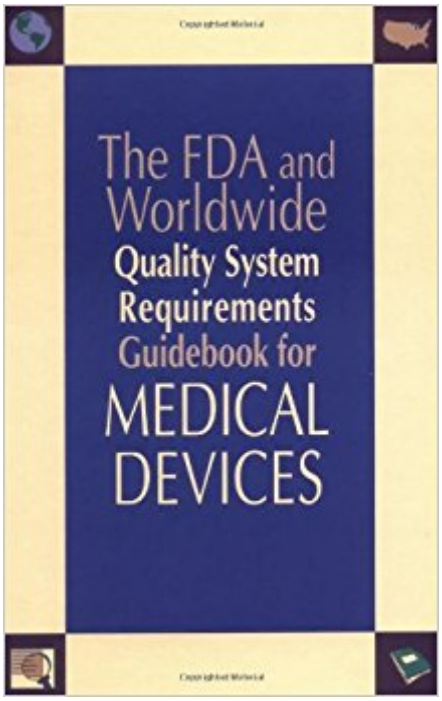
The FDA And Worldwide Quality System Requirements Guidebook For Medical Devices



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 (View shipping rates and policies)

Average Customer Review: 3.5 out of 5 stars 7 customer reviews

Best Sellers Rank: #1,304,614 in Books (See Top 100 in Books) #14 inÂ Books > Law > Business > Regulation #63 inÂ Books > Medical Books > Medicine > Reference > Instruments & Supplies #1289 inÂ Books > Law > Rules & Procedures > Civil Procedure

Customer Reviews

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.

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.

ok

Great product and seller!

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

come on time, work well so far, very happy, happy happy happy happyhappy happy happy happy happy happy happy happy.Thanks

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.

ISO 14971:2000, Medical devices -- Application of risk management to medical devices 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: Properties, Requirements and Applications Plastics in Medical Devices: Properties, Requirements and Applications (Plastics Design Library) Plastics in Medical Devices, Second Edition: 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 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) Mastering the Requirements Process: Getting Requirements Right (3rd Edition) Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology)