medical Journal: Record Your Personal Medical History, Your Family Medical History, Your Medical Visits & Treatment Plans American Medical Association Complete Medical Encyclopedia (American Medical Association (Ama) Complete Medical Encyclopedia) Graphic Design Success: Over 100 Tips for Beginners in Graphic Design: Graphic Design Basics for Beginners, Save Time and Jump Start Your Success (graphic ... graphic design beginner, design skills) Usability Testing of Medical Devices, Second Edition The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition ISO 11135:2014, Second Edition: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition US Army Technical Manual, ARMY DATA SHEETS FOR CARTRIDGES, CARTRIDGE ACTUATED DEVICES AND PROPELLANT ACTUATED DEVICES, FSC 1377, TM 43-0001-39, 1991 Plastics in Medical Devices: Properties, Requirements and Applications (Plastics Design Library) Handbook of Polymer Applications in Medicine and Medical Devices (Plastics Design Library)