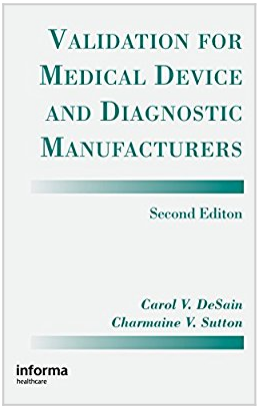

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By Carol V. Desain, Charmaine V. Sutton

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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.

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