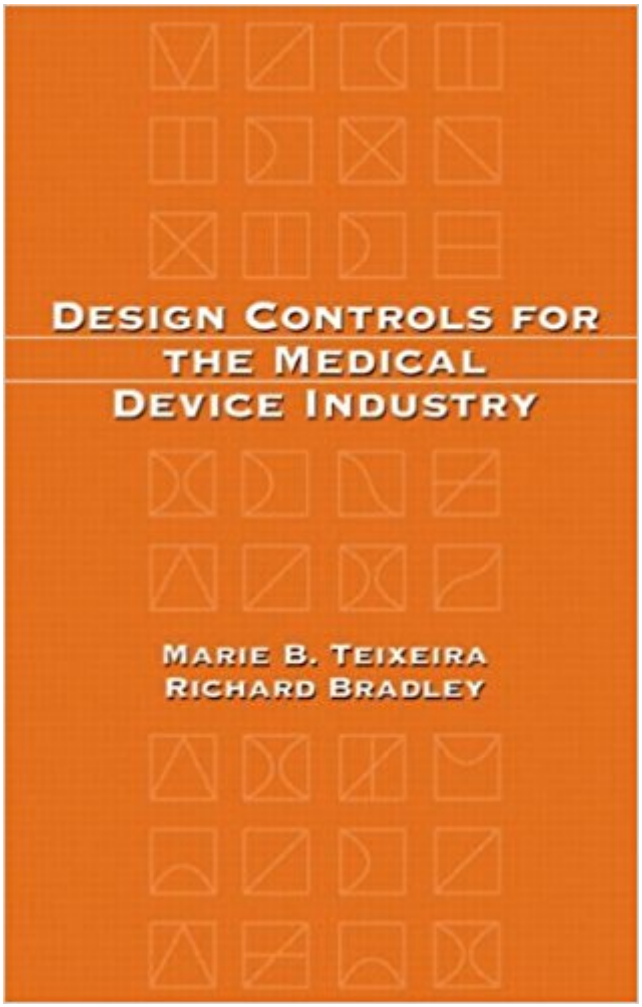
Design Controls For The Medical Device Industry



Synopsis

This reference provides real-world examples, strategies, and templates for the implementation of effective design control programs that meet current ISO 9000 and FDA QSR standards and regulations-offering product development models for the production of safe, durable, and cost-efficient medical devices and systems.Details procedures utilized by leading companies to successfully meet FDA and end-user requirements, manufacture high-quality products, and improve and generate profit.Design Controls for the Medical Device Industry contains valuable guidelines that enable readers to prepare for an FDA audit identify consumer needs, resolve project objectives, and process inconsistencies and discrepancies determine the compatibility of design specifications and manufacturing, installation, and servicing demands ensure that proper design, function, and performance stipulations are understood and met verify and validate design criteria and production schemes eliminate confusion and prevent communication breakdowns allocate and conserve resources perform risk assessment analyses predict potential hazards under normal and fault conditionsPresenting blueprints for the application, evaluation, and refinement of quality assurance and performance practices-from product launch through engineering and assembly-Design Controls for the Medical Device Industry is a clear and indispensable source for biomedical, quality assurance, reliability, software, product design, manufacturing, research and development, and industrial engineers; project directors and managers; biomedical technicians; and upper-level undergraduate and graduate students in these disciplines.

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