Design Controls for the Medical Device Industry, Second Edition

Marie B. Teixeira
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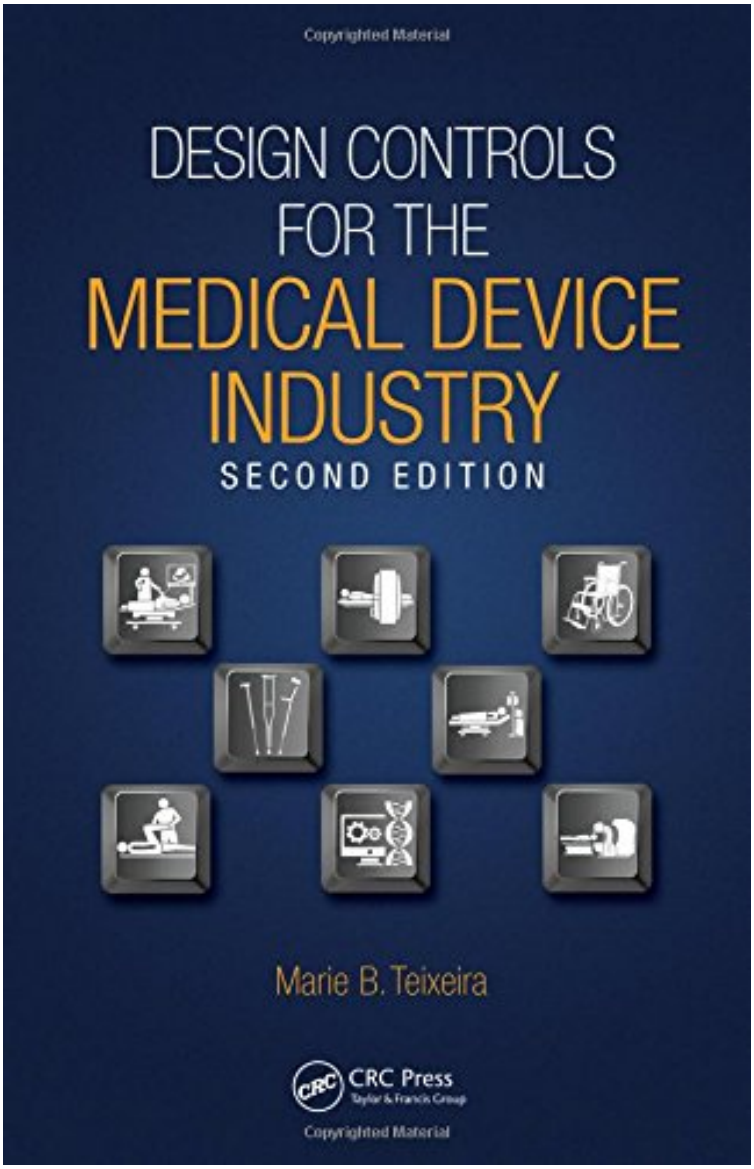

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Marie B. Teixeira : Design Controls for the Medical Device Industry, Second Edition before purchasing it in order to gage whether or not it would be worth my time, and all praised Design Controls for the Medical Device Industry, Second Edition:

The second edition of a bestseller, Design Controls for the Medical Device Industry provides a comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure your companys design control program evolves in accordance with current industry practice. The text assists in the development of an effective design control program that not only satisfies the US FDA Quality System Regulation (QSR) and ISO 9001 and 13485 standards, but also meets todays third-party auditor/investigator expectations and saves you valuable time and money. The authors continual participation in FDA QSR inspections and Notified Body ISO audits is reflected in updates to all chapters and appendices of the book, now bursting at the seams with: New coverage of ISO 9001 and 13485 design control requirements More real-world examples from the medical device industry Additional detail for greater understanding and clarity Fresh templates for practical implementation Extensive references for further study The book addresses design control elements such as design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations and classes in the US, Canada, and Europe.

About the AuthorMarie B. Teixeira is founder and principal consultant for QA/RA Compliance Connection, Inc., Odessa, Florida, USA. She holds a BS from University of Massachusetts Amherst, USA and is an American Society for Quality member, ASQ-certified quality manager and engineer, and RABQSA principle auditor. Previously she served as quality engineer at Raytheon, Norwood, Massachusetts, USA; GTE Government Systems, Needham Heights, Massachusetts, USA; and Sparton Electronics, Brooksville, Florida, USA; as well as director of quality assurance and regulatory affairs at Bioderm, Inc., Tampa Bay, Florida, USA and quality systems manager for regulatory affairs at Smith Nephew, Largo, Florida, USA.