Quality Systems and GMP Regulations for Device Manufacturers

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This book provides a single roadmap for compliance with the US QSR, the European Medical Device Directives, and ISO Standards for device and diagnostic products. Written in case-study format, it begins with information on how to establish a QSR documentation system. Dr. Kuwahara explains implementation methods for each section of the QSRs (21 CFR 820). Documentation requirements and guidelines for what documentation you need for your quality system, why you need it, and how to prepare it are detailed, as well as practical information on efficiently and effectively organizing your records, procedures, work instructions, and Quality Manual. The book shows you how to evaluate your existing documentation's fit with the worldwide quality systems and the GMPs/QSRs. A grid comparing ISO 9001 and US 21 CFR 820 requirements is included.

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