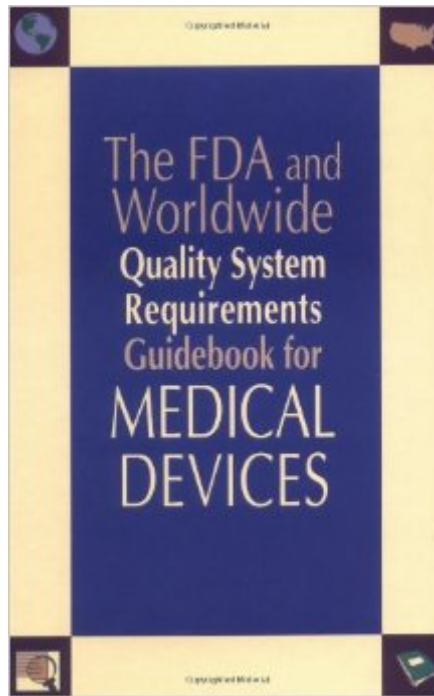


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# The FDA And Worldwide Quality System Requirements Guidebook For Medical Devices



## Synopsis

This guidebook provides essential information 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

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## 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 the FDA CFR 820.

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

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