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39	A	B	C	D	E

PRACTICE QUESTIONS

American Society For Quality (ASQ)

CBAEN

Certified Medical Device Auditor

EDITION

Demo

QUESTIONS

9

FORMAT

Limited Edition PDF

Before you begin

What this is

9 practice questions for American Society For Quality (ASQ) CBAEN , each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, CBAEN
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1

SINGLE CHOICE

According to ISO 19011, which activity is the first step an audit team leader should perform when preparing for an audit?

- ☒ **A Prepare the audit plan and assign work to the audit team**
- ☐ B Conduct the opening meeting with the auditee's management
- ☐ C Select the audit team members based on required competencies
- ☐ D Generate the audit findings and prepare the audit report

ANSWER A

WHY ISO 19011 specifies that, after determining audit feasibility and confirming the audit team leader's appointment, the audit team leader is responsible for preparing the audit plan and assigning work to the team. Selecting team members is the responsibility of the audit program manager (or the body responsible for managing the audit program), not the team leader, and the opening meeting and audit report are conducted after planning.

QUESTION 2

SINGLE CHOICE

Under ISO 13485:2016, which of the following is a documented requirement for the control of design and development changes?

- ☒ **A Design and development changes shall be reviewed, verified, and approved before implementation**
- ☐ B Design and development changes shall be approved only by the regulatory authority
- ☐ C Design and development changes do not require re-validation if they are minor
- ☐ D Design and development changes must be communicated to the user only after release

ANSWER A

WHY ISO 13485:2016 (Clause 7.3.9) requires the organization to control design and development changes, review the changes, evaluate their effect on the product, verify that changes have been made, and approve them before implementation. Approval is the responsibility of the organization (typically a cross-functional design review), not the regulatory authority, and the standard does not exempt any change from review simply because it is minor.

QUESTION 3

SINGLE CHOICE

Which U.S. regulation establishes the Quality System Regulation (QSR) for medical device manufacturers, including requirements for design controls, production controls, and corrective and preventive actions (CAPA)?

- ☒ **A** 21 CFR Part 820
- ☐ **B** 21 CFR Part 11
- ☐ **C** 21 CFR Part 807
- ☐ **D** 21 CFR Part 803

ANSWER A

WHY 21 CFR Part 820 contains the Quality System Regulation for finished medical devices marketed in the United States, covering areas such as design controls, purchasing controls, production and process controls, and CAPA. 21 CFR Part 11 covers electronic records and electronic signatures; 21 CFR Part 807 covers establishment registration and device listing; and 21 CFR Part 807 is for establishment registration, while Part 803 governs medical device reporting (MDR) of adverse events.

QUESTION 4

SINGLE CHOICE

ISO 14971:2019 defines risk management as the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk. Which of the following is the FIRST step in the risk management process according to this standard?

- ☐ A Implementing risk control measures
- ☐ B Estimating and evaluating the risk for each hazardous situation
- ☒ C Identifying hazards and hazardous situations associated with the medical device
- ☐ D Reviewing the risk management report at the conclusion of the process

ANSWER C

WHY ISO 14971:2019 requires the manufacturer first to identify hazards and foreseeable hazardous situations associated with the medical device, and then to estimate and evaluate the associated risks. Risk control measures are implemented only after risks have been estimated and evaluated, and the risk management report is produced at the end of the process once residual risk has been assessed and the overall residual risk judged acceptable.

QUESTION 5

SINGLE CHOICE

During a medical device audit, an auditor observes a worker on the assembly line not wearing the required ESD wrist strap while handling printed circuit board assemblies. Which audit technique is the auditor applying?

- ☐ A Document review
- ☐ B Interviewing
- ☒ C Observation of activities
- ☐ D Reperforming a process step

ANSWER C

WHY Watching the worker and the work environment during the actual activity is a direct observation, one of the four classic audit evidence-gathering techniques described in ISO 19011 (observation, interview, document review, and inspection/reperformance). Document review would involve reviewing procedures or records; interviewing would involve questioning personnel; and reperforming the activity would entail carrying out the procedure again to confirm results.

QUESTION 6

SINGLE CHOICE

Which of the following is the MOST appropriate source of input for triggering a CAPA in a medical device quality system?

- ☒ **A** Routine monitoring of processes such as complaint trends, internal audit findings, and nonconforming product
- ☐ **B** The marketing department's next-year revenue forecast
- ☐ **C** Standard shift schedules and timekeeping records
- ☐ **D** General office supply inventory levels

ANSWER A

WHY ISO 13485:2016 (Clause 8.5.2) requires the organization to take appropriate action to eliminate the causes of nonconformities in order to prevent recurrence, and to use sources such as complaints, returned product, nonconforming product, internal and external audit findings, monitoring and measurement of processes, product identification and traceability records, and management review outputs as triggers for corrective and preventive action. Revenue forecasts, shift schedules, and office supply levels are unrelated to product conformity or process performance.

QUESTION 7

SINGLE CHOICE

Under 21 CFR Part 803 (Medical Device Reporting), which of the following is the primary purpose of requiring manufacturers to report device-related deaths, serious injuries, and certain malfunctions to the U.S. FDA?

- ☒ **A** To detect and correct device problems in a timely manner through post-market surveillance
- ☐ **B** To publicly disclose manufacturing cost data for each device
- ☐ **C** To replace premarket approval requirements with post-market controls
- ☐ **D** To allow manufacturers to delay corrective action until the next inspection

ANSWER A

WHY The purpose of 21 CFR Part 803 is to require manufacturers, importers, and device user facilities to report deaths, serious injuries, and certain malfunctions so the FDA and the manufacturer can identify and address device problems in a timely manner through post-market surveillance. It is not intended to disclose manufacturing costs, does not replace premarket review, and explicitly expects prompt action rather than delayed response.

QUESTION 8

SINGLE CHOICE

ISO 13485:2016 requires the organization to assign a unique device identifier to each medical device where traceability is required. The primary reason for this unique identification is to:

- ☒ **A** Enable product identification and recall of any individual device or lot that may be nonconforming
- ☐ **B** Allow the purchasing department to negotiate volume discounts with suppliers
- ☐ **C** Reduce the amount of label real estate available for marketing graphics
- ☐ **D** Eliminate the need for device history records

ANSWER A

WHY ISO 13485:2016 (Clause 7.5.8) requires unique identification of products where traceability is a requirement, and Clause 8.2.3 links this to monitoring and measurement of products and to recall capability. The unique identifier enables the manufacturer to identify, locate, and recall specific devices or lots in the field if a nonconformity is discovered. Volume discounts, label aesthetics, and elimination of device history records are unrelated to the regulatory intent of unique identification.

QUESTION 9

MULTIPLE CHOICE

Which of the following are primary responsibilities of a Certified Medical Device Auditor (CMDA) when conducting an external audit of a medical device manufacturer? (Choose two.)

- ☒ **A** Objectively collect and evaluate audit evidence to determine the extent of conformity with audit criteria
- ☐ **B** Prescribe specific corrective actions for every nonconformity that is identified
- ☒ **C** Prepare an audit report that accurately reflects the audit findings and conclusions
- ☐ **D** Approve new product submissions on behalf of the regulatory authority

ANSWER A - C

WHY Per ISO 19011, an auditor's responsibilities include objectively collecting and evaluating audit evidence to determine conformity with the audit criteria, preparing the audit report, and maintaining confidentiality. Auditors are expected to determine nonconformities and recommend corrective actions, but they should not prescribe specific corrective actions; that is the auditee's responsibility. Approving submissions on behalf of regulators is outside the auditor's role and would represent a conflict of interest.