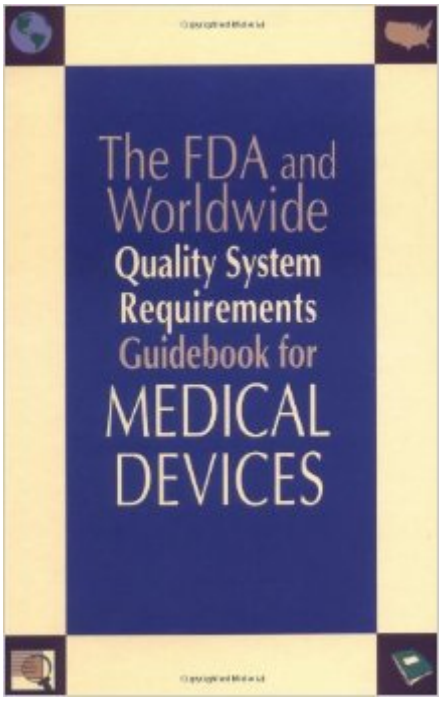
The FDA And Worldwide Quality System Requirements Guidebook For Medical Devices



Synopsis

This guidebook provides essential informantion for anyone who needs to understand and implement the new U.S. Food and Drug Administration (FDA) law for medical devices and international quality system requirements.

Book Information

Hardcover: 210 pages

Publisher: Amer Society for Quality (October 1996)

Language: English

ISBN-10: 0873893778

ISBN-13: 978-0873893770

Product Dimensions: 1 x 6.5 x 9.5 inches

Shipping Weight: 1 pounds

Average Customer Review: 3.9 out of 5 starsÂ Â See all reviewsÂ (7 customer reviews)

Best Sellers Rank: #302,708 in Books (See Top 100 in Books) #3 inÂ Books > Law > Business > Regulation #9 inÂ Books > Medical Books > Medicine > Reference > Instruments & Supplies #224 inÂ Books > Law > Rules & Procedures > Civil Procedure

Customer Reviews

Mfg. Engr. manager for a large medical device company.After spending 2.5 days with an FDA auditor, I realized that I did not know what was expected by the regulatory body in terms of process validations, equipment installation and maintenance and all of the record-keeping and documentation that is required for them.To learn all of that quickly, I purchased and studied this book. For each subject (process validations, equipment, calibration and all other areas), it lists the FDA regulation, the corresponding ISO regulation and then has an "FDA guidance" section that breaks down both into plainer English. It was helpful to have all of the information in one place.The frustrating part with the FDA is that they won’t tell you exactly how to do things, they’ll just lay out the rules and you have to figure out how to get there from here. This book is good at laying out all of the rules.I would recommend this book to any level person who may have to answer to an auditor. There are sections on Design Control, Nonconforming Production, Labeling and Packaging, Statistical Techniques and more that apply to each area of the business.

I bought the book based on only one review, but was a bit disappointed. It did indeed list all relevant code, and referenced it for further study, but the codes themselves are hardly self-explanatory.

Except for some introductory comments, there was very little in the way of further explanation on the topics in this book.I was looking for some interpretation, examples, what is typically done in the real world to meet requirements, etc.It’s a good reference book, but just a starting point in understanding what is necessary to satisfy the FDA in medical device manufacturing. Buy it used if possible, you won’t be using it much except for reference.

This is a great book, but purchase the newer version.....this book is the bible for any supplier auditor! Gives you an interpretation of the standard which is always helpful. I recommend this book to any one who audits tot eh FDA CFR 820.

This book arrived on time and was in great condition on arrival. The book itself is an excellent, concise reference.

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Second Edition 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 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) 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 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) 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 Medical School Admission Requirements The Complete Code of Federal Regulations, Title 21, Food And Drugs, FDA Regulations, 2016 The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (Fourth Edition) FDA Regulatory Affairs: Third Edition