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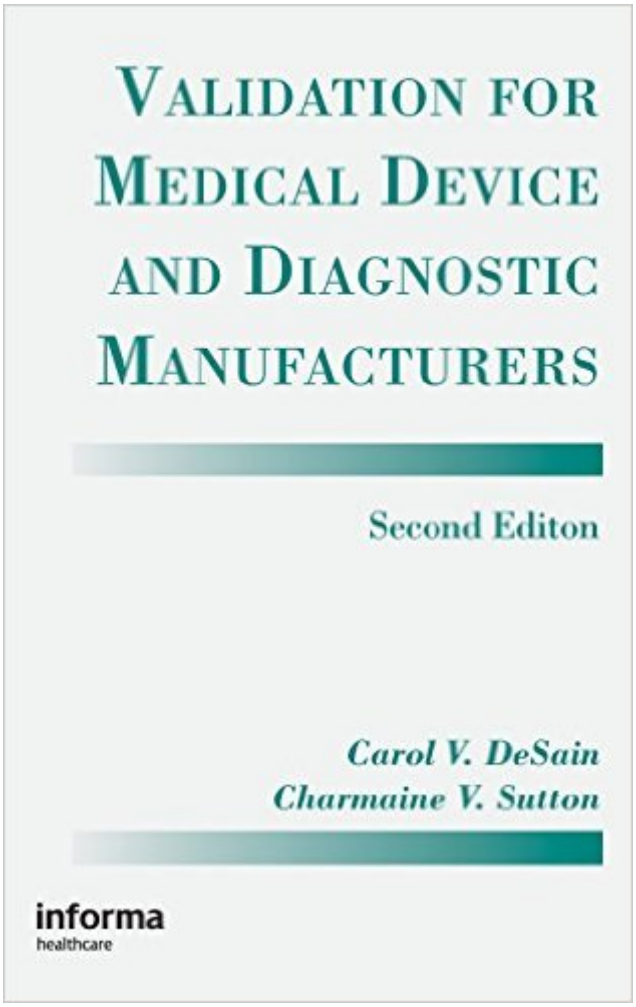
Validation For Medical Device And Diagnostic Manufacturers, Second Edition



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Synopsis

Implementation of FDA's Design Control requirements (21 CFR 820.30) changed an entire industry. Quality System Requirements defined the approach to medical device validation. Product design, manufacturing process, and test method validation studies must be performed before or as a product is transferred to commercial production. Validation studies must demonstrate that product design, process, and test methods/requirements/specifications determined during development can be met in the environment of intended use. This book provides practical guidance on how to develop and validate product designs, manufacturing processes, and test methods that comply with the requirements of QSR.

Book Information

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Customer Reviews

This is a great book if you want to get into the depths of how to truly validate a medical device. But I want to strongly send a message to the publishers that the pricing is absolutely horrendous!! This book cost me over 200 dollars!!! For that price, I don't think it was worth it.

This a great book, if you work on Medical industry or want to know about it this book is for you!! It is easy to comprehend and as Engineer in Medical industry this book has been a lot of help. Don't think twice about it, must buy!!I gave it 4 stars due to the asking price, the book isn't big and the amount being asked for it is ridicolous, I bought it used for less than half the asking price

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