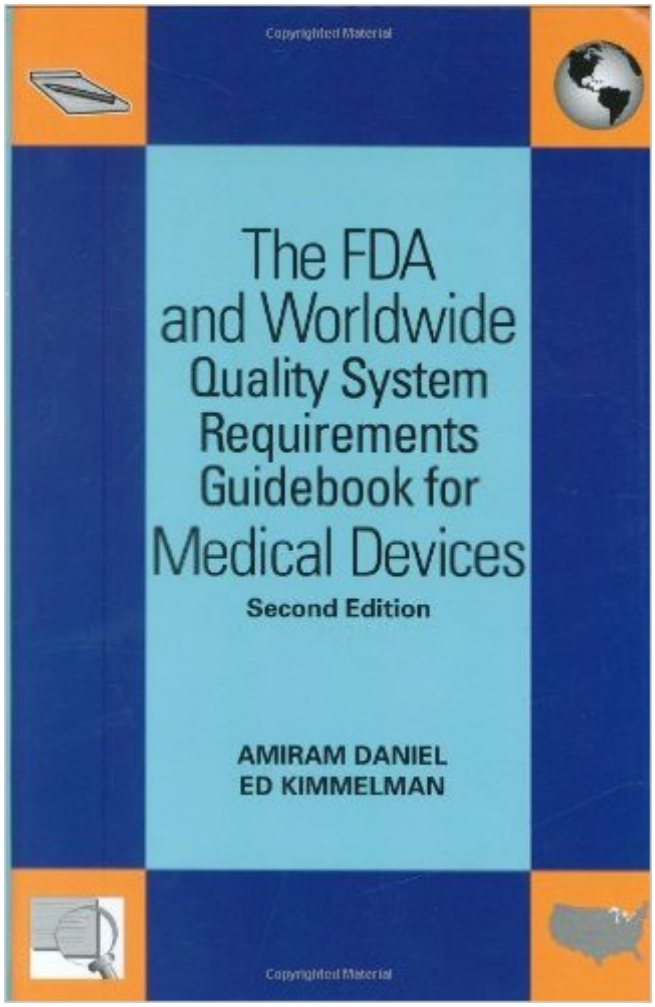
The FDA And Worldwide Quality System Requirements Guidebook For Medical Devices, Second Edition



Synopsis

This new and expanded second edition maintains the organizational approach of the first and includes the requirements and guidance contained in the Quality System Regulation (QSReg), the ISO 13485:2003 standard, the ISO/TR 14969:2004 guidance document, and, as appropriate, a number of the FDA and Global Harmonization Task Force (GHTF) guidance documents. This second edition also addresses a number of additional topics, such as the incorporation of risk management into the medical device organization s QMS, QMS issues related to combination products, the key process interactions within a QMS, effective presentation of and advocacy for a QMS during FDA inspections and third-party assessments, and future FDA compliance and standards activities. The organization of the guidebook is based on the order of the requirements in the QSReg. For each substantive requirement section there is: A verbatim statement of the QSReg requirement. A description of the comparable requirement in ISO 13485:2003, focusing on any additions to or differences from the requirements contained in the QSReg. Excerpts of the FDA responses to relevant comment groups contained in the Preamble to the QSReg. Excerpts from various FDA guidance documents related to quality management systems. A description of the relevant guidance contained in ISO/TR 14969:2004, focusing on any additions to or differences from the guidance in the Preamble and other FDA guidance documents, and, if useful, excerpts from relevant GHTF guidances. Authors notes giving guidance derived from the authors sixty years of regulatory compliance experience. This guidance book is meant as a resource to manufacturers of medical devices, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves and texts on the specific processes and activities contained within the QMS.

Book Information

Hardcover: 336 pages
Publisher: ASQ Quality Press; 2 edition (June 6, 2008)
Language: English
ISBN-10: 0873897404
ISBN-13: 978-0873897402
Product Dimensions: 1 x 6.2 x 9.2 inches
Shipping Weight: 1.4 pounds (View shipping rates and policies)
Average Customer Review: 4.7 out of 5 starsÂ Â See all reviewsÂ (3 customer reviews)
Best Sellers Rank: #182,871 in Books (See Top 100 in Books) #6 inÂ Books > Textbooks >

Medicine & Health Sciences > Reference > Instruments & Supplies #7 inÂ Books > Medical Books > Medicine > Reference > Instruments & Supplies #40 inÂ Books > Law > Health & Medical Law > Medical Law & Legislation

Customer Reviews

Steep price tag but worth it because - This is a good basic reference book for 21 CFR 820. It provides an outline of each requirement of the QSR with cross reference to and comparison with ISO 13485. It contains a matrix of 820 vs. 13485 with authors' notes that describe similarities/differences. It provides reference to the guidance ISO/TR 14969 which clarifies 13485. It also contains a section on process interactions, i.e., how CAPA interacts with Risk Analysis, etc. There is a chapter on Risk Analysis and information on Design Control. The comments to the QSR preamble are included and elaborated on which is helpful in determining the intent of law, useful for interpretation and application of the QSR . The authors offer useful guidance and some interpretation. All in all a good reference for new and/or practicing Quality Assurance staff, device managers, those seeking ISO medical device certification or improving their compliance in preparation for audits.

This is a handy guidebook for any FDA related information on medical devices. This book was an easy read along with the information being easy to understand. This was a syllabus requirement for my class and it was easy to find on and cheaper to purchase here. All guidebooks should follow the format that these authors used to create it.

Now published in a newly expanded and updated second edition, "The FDA Worldwide Quality System Requirements Guidebook for Medical Devices" is a complete and comprehensive reference for Quality System Regulation standards governing the use of medical devices. Now in a new and improved second edition, "The FDA Worldwide Quality System Requirements Guidebook for Medical Devices" addresses many newer topics such as risk management, efficiency, and compliance issues, and much more. Covering both American and international health standards, "The FDA Worldwide Quality System Requirements Guidebook for Medical Devices" is a must for medical device manufacturers, and anyone who must comply with these regulations.

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices

Medical School Admission Requirements (MSAR) 2010-2011: The Most Authoritative Guide to U.S. and Canadian Medical Schools (Medical School Admission Requirements, United States and Canada) ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years Plastics in Medical Devices, Second Edition: Properties, Requirements, and Applications (Plastics Design Library) Requirements Elicitation Techniques - Simply Put!: Helping Stakeholders Discover and Define Requirements for IT Projects Poor-Quality Cost: Implementing, Understanding, and Using the Cost of Poor Quality (Quality and Reliability) ISO 14971:2007, Medical devices - Application of risk management to medical devices Medical Terminology: Medical Terminology Made Easy: Breakdown the Language of Medicine and Quickly Build Your Medical Vocabulary (Medical Terminology, Nursing School, Medical Books) ISO 1940-1:2003, Mechanical vibration -- Balance quality requirements for rotors in a constant (rigid) state -- Part 1: Specification and verification of balance tolerances ISO 1940-2:1997, Mechanical vibration - Balance quality requirements of rigid rotors - Part 2: Balance errors The Instinctive Weight Loss System - New, Groundbreaking Weight Loss Product- 7 CD's, Over 7 hours of Hypnosis for Weight Loss and Mind Reconditioning Sold in Over 40 Countries Worldwide American Medical Association Complete Medical Encyclopedia (American Medical Association (Ama) Complete Medical Encyclopedia) The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (Fourth Edition) IEC 61511-1 Ed. 1.0 b:2003, Functional safety - Safety instrumented systems for the process industry sector - Part 1: Framework, definitions, system, hardware and software requirements Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines FDA Regulatory Affairs: Third Edition Medical School Admission Requirements The Complete Code of Federal Regulations, Title 21, Food And Drugs, FDA Regulations, 2016