FDA Quality System Regulation for Medical Devices (21 CFR Part 820): A Practitioner's Guide to Management Controls (sections 820.20 Management ... 820.22 Quality Audit, and 820.25 Personnel)

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The Practitioner’s Guide to Management Controls was written to provide a simple, single source of information for United States Food and Drug Administration’s (FDA) requirements for Management Controls as described in 21 CFR Part 820 Quality System Regulation (QS Regulation) for Medical Devices. Management Controls include sections 820.20 Management Responsibility, 820.22 Quality Audit, and 820.25 Personnel of this medical device regulation. The Practitioner’s Guide to Management Controls is written for the practitioner to use as a tool to help develop management controls prospectively for a new quality system or to perform gap assessments between existing management controls in a quality system against the FDA requirements and expectations provided in this book.

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