CERTIFIED MEDICAL DEVICE AUDITOR (CMDA)
BODY OF KNOWLEDGE MAP 2020

The Certified Biomedical Auditor (CBA) Body of Knowledge (BoK) has been updated to ensure that the most current state of practice is being tested in the examination. If you would like more information on how a BoK is updated, see a description of the process on http://asq.org/cert/faq/create-body-of-knowledge.

Part of the updating process is to conduct a job analysis survey to determine whether the topics in the 2013 BoK are still relevant to the job role of biomedical auditors and to identify any new topics that have emerged since that BoK was developed. The quantitative results of the CBA job analysis survey showed that most of the topics that were in the 2013 BoK are still relevant to biomedical auditors in 2020. Twelve new topics were added to the 2020 BoK and parts of subtext were removed, as indicated in Table 2.

A further review of the BoK and survey results gathered from all active CBAs identified a shift in the primary practice of current Certified Biomedical Auditors (CBAs) from a focus in the "biomedical" industry to the "medical devices" industry. This feedback resulted in an update to the program name from the "Certified Biomedical Auditor (CBA)" to the "Certified Medical Device Auditor (CMDA)."

The 2020 Certified Medical Device Auditor Body of Knowledge (CMDA BoK) will be introduced at the **November 2020** administration. Both BoKs will be available online until January 1, 2021, at which time the 2013 BoK will be removed.

General comments about ASQ Body of Knowledge updates

When the Body of Knowledge (BoK) is updated for an ASQ exam, most of the material covered in the BoK remains the same. There are very few programs that change significantly over a 5-7 year period. One of the points that we make to all the exam development committees is that ASQ Certification Exams need to reflect "the state of practice" not "the state of the art." This helps to keep the programs grounded in what people currently do, rather than being driven by the latest hot-topic improvement idea or trend. Typically, the biggest change in any updated BoK is in how the content is organized. When a new BoK is announced and posted on the ASQ website, we also include a "BoK Map" that highlights the changes between the two Bodies of Knowledge: old and new. The BoK map also clearly identifies any new content that has been added to the exam, as well as any content that has been removed from the exam.

With regard to exam preparation materials, any of the reference books currently listed on the exam program reference list are available for candidates to use. These are the source materials that the exam development committees use to write questions and verify answers.

Specific comments about the 2020 CMDA Body of Knowledge updates
The CMDA Body of Knowledge mostly stayed the same with the 2020 update. New topics were added to the following sections:

I.	Data privacy (I.C.3)
II.	Data integrity principles (II.B.3)
III.	Complaint files (Part 198) (III.D.11)
IV.	ISO 13485 (IV.A.3) Design control (IV.B) Human factors and usability engineering (IV.B.1) Device shelf life (IV.B.4) General safety and performance requirements (IV.B.5) Labeling (IV.D) Validation (IV.H)
V.	Sampling (V.C.3)

In addition to a total of eleven new topics and minor removal/edits of content, there were five topics that increased in level of cognition: II.A.2, II.A.3, III.A.3, III.A.4, III.D.8, and four topics that decreased in level of cognition: II.D.2. II.E.1, II.E.2, and IV.F.2.

Table 1 below details the change in items allocated to each section of the Body of Knowledge. The section names have remained the same except for Section III that is now *Medical Device Quality Management System Requirements* and Section IV that is now *Technical Medical Device Knowledge*. Table 2, on page 3, presents the 2020 CMDA BoK and maps the topics to the 2013 BoK. Table 3, starting on page 14, presents the 2013 CBA BoK and maps the topics to the 2020 BoK. Details on changes between the two can be found below.

Table 1. BoK Section Item Allocation

BoK Sections	2013 BoK	2020 BoK	Change
I. Auditing Fundamentals	10	12	+2
II. Auditing and Inspection Processes	24	28	+4
III. Medical Device Quality Management System Requirements	47	38	-9
IV. Technical Medical Device Knowledge	40	42	+2
V. Quality Tools and Techniques	14	15	+1

Table 2. 2020 CMDA BoK mapped to the 2013 CBA BoK

2013 BoK Code	2020 BoK Details	Notes
	I. Auditing Fundamentals [12 Questions]	Number of questions increased from 10 to 12
I.A	**A. Types of audits**	
I.A.2	**1. Audits by purpose** Identify and distinguish between audits by purpose: organizational effectiveness, system efficiency, business performance, process effectiveness, risk management, regulatory compliance, supplier qualification, compliance with standards (certification and surveillance), design history file compliance, and for-cause audit. (Analyze)	Removed "conformance to requirements" Added "regulatory compliance, supplier qualification, compliance with standards (certification and surveillance), design history file compliance, and for-cause audit"
I.A.1	**2. Audits by method** Identify and distinguish between audits by method: product, process, system, first-party, second-party, third-party, internal, external, desk, management, department, and function. (Analyze)	Removed "compliance"
I.B	**B. Audit roles and responsibilities** Explain key functions and responsibilities of various audit participants including audit team members, lead auditor, client, auditee, etc. (Understand)	
I.C	**C. Ethical, legal, and professional issues**	
I.C.1	**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)	Updated subtext for clarification
I.C.2	**2. Legal consequences and liability** Identify potential legal and financial ramifications of improper auditor actions (carelessness, negligence, etc.) in various situations, and anticipate the effect that certain audit results can have on an auditee's liability. (Apply)	
NEW	**3. Data privacy** Demonstrate the importance of maintaining confidentiality of personal information reviewed during audits. (Apply)	

2013 BoK Code	2020 BoK Details	Notes
	II. Auditing and Inspection Processes [28 Questions]	Number of questions increased from 24 to 28
II.A	**A. Audit preparation and planning**	
II.A.1	**1. Elements of the audit planning process** Determine and implement steps in audit preparation and planning, such as verifying audit authority, establishing the purpose, scope, and type of audit, audit criteria, and the resources necessary, including the size and number of audit teams. (Evaluate)	Updated subtext for clarification
II.A.2	**2. Auditor selection** Identify and examine various internal or outsourced auditor selection criteria, such as education, experience, industry background, and subject-matter expertise, 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)	Updated subtext for clarification Increased cognitive level to Evaluate
II.A.3	**3. Audit-related documentation** Identify sources of pre-audit information and examine audit-related documentation, such as reference materials and prior audits. (Evaluate)	Increased cognitive level to Evaluate
II.A.4	**4. Auditing tools** Identify the sampling plan or method and procedural guidelines to be used for the specific audit. Select and prepare working papers (checklists, log sheets, etc.) to document the audit. (Create)	
II.A.5	**5. Auditing strategies** Identify and use various tactical methods for conducting an audit, such as forward and backward tracing, discovery, etc. (Apply)	
II.A.6	**6. Logistics** Identify and organize various audit-related logistics, such as travel, safety and security considerations, the need for escorts, translators, confidentiality agreements, and clear right of access. (Apply)	
II.B	**B. Audit performance**	
II.B.1	**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)	Added "classification" Updated subtext for clarification

2013 BoK Code	2020 BoK Details	Notes
II.B.2	**2. Data collection and analysis** Select and apply various data collection methods, such as observing work activities, taking physical measurements, examining paper and electronic documents, etc. Evaluate the results to determine their importance for providing audit evidence. (Evaluate)	
NEW	**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, and accurate (ALCOA). (Evaluate)	
II.B.3	**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)	
II.B.4	**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, and cost of quality. Determine whether additional investigation is required to meet the scope of the audit. (Evaluate)	Removed "or corroborated"
II.B.5	**6. On-site 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)	Updated subtext for clarification
II.B.6	**7. Exit/closing meeting** Formally manage these meetings: reiterate the audit's purpose, scope, scoring, rating, or classification criteria, and create 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 (follow-up audit, additional evidence-gathering, etc.), and clarify who is responsible for performing those steps. (Apply)	Subtopic renamed to "Exit/closing meeting" Added "classification"
II.C	**C. Audit report**	Topic renamed to "Audit report"
II.C.1	**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)	

2013 BoK Code	2020 BoK Details	Notes
II.C.2	**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)	Updated subtext for clarification
II.C.3	**3. Record retention** Identify and apply record retention requirements, including the type of documents and storage considerations. (Apply)	Updated subtext for clarification
II.D	**D. Audit follow-up and closure**	
II.D.1	**1. Elements of corrective and preventive action (CAPA)** Identify and apply the elements of these processes, 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)	Added "(CAPA)" to subtopic title Added "prioritizing actions based on risk" Added "establishing a plan to verify effectiveness of corrective actions"
II.D.2	**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)	Updated subtext for clarification Decreased cognitive level to Apply
II.D.3	**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, re-issuing the corrective action request, etc. (Evaluate)	Updated subtext for clarification
II.D.4	**4. Audit closure** Identify and apply various elements of, and criteria for, audit closure. (Evaluate)	
II.E	**E. Audit procedural references**	
II.E.1	**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)	Removed "GHTF SG4 guidance documents" Added "Medical Device Single Audit Program (MDSAP) audit model" Updated subtext for clarification Decreased cognitive level to Understand

2013 BoK Code	2020 BoK Details	Notes
II.E.2	**2. Quality System Inspection Technique (QSIT) and FDA CPG 7382.845** Understand QSIT auditing requirements and its various subsystems. Explain the purpose and scope of FDA criteria for taking regulatory action on the basis of quality system audit results. (Understand)	Updated subtext for clarification Decreased cognitive level to Understand
	III. Medical Device Quality Management System Requirements [38 Questions]	Section renamed to "Medical Device Quality Management Systems Requirements" Number of questions decreased from 47 to 38
III.A	**A. Regulatory laws and requirements**	
III.A.1	**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 system regulation, 821 – Medical device tracking requirements, and 830 – Unique device identification. (Apply)	Added "4 – Regulation of combination products, 7 – Enforcement policy, 58 – Good laboratory practice for nonclinical laboratory studies, 830 – Unique device identification" Updated subtext for clarification
III.A.2	**2. U.S. requirements (FD&C Act, 201, 301-304, 501-502, 510, 513, 518, 522, 704)** Identify how the FD&C Act defines and differentiates between device classifications and pre-market requirements. Recognize the implications of misbranding and adulteration. (Apply)	Added "522" to subtopic title
III.A.3	**3. EU MDR 2017/745** Recognize requirements of the directive and the key differences between this and U.S. regulations. (Apply)	Subtopic renamed to "EU MDR 2017/745" Increased cognitive level to Apply
III.A.4	**4. Health Canada** Recognize current requirements of the Canadian Medical Device Regulation SOP/98-282 and the key differences between this and U.S. regulations. (Apply)	Updated "Canadian Medical Devices Conformity Assessment System (CMDCAS)" to "Canadian Medical Device Regulation SOP/98-282" Increased cognitive level to Apply
III.A.6	**5. Other international agencies** Recognize requirements enforced by international agencies such as Therapeutic Goods Administration (TGA) and Japanese Pharmaceutical and Medical Device Agency, etc. (Understand)	Removed "State Food and Drug Administration (SFDA), National Health Surveillance Agency Brazil (ANVISA)" Added "Japanese Pharmaceutical and Medical Device Agency"

2013 BoK Code	2020 BoK Details	Notes
III.B	**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)	Renamed topic to "Requirements for in vitro diagnostic (IVD) devices" Updated subtext for clarification
III.C.1	**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)	Updated subtext for clarification
III.D	**D. Quality system regulation (QSR) requirements (21 CFR 820 – parts as shown)**	
III.D.1	**1. Management responsibility (Parts 20, 22, 25)** Assess management's responsibility in establishing and maintaining the quality system: organizational structure and management representative, quality planning/objectives, resources, management reviews, quality audits, personnel training and education, and control of customer property. (Evaluate)	Added "and management representative, quality planning/objectives"
III.D.2	**2. Design controls (Part 30)** 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 history file. (Evaluate)	Subtopic renamed to "Design controls (Part 30)" Removed "system requirements" Added "design and development planning, verification, transfer, changes, and design history file."
III.D.3	**3. Document (Part 40) and record control (Parts 180-186)** Describe and review elements of a document and change control system, including approval processes, retention policies, communication procedures and maintenance of device master records (DMRs), device history records (DHRs), and quality system records. (Analyze)	Removed "design history files (DHFs)"
III.D.4	**4. Purchasing controls and acceptance activities (Parts 50, 80, 86)** Describe supplier qualification and purchasing control requirements for products, components, and services. Describe appropriate identification and acceptance activities, including inspection, test, and verification processes used for incoming products. (Apply)	
III.D.5	**5. Identification and traceability (Parts 60, 65)** Use appropriate methods for identifying and tracing products during all stages of receipt, production, distribution, and installation. (Apply)	

2013 BoK Code	2020 BoK Details	Notes
III.D.6	**6. Production and process controls (Parts 70, 75)** Assess production and process controls, including process validation, monitoring, control of materials, equipment, environment, contamination, and software validation for automated processes.	Removed "22" from subtopic and "and validation procedures" from subtext Updated subtext for clarification
III.D.6	**7. Inspection, measuring, and test equipment (Part 72)** Determine the suitability and calibration of inspection equipment. Ensure calibration is traceable to national or international standards. (Evaluate)	Update subtopic and subtext
III.D.7	**8. Nonconforming product (Part 90)** Determine the adequacy of procedures, processes, and records established for the control and disposition of nonconforming product. (Evaluate)	Increased cognitive level to Evaluate
III.D.8	**9. Corrective and preventive action (CAPA) system (Part 100)** 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)	Added "Assess analysis of quality data sources to determine the need for CAPA."
III.D.9	**10. Product handling, storage, distribution and installation (Parts 140-170)** Determine the adequacy of procedures, processes, and records established for these aspects of product control to ensure product integrity. (Analyze)	
NEW	**11. Complaint files (Part 198)** Determine adequacy of complaint handling procedures, including investigation and determination of Medical Device Reporting. (Evaluate)	
III.D.10	**12. Servicing (Part 200)** 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)	
III.D.11	**13. Statistical techniques (Part 250)** 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, acceptance sampling, etc. (Analyze)	Removed "Interpret commonly used statistical tools and methods (control charts, hypothesis test, etc.) and evaluate the appropriateness of conclusions drawn."

2013 BoK Code	2020 BoK Details	Notes
III.E	**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) and adverse event reporting (AER) requirements. Review the adequacy of requirements and processes for product recall, corrections, removals, and tracking. (Analyze)	Subtopic renamed to "Post-market surveillance" Removed "such as the review and analysis of complaint handling and servicing data and feedback into the risk management and design processes"
	IV. Technical Medical Device Knowledge [42 Questions]	Section renamed to "Technical Medical Device Knowledge" Number of questions increased from 40 to 42
IV.A	**A. Risk management**	
IV.A.1	**1. ISO 14971** Describe the principles of risk management, including risk analysis, evaluation, control, benefit-risk analysis, and the incorporation of production and post-production information. (Evaluate)	Added "benefit-risk analysis" Updated subtext for clarification
IV.A.2	**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)	Updated subtext for clarification
NEW	**3. ISO 13485** Describe and assess the risk-based controls for appropriate processes needed for the quality management system. (Evaluate)	
NEW	**B. Design control**	
NEW	**1. Human factors and usability engineering** Evaluate human factors and usability studies performed during design and development. (Evaluate)	
IV.C	**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)	Removed "FDA Blue Book #G95-1" Added "FDA related guidance", "material characterization" and "Understand the differences between cytotoxicity, sensitization, and irritation."

2013 BoK Code	2020 BoK Details	Notes
IV.I	**3. Packaging** Interpret the appropriate standards for sterile and non-sterile product packaging per ISO 11607, and referenced standards including, ASTM D4169 (Distribution) and ASTM F1980 (Aging). (Understand)	
NEW	**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)	
NEW	**5. General safety and performance requirements** Identify the elements of General Safety and Performance Requirements, per EU MDR 2017/745. (Remember)	
IV.E	**C. Software development and maintenance for products** Identify principles of product software lifecycle 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, and the risk management process. (Understand)	Removed "FDA Pre-Market Submissions Software Guidance" and "ISO 80002" Added "FDA General Principles of Software Validation Guidance" and "cybersecurity considerations"
NEW	**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)	
IV.D	**E. Controlled environments and utility systems**	
IV.D.1	**1. Controlled environments** Identify and interpret controlled environment specifications (per ISO 14644), qualifications, validations, and monitoring (bioburden and endotoxins). Review 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)	Added "(bioburden and endotoxins)" and "housekeeping" Removed "cleaning" and standards"
IV.D.2	**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, or maintenance. (Understand)	
IV.B	**F. Sterile medical devices**	Renamed topic to "Sterile medical devices"

2013 BoK Code	2020 BoK Details	Notes
IV.B.1	**1. Definitions** Describe and distinguish between aseptically processed products and terminally sterilized products. (Understand)	
IV.B.2	**2. Methods** Identify basic elements of sterilization for dry heat, steam, electron beam, ethylene oxide (EtO), and radiation. (Remember)	Subtopic renamed to "Methods" Added "electron beam" Decreased cognitive level to Remember
IV.B.2	**3. Process controls and validation for ethylene oxide (EtO) and radiation** Determine appropriate validation, process controls and monitoring (e.g. dose audits, parametric release, process challenge device (PCD), residuals, etc.) are properly implemented to ensure Sterility Assurance Level (SAL). Ensure the process is documented in accordance with industry standards: ISO 11135, ISO 11137. (Apply)	Subtopic renamed to "Process controls and validation for ethylene oxide (EtO) and radiation" Removed "limulus amebocyte lysate (LAL) testing", "ISO 17665-1", "ISO 11138-1", and "ISO 11737-1" Added "validation" and "Sterility Assurance Level (SAL)"
IV.F	**G. Laboratory testing and failure analysis** Assess procedures and records used for laboratory test methods and determine whether they are appropriate. (Evaluate)	
NEW	**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)	
IV.J	**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)	
IV.H	**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)	Removed "IEC 80001" and "Waste Electrical and Electronic Equipment (WEEE)"
IV.G	**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 the FDA Recognized Consensus Standards Database, the Harmonised Standards Listing, Medical Device Guidances (MEDDEV), Notified Body Operating Group (NBOG), and Europa. (Remember)	

2013 BoK Code	2020 BoK Details	Notes
	V. Quality Tools and Techniques [15 Questions]	Number of questions increased from 14 to 15
V.A	**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). (Analyze)	Added "10) Setting Alert and Action Levels, 11) 5 Whys, 12) Is/Is Not (Kepner-Tregoe)"
V.B	**B. Process improvement techniques**	
V.B.1	**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)	Added "and the effect on PPM"
V.B.2	**2. Six sigma** Identify and define the six sigma DMAIC phases: define, measure, analyze, improve, and control. (Understand)	Updated subtext for clarification
V.B.3	**3. Lean tools** Identify and define various lean tools: 5S, standard operations, kanban (pull), error-proofing, value-stream mapping, etc. (Understand)	
V.B.4	**4. Measurement system analysis (MSA)** Identify and define various MSA terms (bias, linearity, stability, accuracy, precision, repeatability, reproducibility, etc.) and describe how these elements affect measurement systems. (Understand)	
V.B.5	**5. Cost of quality (COQ)** Define and describe the four basic COQ categories: prevention, appraisal, internal failure, and external failure. (Understand)	
V.C	**C. Data types and sampling**	
V.C.1	**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)	

2013 BoK Code	2020 BoK Details	Notes
V.C.2	**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, auditing, etc. (Analyze)	
NEW	**3. Sampling** Identify and interpret sampling plans. Determine if sampling plans are based on risk and statistically valid rationale. (Evaluate)	

Table 3. 2013 CBA BoK mapped to the 2020 CMDA BoK

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
I.				
I.A.1	Audits by method	**I.A.2**	Audits by method	Removed “compliance”
I.A.2	Audits by purpose	**I.A.1**	Audits by purpose	Removed “conformance to requirements” Added “regulatory compliance, supplier qualification, compliance with standards (certification and surveillance), design history file compliance, and for-cause audit”
I.B	Audit roles and responsibilities	**I.B**	Audit roles and responsibilities	
I.C.1	Professional conduct and responsibilities	**I.C.1**	Professional conduct and responsibilities	Updated subtext for clarification
I.C.2	Legal consequences and liability	**I.C.2**	Legal consequences and liability	
II.				
II.A.1	Elements of the audit planning process	**II.A.1**	Elements of the audit planning process	Updated subtext for clarification
II.A.2	Auditor selection	**II.A.2**	Auditor selection	Updated subtext for clarification Increased cognitive level to Evaluate
II.A.3	Audit-related documentation	**II.A.3**	Audit-related documentation	Increased cognitive level to Evaluate
II.A.4	Auditing tools	**II.A.4**	Auditing tools	
II.A.5	Auditing strategies	**II.A.5**	Auditing strategies	
II.A.6	Logistics	**II.A.6**	Logistics	
II.B.1	Opening meeting	**II.B.1**	Opening meeting	Added “classification” Updated subtext for clarification
II.B.2	Data collection and analysis	**II.B.2**	Data collection and analysis	
II.B.3	Communication techniques	**II.B.4**	Communication techniques	

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
II.B.4	Organization and analysis of objective evidence	**II.B.5**	Organization and analysis of objective evidence	Removed "or corroborated"
II.B.5	On-site audit management	**II.B.6**	On-site audit management	Updated subtext for clarification
II.B.6	Exit meeting	**II.B.7**	Exit/closing meeting	Subtopic renamed to "Exit/closing meeting" Added "classification"
II.C.1	Basic elements	**II.C.1**	Basic elements	
II.C.2	Effective audit reports	**II.C.2**	Effective audit reports	Updated subtext for clarification
II.C.3	Record retention	**II.C.3**	Record retention	Updated subtext for clarification
II.D.1	Elements of corrective and preventive action	**II.D.1**	Elements of corrective and preventive action (CAPA)	Added "(CAPA)" to subtopic Added "prioritizing actions based on risk"
II.D.2	Review of corrective action plan	**II.D.2**	Review of corrective action plan	Updated subtext for clarification Decreased cognitive level to Apply
II.D.3	Conducting audit follow-up	**II.D.3**	Conducting audit follow-up	Updated subtext for clarification
II.D.4	Audit closure	**II.D.4**	Audit closure	
II.E.1	International guidelines for auditing quality systems	**II.E.1**	International guidelines for auditing quality systems	Removed "GHTF SG4 guidance documents" Added "Medical Device Single Audit Program (MDSAP) audit model" Updated subtext for clarification Decreased cognitive level to Understand
II.E.2	Quality System Inspection Technique (QSIT) and FDA CPG 7382.845	**II.E.2**	Quality System Inspection Technique (QSIT) and FDA CPG 7382.845	Updated subtext for clarification Decreased cognitive level to Understand
III.				

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
III.A.1	FDA – Code of Federal Regulations (CFR) Title 21	**III.A.1**	FDA – Code of Federal Regulations (CFR) Title 21	Added "4 – Regulation of combination products, 7 – Enforcement policy, 58 – Good laboratory practice for nonclinical laboratory studies, 830 – Unique device identification" Updated subtext for clarification
III.A.2	U.S. requirements (FD&C Act, 201, 301-304, 501-502, 510, 513, 518, 704)	**III.A.2**	U.S. requirements (FD&C Act, 201, 301-304, 501-502, 510, 513, 518, 522, 704)	Added "522" to subtopic
III.A.3	European directive: Medical Device Directive 93/42/EEC (MDD) 14 June 1993 (Article 1) as amended by Directive 2007/47/EC	**III.A.3**	EU MDR 2017/745	Subtopic renamed to "EU MDR 2017/745" Increased cognitive level to Apply
III.A.4	Health Canada	**III.A.4**	Health Canada	Removed "Canadian Medical Devices Conformity Assessment System (CMDCAS)" Increased cognitive level to Apply
III.A.5	Japan			Removed from BoK
III.A.6	Other international agencies	**III.A.5**	Other international agencies	Removed "State Food and Drug Administration (SFDA), National Health Surveillance Agency Brazil (ANVISA)" Added "Japanese Pharmaceutical and Medical Device Agency"
III.B	FDA guidance for the manufacture of (IVD) products			Removed from BoK
III.C.1	ISO 9001, ISO 13485, ISO 17025	**III.C**	International standards for quality systems	Updated subtopic and subtext for clarification
III.C.2				Removed from BoK
III.D.1	Management responsibility (Parts 20, 22, 25)	**III.D.1**	Management responsibility (Parts 20, 22, 25)	Added "and management representative, quality planning/objectives"
III.D.2	Design control system (Part 30)	**III.D.2**	Design controls (Part 30)	Subtopic renamed to "Design controls (Part 30)" Removed "system requirements" Added "design and development planning, verification, transfer, changes, and design history file."

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
III.D.3	Document (Part 40) and record control (Parts 180-186)	**III.D.3**	Document (Part 40) and record control (Parts 180-186)	Removed "design history files (DHFs)"
III.D.4	Purchasing controls and acceptance activities (Parts 50, 80, 86)	**III.D.4**	Purchasing controls and acceptance activities (Parts 50, 80, 86)	
III.D.5	Identification and traceability (Parts 60,65)	**III.D.5**	Identification and traceability (Parts 60,65)	
III.D.6	Production and process controls (Parts 70, 72, 75)	**III.D.6** **III.D.7**	Production and process controls (Parts 70, 75) Inspection, measuring, and test equipment (Part 72)	Removed "22" from subtopic and "and validation procedures" from subtext III.D.6 split into III.D.6 and III.D.7
III.D.7	Nonconforming product (Part 90)	**III.D.8**	Nonconforming product (Part 90)	Increased cognitive level to Evaluate
III.D.8	Corrective and preventive action (CAPA) system (Part 100)	**III.D.9**	Corrective and preventive action (CAPA) system (Part 100)	Added "Assess analysis of quality data sources to determine the need for CAPA."
III.D.9	Product handling, storage, distribution and installation (Parts 140-170)	**III.D.10**	Product handling, storage, distribution and installation (Parts 140-170)	
III.D.10	Servicing (Part 200)	**III.D.12**	Servicing (Part 200)	
III.D.11	Statistical techniques (Part 250)	**III.D.13**	Statistical techniques (Part 250)	Removed "Interpret commonly used statistical tools and methods (control charts, hypothesis test, etc.) and evaluate the appropriateness of conclusions drawn."
III.E	Post-market surveillance (Guidance under section 522 of FD&C Act)	**III.E**	Post-market surveillance	Subtopic renamed to "Post-market surveillance" Removed "such as the review and analysis of complaint handling and servicing data and feedback into the risk management and design processes"
IV.				
IV.A.1	ISO 14971	**IV.A.1**	ISO 14971	Added "benefit-risk analysis" Updated subtext for clarification
IV.A.2	IEC 62366	**IV.A.2**	IEC 62366	Updated subtext for clarification
IV.B.1	Definitions	**IV.F.1**	Definitions	

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
IV.B.2	Methods and process controls	**IV.F.2** **IV.F.3**	Methods Process controls and validation for ethylene oxide (EtO) and radiation	Subtopic renamed to "Methods"; Added "electron beam"; Decreased cognitive level to Remember Subtopic renamed to "Process controls and validation for ethylene oxide (EtO) and radiation"; Removed "limulus amebocyte lysate (LAL) testing", "ISO 17665-1", "ISO 11138-1", and "ISO 11737-1"; Added "validation" and "Sterility Assurance Level (SAL)"
IV.C	Biocompatibility	**IV.B.2**	Biological evaluation	Subtopic renamed to "Biological evaluation" Removed "FDA Blue Book #G95-1" Added "FDA related guidance", "material characterization" and "Understand the differences between cytotoxicity, sensitization, and irritation."
IV.D.1	Controlled environments	**IV.E.1**	Controlled environments	Added "(bioburden and endotoxins)" and "housekeeping" Removed "cleaning" and standards"
IV.D.2	Utility systems	**IV.E.2**	Utility systems	
IV.E	Software development and maintenance for products	**IV.C**	Software development and maintenance for products	Removed "FDA Pre-Market Submissions Software Guidance" and "ISO 80002" Added "FDA General Principles of Software Validation Guidance" and "cybersecurity considerations"
IV.F	Laboratory testing and failure analysis	**IV.G**	Laboratory testing and failure analysis	
IV.G	Sources for new and evolving standards	**IV.K**	Sources for new and evolving standards	
IV.H.1	IEC 60601-1 and IEC 80001	**IV.J.1**	IEC 60601-1	Removed "IEC 80001"
IV.H.2	Restriction of Hazardous Substances (RoHS) directive	**IV.J.2**	Restriction of Hazardous Substances (RoHS) directive	
IV.H.3	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	**IV.J.3**	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	
IV.H.4	Waste Electrical and Electronic Equipment (WEEE)			Removed from BoK

2013 BoK		2020 BoK		Notes
Code	**Label**	**Code**	**Label**	
IV.I	Packaging	**IV.B.3**	Packaging	
IV.J	Reprocessing/reuse and cleaning of medical devices	**IV.I**	Reprocessing/reuse and cleaning of medical devices	
V.				
V.A	Quality control and problem-solving tools	**V.A**	Quality control and problem-solving tools	Added "10) Setting Alert and Action Levels, 11) 5 Whys, 12) Is/Is Not (Kepner-Tregoe)"
V.B.1	Process capability	**V.B.1**	Process capability	Added "and the effect on PPM"
V.B.2	Six sigma	**V.B.2**	Six sigma	Updated subtext for clarification
V.B.3	Lean tools	**V.B.3**	Lean tools	
V.B.4	Measurement system analysis (MSA)	**V.B.4**	Measurement system analysis (MSA)	
V.B.5	Cost of quality (COQ)	**V.B.5**	Cost of quality (COQ)	
V.C.1	Qualitative and quantitative analysis	**V.C.1**	Qualitative and quantitative analysis	
V.C.2	Attributes and variables data	**V.C.2**	Attributes and variables data.	