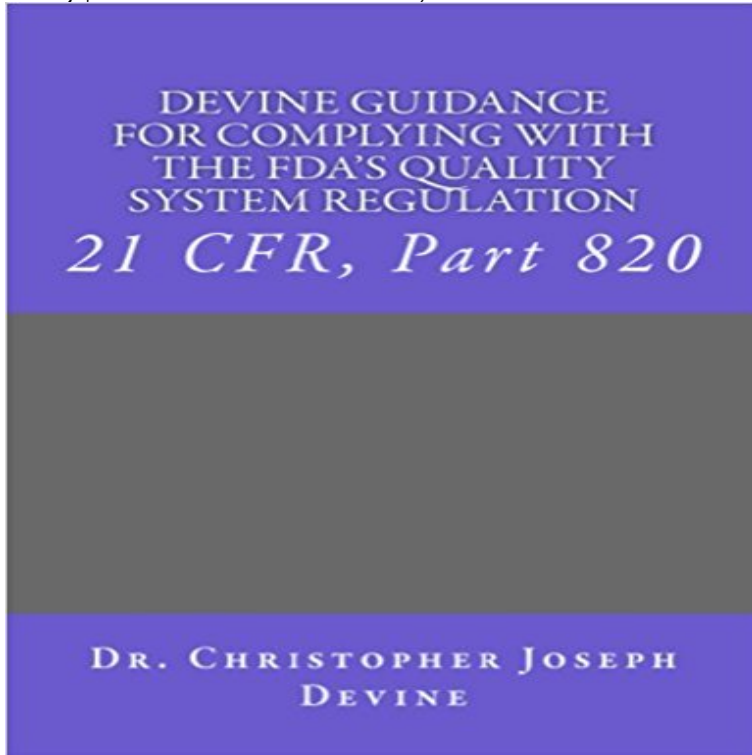


Devine Guidance For Complying With The FDAs Quality System Regulation - 21 CFR, Part 820



The purpose of Dr. Ds first book (Devine Guidance for Complying with the FDAs Quality System Regulation) is to breakdown and analyze the requirements depicted in the 21 CFR, Part 820. The doctor tackles each of the subparts and sections sequentially and hopes the readers are able to glean some useful information while enjoying the common-sense, objective, and no-nonsense approach to complying with each of the requirements. In support of providing a better understanding for what the agency is searching for by the way of compliance, each chapter of the book is supported by excerpts of warning letters extracted from the FDAs website. For those of you that are frequent followers of Dr. Ds weekly rants, posted in The Medical Device Summit, you will recognize the often poignant prose employed by Dr. D. Now granted, the topics of regulatory and quality compliance can be extremely boring to write about; however, the doctor has taken some liberties in an effort to ensure reader boredom does not occur. That being said, Dr. D really hopes you enjoy this book!

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