Iso 13485:2003 & Fda Qsr (21 Cfr 820) Quality Manual, 34 Procedures And Forms

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✔ Verified Book of Iso 13485:2003 & Fda Qsr (21 Cfr 820) Quality Manual, 34 Procedures And Forms

Summary:

Template documentation on CD-ROM includes a quality manual, 34 operational procedures, and forms. While organized into an ISO 13485:2003 system, the documentation also specifically covers FDA QSR (21 CFR 820) requirements, and thus complies with both the international and US FDA regulations (if you don't need to comply with US regulations, there are instructions how to take out QSR-related sections). This fully developed two-level documentation defines a generic quality system that is simple, natural and free from excessive paperwork; and defines the baseline for satisfying certification requirements. The CD ROM provides automated document templates, tutorials on how to adapt the documentation to fit your company and how to upgrade from the old ISO 13485:1996 system, text servers, and many other features to help you develop your ISO 13485 documentation.