The ASQ Certified Medical Device Auditor Handbook

Fourth Edition

ASQ Medical Device Division
Scott A. Laman, Editor

Supports preparation for the ASQ Certified Medical Device Auditor (CMDA) certification

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Preface

The ASQ Certified Medical Device Auditor Handbook (formerly *The Biomedical Quality Auditor Handbook)* was developed by the American Society for Quality (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 original Certified Biomedical Auditor (CBA) certification was initially introduced as an add-on to the Certified Quality Auditor (CQA) certification in 2000 and became the stand-alone CBA certification in 2005. In 2020, recognizing that the membership of the division is better represented by the description "medical device" than by "biomedical," division leadership proposed and the ASQ Board of Directors approved the name change to Medical Device Division. For consistency and to attract appropriate candidates for certification, the ASQ Certification Board followed suit with a change to the name of the certification exam to Certified Medical Device Auditor.

Obtaining the CMDA credential establishes the competence of an auditor in the medical device industry, with the CMDA described as understanding the principles of standards, regulations, directives, and guidance for auditing a medical device quality system. The CMDA certification exam is supported by its Body of Knowledge (BoK) and reference list that define the exam scope, with both elements maintained concurrently and generally updated every five years.

Regulations and guidance affecting the medical device industry continually evolve. Although new or updated requirements may be introduced at any time, revisions to the exam BoK, reference list, and exam maintain their five-year review cycle. Consequently, contents of this handbook and CMDA certification differ from the current state of the medical device industry.

The fourth edition of *The ASQ Certified Medical Device Auditor Handbook*, as a primary source of information for certification exam preparation, correlates to the 2020 certification exam BoK and reference list. This edition has been reorganized to align more closely with the BoK and includes a significant amount of brand-new material. As a result, the number of chapters in the fourth edition has increased from 24 to 28. Many other chapters and parts of chapters have been substantially rewritten, and all have been reviewed for accuracy and to reference current versions of the standards and regulations.

Each chapter of the third edition was initially compared to the requirements of the 2020 BoK via a gap analysis. Existing chapters were classified as:

- Review and update as necessary when there were no changes to the BoK topic addressed, or if there were only minor changes to content.
- Update the new BoK when there were significant content changes to the BoK topic addressed.
- Write new content when the new BoK covered a subject that was not in the third edition.

Part I on Auditing contains new content on data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP).

Part II on Medical Device Quality Management System Requirements contains an entirely new Chapter 6, as the subject of "The EU Medical Device Regulation" has replaced "The EU Medical Device Directives." Chapters 4 and 5 have been switched to be consistent with the sequencing in the 2020 BoK. Chapter 4 has been rewritten and enhanced with new content on various codes of federal regulations that were not in the third edition. Chapter 8 on In Vitro Diagnostic (IVD) devices has also been substantially rewritten.

Part III on Technical Medical Device Knowledge contains new content for Chapter 13 (Human Factors and Usability Engineering), Chapter 16 (General Safety and Performance Requirements, 18 (Labeling), and Chapter 22 (Validation). Chapter 12 (Risk Management) has been rewritten to cover ISO 14971:2019 and the risk management requirements in IEC 62366 for usability engineering and ISO 13485 for quality system risk management. Chapter 17 (Software Development and Maintenance for Products) has been rewritten with additional content on the applicable guidances, as well as cybersecurity considerations.

Part IV on Quality Tools and Techniques has been improved with additional details and explanations. New content includes 5 Whys, is/is not (Kepner-Tregoe), setting alert and action limits, levels of measurement, and sampling. A related subject, test method validation and measurement systems analysis, is covered in Chapter 22 as part of validation.

Topics in this handbook are described in summary fashion and are not intended as a stand-alone tool for exam preparation. It is suggested that exam candidates read and understand the reference material to have a complete background in any one topic. The combination of this publication and reference materials is intended to provide a well-rounded background in medical device auditing.

The ASQ Medical Device Division believes this handbook will be a useful resource to those medical device professionals preparing for the CMDA exam.

Scott A. Laman
General Editor, Fourth Edition

Acknowledgments

Many people contributed to the fourth edition of this book, including some who were involved in the development of previous editions.

First, an effort of this magnitude begins with obtaining the wisdom and advice of previous editors of similar handbooks. Initial discussions with Grace Duffy, Mark Durivage, and Heather Crawford were immensely valuable to provide direction and, more importantly, instill vision and confidence that the task was achievable.

The ASQ Medical Device Division leadership has been fully supportive and involved with recommendations for contributors and stepping up to do some of the hands-on work themselves. The book name change that followed from the division name change originated from the vision of division leaders such as the following who requested the name change from "Biomedical Division" to "Medical Device Division" in January 2020.

Karen Brozowski, chair (2020)

Jim Shore, past chair (2019)

Teresa Cherry, past chair (2018)

Shreya Chandrasekhar, treasurer (2020)

Lisa Grosskopf, chair elect (2020)

The editor and the ASQ Medical Device Division would like to thank the following authors who reviewed, updated, and, as necessary, wrote new content:

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Finally, I would like to thank my wife, Krista, for her support throughout 2020, as this book took a tremendous amount of time with so much going on personally, at work, in the family, and throughout the world.

Part I

Auditing

Chapter 1 Auditing Fundamentals

Chapter 2 Auditing and Inspection Processes

Chapter 3 Audit Procedural References

Chapter 1

Auditing Fundamentals

AUDITS BY PURPOSE

Organizations conduct quality audits for a wide variety of reasons, including the assessment of the effectiveness, efficiency, and compliance of systems, processes, subprocesses, tasks, subtasks, products, assemblies, subassemblies, components, materials, and services. The reasons organizations undertake auditing activities vary. Some organizations perform audits merely to comply with regulations, standards, and guidances. Other organizations embrace auditing as part of a proactive risk management program, which is perceived within the organization as being a value-added activity through identifying previously unidentified risks, seeking opportunities for improving effectiveness and efficiency, ensuring compliance, and verifying the effectiveness of corrective actions from previously identified issues. See Figure 1.1 for further explanation of the differences between effectiveness and efficiency.

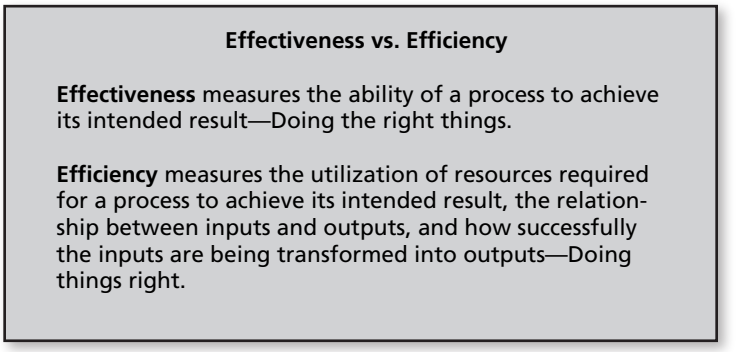

Figure 1.1 Effectiveness vs. efficiency.

Internal auditing activities may also be performed to assess medical device and facility registration status. The medical device registration status will usually review the associated design history file (DHF) of the medical device to assess whether significant changes or modifications in the design, components, method of manufacture, or intended use require an updated device registration.

Audits can also be used to assess the capability of potential suppliers, reassess current suppliers, evaluate future supplier partnerships, and ensure supplier corrective actions have been effectively implemented.

Certification audits are usually used by organizations to obtain ISO registration, for example, ISO 13485, and normally consist of an initial certification audit, surveillance audits (partial system audits) following years one and two, and a full recertification audit in year three.

Regulatory inspections are performed by regulatory agencies and competent authorities to determine the organization's level of compliance with regulations including marketing authorization, post-market surveillance activities, and quality management system (QMS) requirements. U.S. FDA regulatory inspections can be used for: routine inspections, pre-market product approvals (PMAs), for-cause inspections, or compliance follow-up activities.

Routine FDA regulatory inspections are mandated by law to be expected every two years for manufacturers of Class II or Class III medical devices. The purpose of routine regulatory inspections is to assess whether the organization is in compliance with requirements. Routine FDA inspections target the four major subsystems of the quality management system including:

- Corrective and preventive actions (CAPA)
- Design controls (if applicable)
- Management controls
- Production and process controls

PMA preapproval and post-market inspections assess the organization's systems, methods, and procedures for the specific PMA devices to ensure the firm's quality management system is effectively established (defined, documented, and implemented).

For-cause regulatory inspections are generally performed when regulatory authorities perceive a public health threat, detect or suspect any fraudulent activity, detect or suspect counterfeit products, recognize a trend in reportable activities or adverse events, or are acting on a formal whistleblower complaint.

Regulatory compliance follow-up inspections are performed when the organization was issued significant 483 observations or a warning letter. The FDA will verify that the actions taken in response to those observations were adequately corrected.

Due diligence audits are performed by organizations when considering mergers and acquisitions to assess the degree of regulatory compliance, including facility registrations and marketing authorizations.

Audits can be used for a variety of reasons, including the assessment of organizational effectiveness, system efficiency, business performance, process effectiveness, risk management, regulatory compliance, supplier qualification, compliance with standards (certification and surveillance), and supporting mergers and acquisitions. Regardless of the reason for performing an audit, a risk-based process should always be employed.

AUDITS BY METHOD

There are several types of audits as defined by ISO 19011:2018 *Guidelines for auditing management systems*. The three primary types of audits include first, second, and third party.

First Party

First-party audits are usually referred to as internal audits. Internal audits are performed on behalf of the organization either by trained internal auditors or a qualified consultant to audit a product, process, or system to ensure compliance with standards, regulations, product, and internal requirements. Internal audits typically look for problematic areas, procedural misalignments, opportunities for improvement, and the overall effectiveness of the quality management system.

Internal audits are generally more in depth than the other audits and are used as a tool to foster continuous improvement.

External audits include those generally called second- and third-party audits. Second-party audits are conducted by parties who have an interest in the organization, such as customers, or by other individuals on their behalf. Third-party audits are conducted by independent auditing organizations, such as those providing certification/registration of conformity or governmental agencies.

Second Party

A second-party audit is when an organization performs an audit of a supplier to ensure that specified requirements are met. These requirements may include process validations, continuous process monitoring, traceability of materials, components, subassemblies, assemblies and parts, requirements for special cleanliness standards, requirements for specific documentation, and good manufacturing practices. Service suppliers may be evaluated for the ability to meet contractual requirements, maintain documentation, and follow procedural requirements.

Second-party audits can also be used as part of a supplier qualification and monitoring program. For monitoring programs, these audits can be done off-site through a review of documents and records submitted by the supplier. When initially qualifying a supplier, these audits should be performed on-site.

Third Party

Third-party audit occurs when an organization wants to acquire third-party registration, certification, or accreditation to a particular QMS. Third-party audits are conducted by independent agencies to verify that the organization has successfully established, implemented, and maintains a compliant QMS.

Audits are further characterized by what is being audited, such as products, processes, and systems (Figure 1.2). Product audits assess whether products are meeting requirements. Process audits evaluate whether processes are operating properly. System audits assess the adequacy of the QMS.

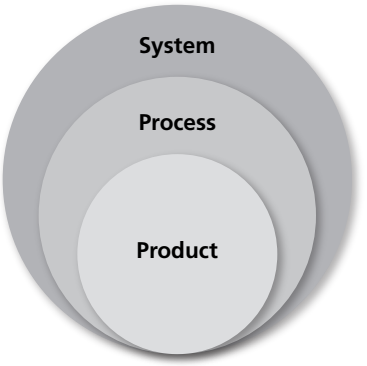

Figure 1.2 Types of audits.

Process approach audits are detailed audits that evaluate how a process is performing through its life cycle from input and processing, to output and improvement.

AUDIT ROLES AND RESPONSIBILITIES

Audits are authorized and/or requested by the client. The client is the organization or person requesting an audit. In the case of an internal audit, the audit client can also be the auditee or the person managing the audit program. Requests for external audit can come from sources such as regulators, contracting parties, or potential clients. The auditor is the individual(s) conducting the audit. The auditee is the organization that is being audited.

Each audit will have a least one auditor, who is referred to as the lead auditor. For more complex audits, an audit team overseen by the lead auditor may be required. The audit team may consist of one or more additional auditors (including auditor trainees) as well as technical experts. Technical experts may be used to provide specific knowledge or expertise related to the organization, activity, process, product, service, or discipline to be audited. Additionally, technical experts may help address cultural and language issues. Regardless of the purpose for using a technical expert, they do not act as auditors unless they are specifically trained and part of the audit team.

During the audit, the auditee (the organization being audited) may request to provide a guide. Guides should aid the audit team and act at the request of the audit team. Guides are responsible for assisting auditors in identifying individuals to participate in interviews and confirming timings and locations. They ensure that rules concerning location-specific arrangements for access, health and safety, environmental, security, confidentiality, and other issues are known and respected by the audit team and any potential risks are addressed. Guides witness the audit on behalf of the auditee, and, when appropriate, provide clarification or assist in collecting information.

PROFESSIONAL CONDUCT AND RESPONSIBILITIES

Objective auditing is characterized by a reliance on seven key principles. These principles help ensure the audit program and audits are effective tools in support of management policies by delivering information that can be used to identify issues and opportunities for improvement and to enhance performance.

ISO 19011:2018 *Guidelines for auditing management systems* provides the following key principles:

- Integrity
- Fair presentation
- Due professional care
- Confidentiality
- Independence
- Evidence-based approach
- Risk-based approach

Auditors and audit program management should perform their work with honesty, diligence, and responsibility; observe and comply with any applicable legal requirements; demonstrate their competence while performing their work; and perform their work in an impartial manner by remaining fair and unbiased.

Auditors and audit program management should not get drawn into company/department politics and should be sensitive to any influences that may be exerted on their judgement while carrying out an audit.

Audit findings, audit conclusions, and audit reports must be unbiased and must accurately and objectively reflect the activities of the audit. Obstacles encountered during the audit and unresolved issues between the audit team and the auditee should be documented and reported.

Auditors must exercise due professional care. Due professional care is having the ability to make reasoned judgements in all audit situations.

Auditors are usually required to sign a non-disclosure agreement (NDA). This should be done before the audit in case a legal review of the agreement is needed prior to the audit.

Auditors must be independent of the activity being audited wherever practicable and in all cases act in a manner that is free from bias and conflict of interest. For internal audits, auditors should be independent from the operating managers of the function being audited. Auditors should maintain objectivity throughout the audit process to ensure the audit findings and conclusions are based only on the audit evidence.

For small organizations, it may not be possible for internal auditors to be fully independent of the activity being audited, but every effort should be made to remove bias and encourage objectivity.

Audit evidence should be verifiable. Audits are generally based on a sampling of the information available, since an audit is conducted during a finite period and with finite resources. An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

An audit approach that considers risks and opportunities should be employed by auditors and audit program management. A risk-based approach should influence the planning, conducting, and reporting of audits to ensure that audits are focused on matters that are significant.

The ASQ Code of Ethics establishes global standards of conduct and behavior for its members, certification holders, and anyone else who may represent or be perceived to represent ASQ. The ASQ Code of Ethics requires individuals to act with integrity and honesty; demonstrate responsibility, respect, and fairness; and safeguard proprietary information and avoid conflicts of interest.

LEGAL CONSEQUENCES AND LIABILITY

Liabilities of an auditor for negligence and misfeasance (breach of duty or trust) can involve civil and criminal penalties. An auditor is in a contractual relationship with a client. If the auditor does not perform the audit according to contract terms, the client can sue for breach of contract. A client may seek remedies for breach of contract for: (1) specific performance; (2) general monetary damages for losses incurred as a result of the breach; and (3) consequential damages that occur indirectly as a result of the breach.

DATA PRIVACY

Maintaining confidentiality of any personal information that is reviewed during audits is essential for maintaining the integrity of the auditor and the audit program. As a medical device auditor, there may be times that the data encountered are subject to the U.S. Health Insurance Portability and Accountability Act (HIPPA) and EU General Data Protection Regulation 2016/679 (GDPR).

HIPPA gives patients control over the use of their health information and defines boundaries for the use/disclosure of health records by covered entities. HIPPA helps to limit the use of personal health information (PHI) with the aim of minimizing inappropriate disclosure.

GDPR is a regulation in the European Union (EU) pertaining to data protection and privacy, and addresses the transfer of personal data outside the EU. The GDPR gives control to individuals over their personal data. GDPR applies to any enterprise—regardless of its location and the data subjects' citizenship or residence—that is processing the personal information of data on subjects inside the EU.

Auditors must exercise discretion in the use and protection of information that is acquired during the audit. Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This concept includes the handling of sensitive or confidential information including copyrights, patents, trademarks, products, processes, clients, and customers.

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About the Editor

Scott A. Laman

Scott A. Laman has 35 years of experience in applying quality and statistical principles to research; product and process development; quality and reliability engineering; and risk management in the chemical, plastics, and medical industries. He has executed multi-site organizational changes, led corrective and preventive projects to improve quality systems, implemented new global and local quality system processes, and executed numerous manufacturing improvement projects as a hands-on quality manager and engineer. He is currently Senior Manager, Quality Engineering and Risk Management at Teleflex, Inc. in Wyomissing, PA and leads a multi-functional department that supports new product development, sustaining engineering, compliance, and post-market surveillance.

Scott holds B.S. and M.S. degrees in Chemical Engineering from Syracuse University. He is a PMI-certified Project Management Professional (PMP), Fellow of the American Society for Quality (ASQ), and holds ASQ certifications of Quality Engineer, Reliability Engineer, Manager of Quality/Organizational Excellence, Six Sigma Black Belt, Quality Auditor, Medical Device Auditor, and Supplier Quality Professional.

As a member of ASQ, he is a Past Chair of the Certification Board and led the development of a complete documentation system for the board's policies, procedures, and forms. He is also a Past Chair of the Professional Ethics and Qualifications Committee and led the development of the current ASQ Code of Ethics and committee operating procedures. He is an active member of the *Quality Progress* (QP) journal Administrative Committee with responsibility for editorial reviews and manuscript disposition. His 30 published contributions to QP include several feature articles and columns of various types.

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