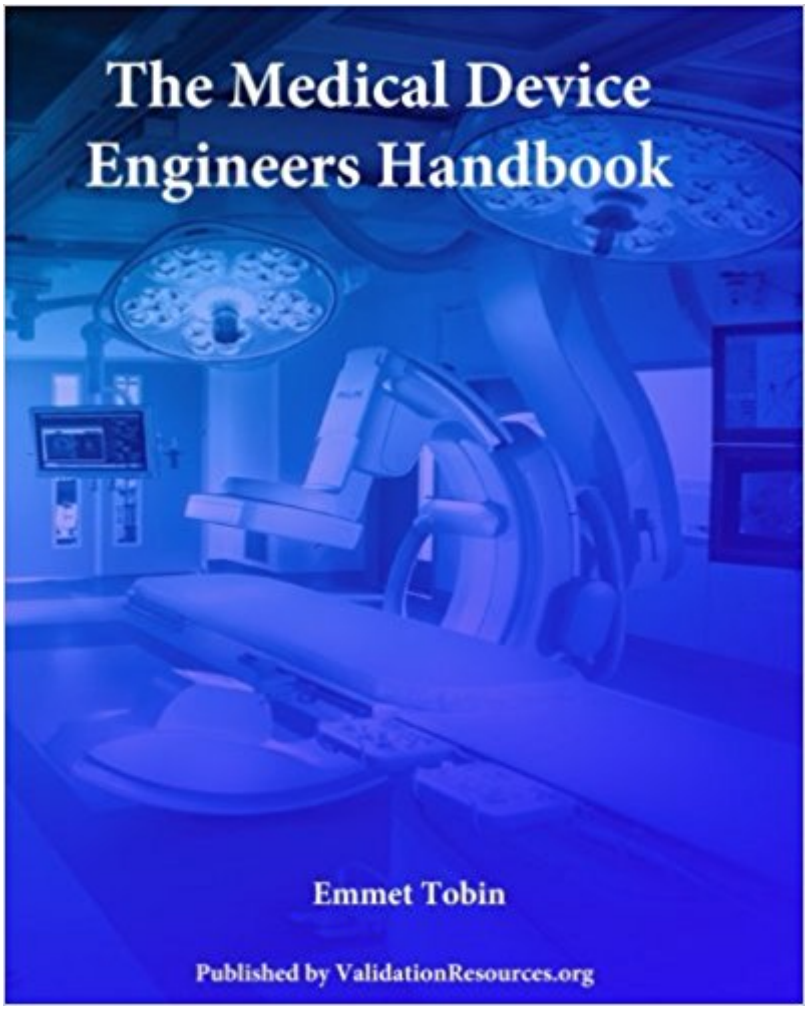
The Medical Device Engineers Handbook



Synopsis

This book aims to create a new standard resource for engineers working in the medical device industry. The objective was to produce an all-in-one reference-style book serving the needs of engineers at different levels in their career journey. It is based on over a decade of experience working within the industry. It draws not only on this experience but on best practices and widely accepted conventions. These practices and conventions are typically shaped by the demands of regulatory bodies and international organisations. Chapters include: Design Controls Validation Planning Risk Management Facilities and Utilities Validation Equipment and Software Validation Process Validation Packaging Validation Test Method Validation 21 CFR Part 11 Electronic Records Measurement Good Manufacturing Practices ISO 13485 Lean Basics Six Sigma Basics Polymer Processing Tools Useful References Page Count (Over 200 pages)

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