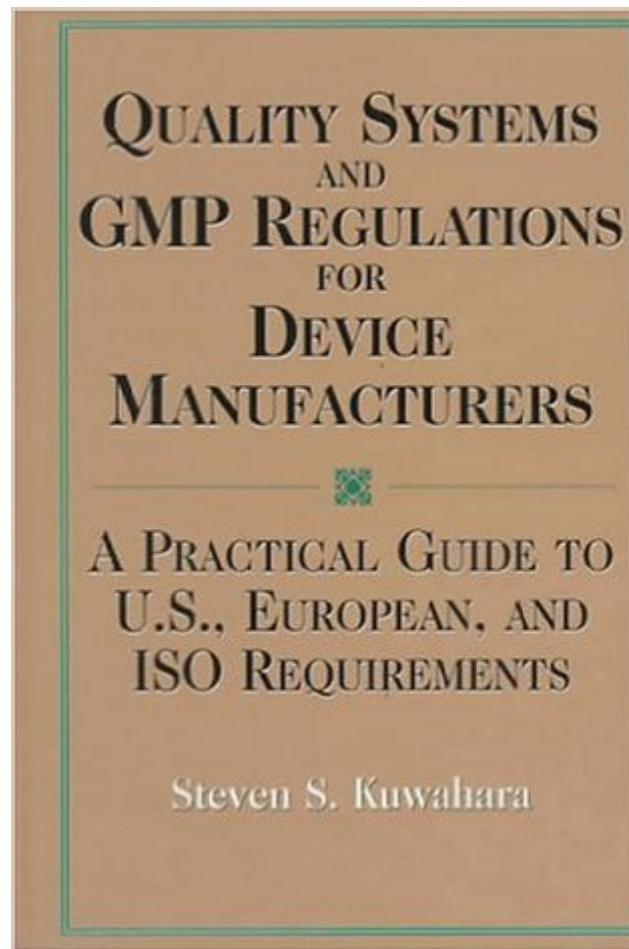


The book was found

Quality Systems And GMP Regulations For Device Manufacturers



Synopsis

This book provides a single roadmap for compliance with the US QSR, the European Medical Device Directives, and ISO Standards for device and diagnostic products. Written in case-study format, it begins with information on how to establish a QSR documentation system. Dr. Kuwahara explains implementation methods for each section of the QSRs (21 CFR 820). Documentation requirements and guidelines for what documentation you need for your quality system, why you need it, and how to prepare it are detailed, as well as practical information on efficiently and effectively organizing your records, procedures, work instructions, and Quality Manual. The book shows you how to evaluate your existing documentation's fit with the worldwide quality systems and the GMPs/QSRs. A grid comparing ISO 9001 and US 21 CFR 820 requirements is included.

Book Information

Hardcover: 256 pages

Publisher: CRC Press; 2nd edition (March 31, 1998)

Language: English

ISBN-10: 087389426X

ISBN-13: 978-0873894265

Product Dimensions: 0.8 x 6.2 x 9.5 inches

Shipping Weight: 1.2 pounds

Average Customer Review: 4.0 out of 5 stars [See all reviews](#) (1 customer review)

Best Sellers Rank: #1,691,458 in Books (See Top 100 in Books) #55 in [Books > Textbooks > Medicine & Health Sciences > Reference > Instruments & Supplies](#) #84 in [Books > Medical Books > Medicine > Reference > Instruments & Supplies](#) #670 in [Books > Business & Money > Management & Leadership > Quality Control & Management > Total Quality Management](#)

Customer Reviews

This book provides extensive information for specialists in companies that have to comply with FDA regulations. It also has some good information on auditing that will be useful to quality engineers and auditors with limited experience in International Organization for Standardization (ISO), Food and Drug Administration (FDA), Code of Federal Regulations (CFR) and Good Manufacturing Practices (GMP) requirements. CFR standards are tough. Compliance with them, following the lead of this book, should help a company comply with the ISO standards. Companies that comply with the ISO standards, however, might not comply with the CFR requirements This book leads the reader through a series of steps that will help the company meet CFR requirements. It goes into

extensive detail identifying and interpreting the various CFRs so that the readers will not take them too lightly. Some CFRs are much too vague and can lull newcomers to the field into thinking that they are in compliance when they are not. I would have rated this book as a 5 except that only a limited number of quality practitioners have a need for this material on GMP compliance. Hank Lefevre, CQE & PE

[Download to continue reading...](#)

Quality Systems and GMP Regulations for Device Manufacturers Practical Linux Programming: Device Drivers, Embedded systems, and the Internet (with CD- ROM) (Programming Series) Medical Device Technologies: A Systems Based Overview Using Engineering Standards (Academic Press Series in Biomedical Engineering) Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2015 (Orange Guide) (The Orange Guide 2015) Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2015: The Orange Guide Limoges Boxes: A Complete Guide- Contains More Than 400 Full-Color Photos, a Value Guide, and Manufacturers' Marks Identification Guide WORLDWIDE JEWELRY MANUFACTURERS: INDEX: Jewelry Factory and Jewelry Suppliers-Contacts Data Century of Excellence: Krug Bros. & Co. Furniture Manufacturers Birmingham Cartridge Manufacturers, The Lean Six Sigma: The Ultimate Guide To Lean Six Sigma With Tools For Improving Quality And Speed! (Lean, Six Sigma, Quality Control) Axiomatic Quality: Integrating Axiomatic Design with Six-Sigma, Reliability, and Quality Engineering Quality Management Exam Review for Radiologic Imaging Sciences (Quality Management Review) Quality Management for Organizational Excellence: Introduction to Total Quality (8th Edition) Quality Management for Organizational Excellence: Introduction to Total Quality (7th Edition) Shakers : compendium of the origin, history, principles, rules and regulations, government, and doctrines of the United Society of Believers in Christ's Second Appearing Building Biotechnology: Biotechnology Business, Regulations, Patents, Law, Policy and Science Code of Federal Regulations, Title 21, Food and Drugs, Pt. 200-299, Revised as of April 1, 2016 Equity Crowdfunding for Investors: A Guide to Risks, Returns, Regulations, Funding Portals, Due Diligence, and Deal Terms (Wiley Finance) Restaurant Franchising: Concepts, Regulations and Practices, Third Edition Federal Income Tax: Code and Regulations--Selected Sections 2016-2017

[Dmca](#)