Devine Guidance for Managing Key Attributes of a FDA-Compliant Quality Management System: 21 CFR, Part 820 Compliance (Volume 5)

Dr. Christopher Joseph Devine

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The salient purpose of this book is to provide the readers some additional insight into not only entering devices into the US market place but actually keeping them there. Dr. Devine actually loves the US device market place because the FDA regulations are relatively static. Now that doesn't mean the FDA does not adopt and change to an increasingly dynamic medical device environment in the United States. However, it does mean that FDA is careful when implementing changes to regulatory and statutory requirements versus the EU where the directives change just for the sake of change. Another point the author is compelled to make is that once devices are cleared and or approved (depending on regulatory pathway), they will remain available on the US market, providing they remain safe and effective; however, in Europe not so much.

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