



Design Controls for the Medical Device Industry, Second Edition

Marie B. Teixeira

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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 company's 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 today's third-party auditor/investigator expectations and saves you valuable time and money.

The author's 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.

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