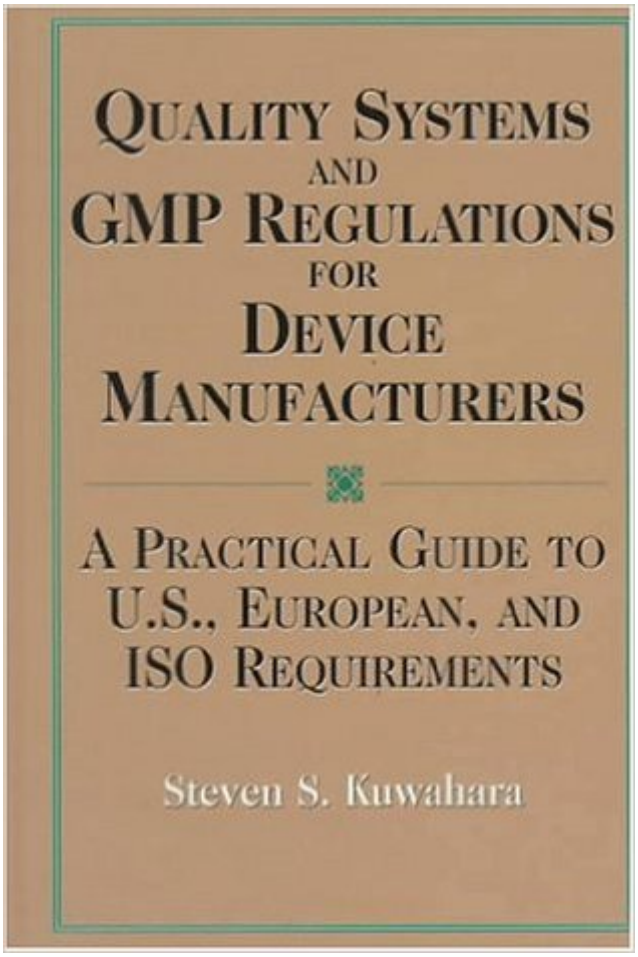
Quality Systems And GMP Regulations For Device Manufacturers



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

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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