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This handbook supports the quality auditor Body of Knowledge (BoK), developed for the ASQ Certified Quality Auditor (CQA) program. This fourth edition addresses new and expanded BoK topics, common auditing (quality, environmental, safety, and so on) methods, and process auditing.

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single source for auditors, audit managers, audit teams, and quality professionals in the field.

The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include:

- A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP)
- Current information about federal and international regulations
- New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations
- A thorough explanation of quality tools and techniques

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This book is an excellent reference for learning and applying basic quality auditing principles. Examples and checklists throughout the book help make this one of the best single-source reference guides. Quality practitioners, registrars, and those preparing for certification exams will find this book to be a useful tool. the new

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edition expands on established techniques and addresses both internal and supplier auditing as it relates to any quality management system, including ISO 9001, GMP, automotive, and others.

This handbook is a comprehensive reference source designed to help professionals address organizational issues from the application of the basic principles of management to the development of strategies needed to deal with the technological and societal concerns of the new millennium. The content of this fourth edition has been revised to reflect a more current global perspective and to match the updated Body of Knowledge (BoK) of ASQ's Certified Manager of Quality/Organizational Excellence (CMQ/OE). In order to provide a broad perspective of quality management, this book has specifically been written to address:

- Historical perspectives relating to the evolution of particular aspects of quality management, including recognized experts and their contributions
- Key principles, concepts, and terminology relevant in providing quality leadership, and communicating quality needs and results
- Benefits associated with the application of key concepts and quality management principles
- Best practices describing recognized approaches for good quality management
- Barriers to success,

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including common problems that the quality manager might experience when designing and implementing quality management, and insights as to why some quality initiatives fail □ Guidance for preparation to take the CMQ/OE examination. Organized to follow the BoK exactly, throughout each section of this handbook the categorical BoK requirements associated with good quality management practices for that section are shown in a box preceding the pertinent text. These BoK requirements represent the range of content and the cognitive level to which multiple-choice questions can be presented. Although this handbook thoroughly prepares individuals for the ASQ CMQ/OE exam, the real value resides in post-exam usage as a day-to-day reference source for assessing quality applications and methodologies in daily processes. The content is written from the perspective of practitioners, and its relevance extends beyond traditional product quality applications.

This book is an introductory book on improving the quality of a process or a system, primarily through the technique of statistical process control (SPC). There are numerous technical manuals available for SPC, but this book differs in two ways: (1) the basic tools of SPC are introduced in a no-nonsense, simple, non-math manner, and (2) the methods can be learned and practiced in an uncomplicated fashion using free software (eZ SPC 2.0), which is available to all readers online as a downloadable product. The book explains QC7 Tools, control charts, and statistical analysis including basic design of experiments. Theoretical explanations

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of the analytical methods are avoided; instead, results are interpreted through the use of the software.

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