CERTIFIED MEDICAL DEVICE AUDITOR (CMDA)
BODY OF KNOWLEDGE – 2026

The topics in this body of knowledge (BoK) include additional detail in the form of subtext explanations and cognitive level. These details will be used by the Exam Development Committee as guidelines for writing test questions and are designed to help candidates prepare for the exam by identifying specific content within each topic that may be tested. The subtext is not intended to limit the subject matter or be all-inclusive of what might be covered in an exam but is intended to clarify how the topics relate to a Medical Device Auditor's role. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A more comprehensive description of cognitive levels is provided at the end of this document.

I. Auditing Fundamentals (15 Questions)

A. Types of audits

1. Audits by purpose
Identify and distinguish between audits by purpose: organizational effectiveness, system efficiency, business performance, process effectiveness, risk management, regulatory compliance, supplier management, compliance with standards (certification and surveillance), design and development, for-cause audit, and follow-up audit. (Analyze)

2. Audit types
Identify and distinguish between audit types: product, process, system, first-party, second-party, third-party, internal, external, desk, management, department, function, onsite, remote, and hybrid. (Analyze)

B. Audit roles and responsibilities

Explain key functions and responsibilities of various audit participants, including audit team members, lead auditor, client, and auditee. (Understand)

C. Ethical, legal, and professional issues

1. Professional conduct and responsibilities
Define and apply the ASQ Code of Ethics, concepts of due diligence and due care with respect to confidentiality and conflict of interest, and various factors that influence audit credibility, including auditor independence, objectivity, and qualifications. (Apply)

2. Legal consequences and liability
Identify potential legal and financial ramifications of improper auditor actions (e.g., carelessness and negligence) in various situations and anticipate the effect that certain audit results can have on an auditee's liability. (Apply)

3. Data privacy
Demonstrate the importance of maintaining confidentiality of personal (e.g., HIPAA and EU GDPR) and proprietary business information reviewed during audits. (Apply)

II. Auditing and Inspection Processes (25 Questions)

A. Audit preparation and planning

1. Elements of the audit planning process
   Determine and implement steps in audit preparation and planning using a risk-based approach, such as verifying audit authority, establishing the purpose, scope, and type of audit, audit criteria, audit schedule and duration, and the resources necessary, including the size and number of audit teams. (Evaluate)
2. Auditor selection
   Identify and examine various internal or outsourced auditor selection criteria, such as education, experience, industry background, subject-matter expertise, absence of conflict of interest, and the characteristics that make auditors effective, such as interpersonal skills, problem-solving skills, attention to detail, cultural sensitivity, and ability to work independently as well as in a group or on a team. (Evaluate)
3. Audit-related documentation
   Identify sources of pre-audit information and examine audit-related documentation, such as reference materials and prior audits. (Evaluate)
4. Auditing tools
   Identify the sampling plan or method and procedural guidelines to be used for the specific audit. Select and prepare working papers (e.g., checklists and log sheets) to document the audit. (Create)
5. Auditing strategies
   Identify and use various tactical methods for conducting an audit, such as forward and backward tracing, discovery, etc., using risk-based decisions. (Apply)
6. Logistics
   Identify and organize various audit-related logistics, such as travel, safety and security considerations, the need for escorts, translators, confidentiality agreements, communications, information transfer, and clear right of access. (Apply)

B. Audit performance

1. Opening meeting
   Manage the opening meeting of an audit, including identifying the audit's purpose and scope, describing any scoring, rating, or classification criteria for potential audit findings, creating a record of the attendees, reviewing the audit schedule, and answering questions as needed. (Apply)
2. Data collection and analysis
   Select and apply various data collection methods, such as observing work activities, taking physical measurements, and examining paper and electronic documents. Evaluate the results to determine their importance for providing audit evidence. (Evaluate)
3. Data integrity principles
   Examine record-keeping requirements for data acquisition systems to ensure data integrity. Evaluate the data collected during an audit to ensure it is attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available (ALCOA+). (Evaluate)

4. Communication techniques
   Define and apply appropriate interviewing techniques (e.g., when to use various question types, the significance of pauses and their length, when and how to prompt a response), in various situations, including when supervisors are present, when conducting multiple interviews, and when using a translator. Identify typical conflict situations and use appropriate techniques to resolve them. (Apply)
5. Organization and analysis of objective evidence
   Identify and differentiate sources of objective evidence, such as observed, measured, confirmed, and documented. Classify evidence in terms of significance, severity, frequency, and level of risk. Evaluate the evidence for its potential impact on product, process, system, cost of quality, and regulatory compliance. Determine whether additional investigation is required to meet the scope of the audit. (Evaluate)
6. Onsite audit management
   Interpret situations throughout audit performance to determine whether time is being managed well and when changes need to be made, such as revising planned audit team activities, reallocating resources, and adjusting the audit plan. Communicate with the auditee about any changes or other events related to the audit. (Analyze)
7. Exit/closing meeting
   Formally manage exit/closing meetings by reiterating the audit's purpose, scope, scoring, rating, or classification criteria, and creating a record of the attendees. Present the audit results and obtain concurrence on evidence that could lead to an adverse conclusion. Discuss the next steps in the process (e.g., follow-up audit, additional evidence-gathering) and clarify who is responsible for performing those steps. (Apply)

C. Audit report

1. Basic elements
   Define, plan, and apply the steps in generating an audit report, including reviewing and finalizing results, organizing details, obtaining necessary approvals, and distributing the report. (Create)
2. Effective audit reports
   Report observations and nonconformances accurately; cite objective evidence, procedures, and requirements; and develop and evaluate various components, such as executive summaries, prioritized data, graphic presentation, and the impact of nonconformances. (Create)
3. Record retention
   Identify and apply record retention requirements, including the type of documents and storage considerations. (Apply)

D. Audit follow-up and closure

1. Elements of corrective and preventive action (CAPA)
   Identify and apply elements of CAPA, including problem identification, prioritizing actions based on risk, assignment of responsibility, root cause analysis, and establishing a plan to verify effectiveness of corrective actions to prevent recurrence. (Analyze)

2. Review of corrective action plan
   Use various criteria to evaluate the acceptability of corrective action plans. Identify and apply strategies for negotiating changes to unacceptable plans. (Apply)
3. Conducting audit follow-up
   Use various methods to verify and evaluate the effectiveness of corrective actions taken, such as re-examining procedures, observing revised processes, and conducting follow-up audits or re-audits. Develop strategies when corrective actions are not implemented or are not effective, such as communicating to the next level of management and re-issuing the corrective action request. (Evaluate)
4. Audit closure
   Identify and apply various elements of, and criteria for, audit closure. (Evaluate)

E. Audit procedural references

1. International guidelines for auditing quality systems
   Understand general auditing principles as described in ISO 19011 and the Medical Device Single Audit Program (MDSAP) audit model. (Understand)
2. FDA CPG 7382.850
   Explain the purpose and scope of FDA inspection criteria for taking regulatory action based on quality management system inspection results. (Understand)

III. Medical Device Quality Management System Requirements (38 Questions)

A. Regulatory laws and requirements

1. FDA - Code of Federal Regulations (CFR) Title 21
   Identify, define, and apply the following FDA requirement parts: 4 – Regulation of combination products, 7 – Enforcement policy, 11 – Electronic records; signatures, 58 – Good laboratory practice for nonclinical laboratory studies, 801 – Labeling, 803 – Medical device reporting, 806 – Medical devices; reports of corrections and removals, 807 – Establishment registration and device listing for manufacturers and initial importers of devices, 820 – Quality management system regulation, 821 – Medical device tracking requirements, and 830 – Unique device identification. (Apply)
2. U.S. requirements (FD&C Act, 201, 301-304, 501-502, 510, 518, 522)
   Identify how the FD&C Act defines and differentiates between device classifications and pre-market requirements. Recognize the implications of misbranding and adulteration. (Apply)
3. EU MDR 2017/745
   Recognize requirements of EU MDR 2017/745 and the key differences between this and U.S. regulations. (Apply)
4. Health Canada
   Recognize current requirements of the Canadian Medical Device Regulation SOR/98-282 and the key differences between this and U.S. regulations. (Apply)
5. Other international agencies
   Recognize requirements enforced by international agencies, such as Therapeutic Goods Administration (TGA), Japanese Pharmaceutical and Medical Device Agency, China NMPA, and Brazil ANVISA. (Understand)

B. Requirements for in vitro diagnostic (IVD) devices

Recognize the requirements of 21 CFR 809 and IVDR 2017/746 as they apply to in vitro diagnostic (IVD) devices. (Understand)

C. International standards for quality systems

Evaluate the selection and use of the following quality system standards: ISO 9001, ISO 13485, and ISO 17025. (Evaluate)

D. Quality Management System Regulation (QMSR) requirements incorporating ISO 13485:2016

1. Management responsibility (ISO 13485:2016: 4.1, 5.1–5.6, 6.1, 6.2, 7.1, 8.2.4)
   Assess management's responsibility in establishing and maintaining the quality system: organizational structure and management representative, quality planning/objectives, resources, management reviews, quality audits, and personnel training and education. (Evaluate)
2. Design and development (QMSR: 820.10(c) and ISO 13485:2016: 7.1-7.3)
   Evaluate the scope, purpose, and implementation of controls and their elements, including design and development planning, input, output, review, verification, validation, transfer, changes, and design and development files. (Evaluate)
3. Document and record control (QMSR: 820.35 and ISO 13485:2016: 4.2)
   Describe and review elements of a document and change control system, including document access and distribution control, approval processes, retention policies, communication procedures and maintenance of medical device files (MDFs), device records, and quality records. (Analyze)
4. Purchasing controls and acceptance activities (ISO 13485:2016: 7.4)
   Describe supplier qualification and purchasing control requirements for products, components, and services, including risk-based classification of suppliers. Describe appropriate identification and acceptance activities, including receiving and evaluating supplier-provided data (e.g., Certificates of Analysis [CoA]), and inspection, test, and verification processes used for incoming products. (Apply)
5. Identification and traceability (QMSR: 820.10(b-d) and ISO 13485:2016: 7.5.8, 7.5.9)
   Use appropriate methods for identifying and tracing products during all stages of receipt, production, distribution, installation, and throughout the device lifecycle (e.g., servicing and returns). (Apply)
6. Production and process controls (QMSR: 820.45 and ISO 13485:2016: 6.3, 6.4, 7.1, 7.5)
   Assess production and process controls, including process validation, monitoring, control of materials, equipment, buildings, environment, contamination, and software validation for automated processes. (Evaluate)
7. Inspection, measuring, and test equipment (ISO 13485:2016: 7.6)
   Determine the suitability and calibration of inspection equipment. Review calibration records and ensure calibration is traceable to national or international standards. (Evaluate)

8. Nonconforming product (QMSR: 820.10(b) and ISO 13485:2016: 8.3)
   Determine the adequacy of procedures, processes, and records established for the identification, control, evaluation, and disposition of nonconforming product. (Evaluate)
9. Analysis and improvement (ISO 13485:2016: 8.4, 8.5)
   Assess analysis of quality data sources to determine the need for CAPA. Define and distinguish between corrective action and preventive action. Review CAPA procedures, processes, and records to evaluate the effectiveness of the system. (Evaluate)
10. Product handling, storage, distribution, and installation (ISO 13485:2016: 7.5.3, 7.5.10, 7.5.11)
    Determine the adequacy of procedures, processes, and records established for these aspects of product control, including customer property, to ensure product integrity. (Analyze)
11. Complaint files (QMSR: 820.35(a) and ISO 13485:2016: 8.2.1–8.2.3)
    Determine the adequacy of complaint handling procedures, including investigation and determination of medical device reporting and incident reporting. (Evaluate)
12. Servicing (QMSR: 820.35(b) and ISO 13485:2016: 7.5.1, 7.5.4, 8.2.2)
    Determine the adequacy of procedures, processes, and records established for products that require servicing activities, such as troubleshooting and repair. Evaluate service reports for events that must be reported to the FDA to ensure that they are included in the complaint handling process. (Analyze)
13. Statistical techniques (ISO 13485:2016: 5.6.2, 7.3.6, 7.3.7, 7.5.6, 7.5.7, 8.1, 8.2.5, 8.2.6, 8.4)
    Determine the adequacy and validity of statistical techniques and sampling plans used to measure process capability and acceptability of product characteristics. Evaluate the rationale for statistical techniques used in quality systems, including design verification and validation, and acceptance sampling. (Analyze)

E. Post-market surveillance

Determine the appropriateness of the procedures, processes, and records established for the control of post-market surveillance activities. Define and describe vigilance, medical device reporting (MDR), adverse event reporting (AER), and trend reporting (e.g., EU MDR / IVDR) requirements. Review the adequacy of requirements and processes for product recall, corrections, removals, and tracking. (Analyze)

IV. Technical Medical Device Knowledge (42 Questions)

A. Risk management

1. ISO 14971; ISO / TR 24971
   Describe the principles of risk management, including risk analysis, evaluation, control, benefit-risk analysis, and the incorporation of production and post-production information. (Evaluate)

2. IEC 62366
   Determine whether the processes used for identification of known or foreseeable hazards are suitable in both normal and fault conditions, including hazards arising from device use. Verify that risk control measures have been implemented in design and production. (Evaluate)
3. ISO 13485
   Describe and assess the risk-based controls for appropriate processes needed for the quality management system. (Evaluate)

B. Design control

1. Human factors and usability engineering
   Evaluate human factors and usability studies performed during design and development. (Evaluate)
2. Biological evaluation
   Describe material characterization and the principles of biocompatibility test selection rationale as described in ISO 10993-1 and FDA-related guidance. Understand the differences between cytotoxicity, sensitization, and irritation. (Understand)
3. Packaging
   Interpret the appropriate standards for device packaging, including sterile and non-sterile product packaging per ISO 11607, and referenced standards, including ASTM D4169 (distribution) and ASTM F1980 (aging). (Understand)
4. Device shelf life
   Explain how a device's useful life / shelf life is determined and discuss the various parameters that determine the length of time a device will remain within acceptable specifications (e.g. sterility or package integrity). (Understand)
5. General safety and performance requirements (GSPR)
   Identify the elements of GSPR, per EU MDR 2017/745. (Remember)

C. Software development and maintenance for products

Identify principles of the software lifecycle for devices with software and Software as a Medical Device (SaMD) in accordance with FDA General Principles of Software Validation Guidance and IEC 62304. Describe the software development lifecycle model, including V&V, cybersecurity considerations, change control methods, the risk management process, and technologies, such as large language models (e.g., artificial intelligence [AI]). (Understand)

D. Labeling

Identify labeling requirements for devices, instructions for use (IFU), and promotional / marketing material (per 21 CFR 801). Understand the use of symbols (per ISO 15223) and UDI/GTIN/UPC (per 21 CFR 830). (Understand)

E. Controlled environments and utility systems

1. Controlled environments
   Identify and interpret controlled environment specifications (per ISO 14644), qualifications, validations, and monitoring (e.g., bioburden, endotoxins, airborne particulate, microbial contamination, temperature, and humidity). Review contamination control measures, pest control, housekeeping, disinfection, and sanitization processes in terms of controlled environment specifications and

classifications. Verify that appropriate training and personnel practices are used in controlled environments. (Analyze)

2. Utility systems
   Describe utility setups in medical device manufacturing facilities for water, compressed gas, heating, ventilation, and air conditioning (HVAC) systems, including whether they require qualification, validation, monitoring programs, or maintenance. (Understand)

F. Sterile medical devices

1. Definitions
   Describe and distinguish between aseptically processed products and terminally sterilized products; cleaning, disinfection, and sterilization; and chemical vs. biological indicators. (Understand)
2. Methods
   Identify basic elements of sterilization for dry heat, steam, ethylene oxide (EtO), vaporized hydrogen peroxide, gamma irradiation, and electron beam irradiation. (Remember)
3. Process controls and validation for ethylene oxide (EtO) and irradiation
   Determine appropriate sterilization validation, process controls, and monitoring (e.g. dose audits, parametric release, process challenge device [PCD], residuals) are properly implemented to ensure sterility assurance level (SAL). Ensure the process is documented in accordance with industry standards: ISO 11135, ISO 11137, and ISO 11737. (Apply)

G. Laboratory testing and failure analysis
Assess procedures and records used for laboratory test methods and evaluate failure analysis procedures and records to determine whether they are appropriate. (Evaluate)

H. Validation
Define and evaluate elements of different types of validations, such as process (IQ/OQ/PQ per GHTF/SG3/N99-10), cleanliness, test method, and rework. (Evaluate)

I. Reprocessing/reuse and cleaning of medical devices
Identify elements of reprocessing and cleaning validations in accordance with the FDA Guidance on Reprocessing of Reusable Devices. (Understand)

J. Common medical device directives and standards
Define and describe elements of various standards and directives as they relate to medical devices. (Understand)

1. IEC 60601-1
2. Restriction of Hazardous Substances (RoHS) directive
3. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
4. Waste Electrical and Electronic Equipment (WEEE)

K. Sources for new and evolving standards

Describe the sources for standards and guidance documents that form the basis for industry norms and standards, such as ANSI, ISO, ASTM, the FDA Recognized Consensus Standards Database, the Harmonised Standards Listing, Medical Device Coordination Group (MDCG), Notified Body Operating Group (NBOG), and Europa. (Remember)

V. Quality Tools and Techniques (15 Questions)

A. Quality control and problem-solving tools

Identify, interpret, analyze, and draw conclusions based upon: 1) Pareto charts, 2) cause and effect diagrams, 3) flowcharts, 4) statistical process control (SPC) charts, 5) check sheets, 6) scatter diagrams, 7) histograms, 8) root cause analysis, 9) plan-do-check-act (PDCA), 10) Setting Alert and Action Levels, 11) 5 Whys, 12) Is/Is Not (Kepner-Tregoe), 13) failure mode and effects analysis (FMEA), 14) fault tree analysis (FTA), and 15) affinity diagrams. (Analyze)

B. Process improvement techniques

1. Process capability
   Identify and interpret various process capability indices, such as C_p, C_{pk}, P_p, and P_{pk}. Recognize how these metrics are used in relation to established requirements and the effect on PPM. (Understand)
2. Six sigma
   Identify and define the six sigma DMAIC phases: define, measure, analyze, improve, and control, and recognize key tools, such as design of experiments (DOE). (Understand)
3. Lean tools
   Identify and define various lean tools, such as 5S, standard operations, kanban (pull), error-proofing, value-stream mapping, kaizen, and daily management (e.g., Gemba walk, dashboard, daily huddles). (Understand)
4. Measurement system analysis (MSA)
   Identify and define various MSA terms (e.g., bias, linearity, stability, accuracy, precision, repeatability, and reproducibility), and describe how these elements affect measurement systems. (Understand)
5. Cost of quality (COQ)
   Define and describe the four basic COQ categories: prevention, appraisal, internal failure, and external failure. (Understand)

C. Data types and sampling

1. Qualitative and quantitative analysis
   Describe qualitative data in terms of the nature, type, or other characteristics of an observation or condition. Describe how quantitative data is used to detect patterns or trends. Identify how such analyses can indicate whether a problem is systemic or isolated. (Analyze)
2. Attributes and variables data
   Determine whether to use an attributes sampling plan or variables sampling plan in various situations, such as process monitoring and control, receiving inspection, and auditing. (Analyze)

3. Sampling
Identify and interpret sampling plans. Determine if sampling plans are based on risk and statistically valid rationale. (Evaluate)

Levels of Cognition
Based on Bloom's Taxonomy – Revised (2001)

In addition to **content** specifics, the subtext for each topic in this BOK also indicates the intended **complexity level** of the test questions for that topic. These levels are based on "Levels of Cognition" (from Bloom's Taxonomy – Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember
Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand
Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply
Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze
Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate
Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create
Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.