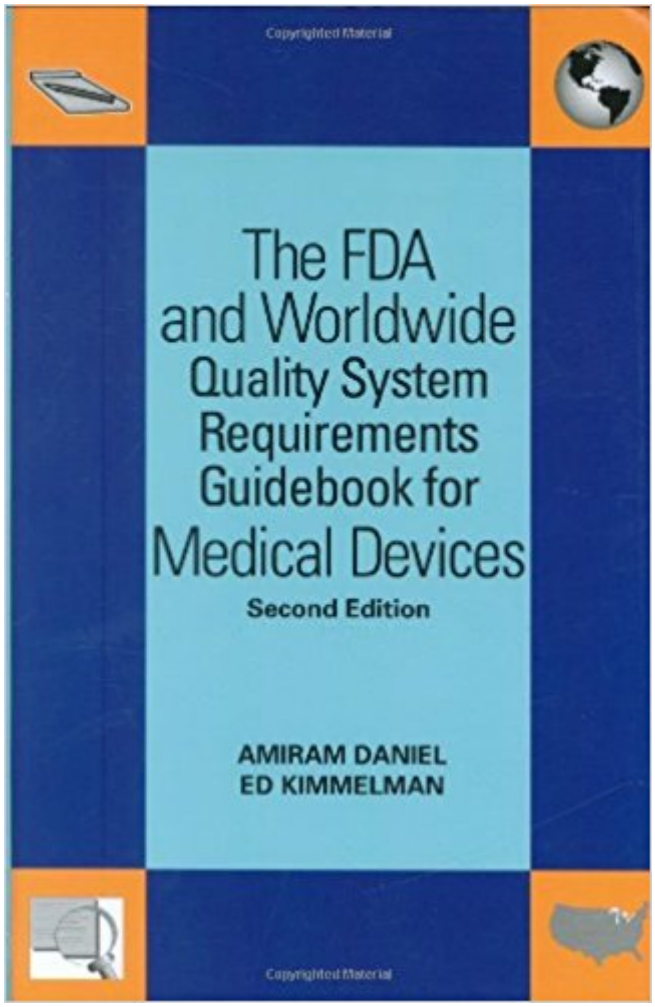
The FDA And Worldwide Quality System Requirements Guidebook For Medical Devices, Second Edition



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

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Customer Reviews

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.

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.

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.

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Veterinary Medical School Admission Requirements (VMSAR): 2017 Edition for 2018 Matriculation (Veterinary Medical School Admission Requirements in the United States and Canada) Veterinary Medical School Admission Requirements (VMSAR): 2016 Edition for 2017 Matriculation (Veterinary Medical School Admission Requirements in the United States and Canada) ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes 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 Plastics in Medical Devices, Second Edition: Properties, Requirements, and Applications (Plastics Design Library) ISO 14971:2007, Medical devices - Application of risk management to medical devices ISO 14971:2000, Medical devices -- Application of risk management to medical devices Plastics in Medical Devices: Properties, Requirements and Applications Plastics in Medical Devices: Properties, Requirements and Applications (Plastics Design Library) Implement AS 9100 Rev D for Business Excellence: Quality Management System Requirements for Aviation, Space and Defence Organisations, includes ISO 9001:2015 The Quality System Compendium: Gmp Requirements & Industry Practice Mastering the Requirements Process: Getting Requirements Right (3rd Edition) Iso 15189:2012, Medical laboratories - Requirements for quality and competence The Software Requirements Memory Jogger: A Pocket Guide to Help Software And Business Teams Develop And Manage Requirements (Memory Jogger) ACI 318.2-14: Building Code Requirements for Concrete Thin Shells (ACI 318.2-14) and Commentary on Building Code Requirements for Concrete Thin Shells (ACI 318.2R-14) Nutrient Requirements of Dogs and Cats (Nutrient Requirements of Domestic Animals) Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology)