



The Biomedical Quality Auditor Handbook, Second Edition

ASQ Biomedical Division and Bruce Haggar, editor

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This handbook serves as a reference source for the application of quality auditing principles to the biomedical industry, including coverage specifically pertaining to medical devices. The book focuses on the understanding of domestic and international concepts and principles of biomedical quality auditing, and includes information on related regulations, directives, standards, and guidance. The book covers a wide range of subjects that have specific interpretations unique to the biomedical industry. In addition to being a peerless reference for ASQ's Biomedical Auditor certification (CBA), this book is a valuable reference for biomedical professionals who want to execute better audits for medical devices and gain basic knowledge of biomedical technical areas and regulatory requirements.



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