SAMPLE EXAMINATION

The purpose of the following sample examination is to present an example of what is provided on exam day by ASQ, complete with the same instructions that are given on exam day.

The test questions that appear in this sample examination are retired from the CBA pool and have appeared in past CBA examinations. Since they are now available to the public, they will NOT appear in future CBA examinations. This sample examination WILL NOT be allowed into the exam room.

Appendix A contains the answers to the sample test questions. ASQ will not provide scoring and analysis for this sample examination. Remember: These test questions will not appear on future examinations so your performance on this sample examination may not reflect how you perform on the formal examination. A self-appraisal of how well you know the content for the specific areas of the body of knowledge (BOK) can be completed by using the worksheet in Appendix B.

On page 2 of the instructions, it states “There are 135 questions on this 4-hour examination.” Please note that this sample exam only contains 30 questions.

If you have any questions regarding this sample examination, please email cert@asq.org

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Please print your name above. Read all the instructions before beginning the examination. If you are unsure about any part of the instructions, consult your proctor. In order for ASQ to be able to properly scan the Scantron answer sheet you must completely fill in the circle. Each circle must be filled in dark enough for the scanner to properly pick up the answer you chose. If not this could result in the exam not being scored correctly, or potentially delay your results.

**General Instructions**

All answers must be recorded on the Scantron Answer Sheet; no exam will be graded with the answers marked in the exam booklet.

1. Using a soft lead pencil (#2 or softer) only, blacken the circle of the correct answer. **Do not use ink.** If you change your answer, be sure to erase the previous answer completely.

2. Each question has ONE correct answer only.

3. This is a timed test; do not linger over difficult questions. Instead, skip the questions of which you are unsure; return to them when you reach the end of the test.

4. Do not fold, staple, or tear the answer sheets.

5. Although this is an open book examination and personally generated materials/notes from training or refresher courses are allowed, the following conditions apply:
   - Each examinee must make his/her reference materials available to the proctor for review.
   - Absolutely no collections of questions and answers or weekly refresher course quizzes are permitted. Reference sources that contain such copy are not allowed unless the questions and answers are removed or obscured. **Examples of such sources include but are not limited to refresher and preparatory primers.**
   - **Calculator Policy:** With the introduction of palmtop computers and increasing sophistication of scientific calculators, ASQ has become increasingly aware of the need to limit the types of calculators that are permitted for use during the examinations. **Any silent, hand-held, battery-operated calculator WITHOUT an alphabetic keyboard will be permitted; however, all programmable memory must be cleared from the calculator before you enter the exam room.** The examination is written so that a simple calculator will be sufficient to perform calculations.
   - No laptop or palmtop computers are allowed.
   - No Cell Phones are allowed in exam room
   - Reference materials and calculators may not be shared.

6. When you have finished, check your answer sheet to be sure it is properly identified with your name and member number. Return your examination booklet, answer sheet, examinee comment form and scratch paper to your proctor. You must sign the roster sheet to signify the return of your test booklet.

7. It is strictly forbidden to copy or remove examination materials. You will be disqualified from the examination and not certified by ASQ if you breach this trust.

8. **TEST RESULTS** – you can check your test results 7-9 days after the exam date by logging into the [www.asq.org](http://www.asq.org) website and navigating to the Certification webpage. Otherwise, your exam results will be mailed in approximately three weeks. **Please Be Patient** we do not answer telephone requests for results.
Special Instructions
1. Please note that your answer sheet has been personalized with your name, member number, section number, and test type.
2. Do NOT make any changes to these parts of the answer sheet. Doing so will only delay your exam results. Notify the Proctor of any changes.
3. If you don’t have a personalized answer sheet, see your Proctor for further instructions.
4. There are 135 questions on this 4-hour examination. Please check that you have the correct number of questions.

STOP
DO NOT CONTINUE UNTIL INSTRUCTED
CERTIFIED BIOMEDICAL AUDITOR Test

Directions: Each of the questions or incomplete statements below is followed by four suggested answers or completions. Select the one that is best in each case and then fill in the corresponding space on the answer sheet.

Please note: Throughout the test, the Food and Drug Administration is referred to as “FDA,” and the Food, Drug, and Cosmetic Act is referred to as “FD&C Act.” All other abbreviations (e.g., ISO, GHTF) are expected to be understood by the candidate and are associated with their numeric standard, guideline title, etc.

1. Software configuration management is used to control software
   (A) development staffing and other resources
   (B) program versions
   (C) module testing
   (D) development planning

2. Which of the following best describes an in vitro diagnostic (IVD) product?
   (A) A medical device used for diagnosis of disease or patient care and management
   (B) Clinical chemistry and microbiology devices used to diagnose and manage diseases
   (C) A device used for diagnosis, screening, therapeutic drug monitoring, and anti-microbial susceptibility
   (D) A reagent, instrument, or system used in diagnosis to mitigate, treat, or prevent disease

3. An auditor should use a histogram in a quality audit to do which of the following?
   (A) Provide objective evidence that the auditee uses statistical process control (SPC)
   (B) Expose patterns that are normally difficult to detect
   (C) Interpret data for a trend chart
   (D) Identify a stratified tally diagram

4. If the residual risk for a medical device is unacceptable, the manufacturer is required to perform which of the following analyses?
   (A) Fault tree analysis (FTA)
   (B) Risk/benefit analysis
   (C) Option analysis
   (D) Failure mode and effects analysis (FMEA)

5. To ensure that a quality system satisfies the requirements of the Quality System Regulation, management reviews should be conducted
   (A) every 3 months
   (B) every 6 months
   (C) once a year
   (D) at established intervals with sufficient frequency

6. According to the Quality System Regulation, how often must corrective and preventive action information be submitted for management review?
   (A) Quarterly
   (B) Semi-annually
   (C) In accordance with industry standards
   (D) As established by procedure
7. An audit team leader should select the audit team primarily on the basis of their
   (A) understanding of the principles of quality systems
   (B) experience in negotiating skills
   (C) business system experience
   (D) previous working relationship with the auditees

8. According to QSI, an investigator who is reviewing production and process controls should select a process that is associated with
   (A) revenue generation
   (B) high-risk devices
   (C) high-volume production
   (D) the last inspection conducted

9. According to ISO 10993, biocompatibility testing is required to be performed on
   (A) development samples
   (B) raw materials
   (C) work in process
   (D) final product

10. The use of interviews to compare the responses of two different groups of people who interface with each other on the job is an efficient way for an auditor to
   (A) improve interpersonal dynamics within and between the groups
   (B) verify information and detect differences or exceptions
   (C) determine the effectiveness of internal control
   (D) involve more people in the audit process

11. The primary purpose of collecting data during an audit is to
   (A) provide the basis for drawing correct conclusions about items audited
   (B) develop a statistical confidence level in the audit findings
   (C) prove the validity of nonconformances
   (D) identify the root cause of nonconformances

12. According to the Medical Device Directive, the purpose of a clinical investigation is to
   (A) determine whether a device has any economic value
   (B) uncover and assess risks of undesirable side effects when a device is used under normal conditions
   (C) mitigate risks observed when a device is used under abnormal conditions
   (D) ensure that a device works properly even when used in abnormal conditions

13. When member states of the European Community (EC) adopt the concept of harmonized standards, it means that they
   (A) no longer have to use their own national standards as requirements for medical devices
   (B) presume compliance of devices accepted as conforming to relevant national standards
   (C) use only the central set of standards developed by the GHTF as medical device requirements
   (D) can modify their national standards for essential requirements without regard to the standards or requirements of the other member states
14. According to FDA guidance, code-based software testing is also known as
   (A) functional testing
   (B) regression testing
   (C) validation testing
   (D) structural testing

15. The rationale for putting a device on the market should be based on a risk analysis showing that
   (A) the medical benefits exceed any residual risks
   (B) the risks have been minimized
   (C) all risks have been evaluated
   (D) a step-by-step analysis has been conducted and the risks have been quantified

16. Which of the following types of audit is appropriate for goods that are ready for shipment?
   (A) Process
   (B) Systems
   (C) Shipping
   (D) Product

17. Comparing how a process is actually performed against the documented work instruction for that process is an example of which of the following techniques?
   (A) Quantitative
   (B) Qualitative
   (C) Statistical
   (D) Random sampling

18. According to the Quality System Regulation, device packaging must be designed to
   (A) allow for sterilization of the device
   (B) protect the device from alteration or damage
   (C) be child-proof
   (D) be tamper-proof

19. The term “bioburden” is defined as the
   (A) inoculated product that contains known populations of microorganisms
   (B) supporting material on which a defined number of specified microorganisms can be deposited
   (C) irradiator that can be loaded and unloaded with a product
   (D) population of viable organisms on a product or package

20. An auditee has initiated the corrective action process for the nonconformities identified during an audit even before the closing meeting occurs. How could the lead auditor best handle this at the closing meeting?
   (A) Require corrective action plans only for the outstanding items.
   (B) Recommend that the auditee wait until the report is issued to begin corrective action.
   (C) Document only the items that have not been corrected because those that have been corrected are no longer findings.
   (D) Report all nonconformities as well as corrective actions already taken.
21. A company has just begun to manufacture devices for human use. The company must register with the FDA within
   (A) 10 days after the FDA approves the product
   (B) 10 days after the first commercial distribution of the product
   (C) 30 days after the first commercial distribution of the product
   (D) 90 days after the first commercial distribution of the product

22. According to the FD&C Act, one mission of the FDA is to ensure that
   (A) human foods are inspected in accordance with government requirements
   (B) human and veterinary drugs are safe and effective
   (C) devices intended for human use are statistically reliable
   (D) cosmetics meet color additive requirements

23. Which of the following is prohibited by the FD&C Act for medical devices offered for sale in interstate commerce?
   (A) Violation of an injunction
   (B) Removal of product labels
   (C) Failure to comply with civil penalties
   (D) Failure to surrender product for seizure

24. According to the GHTF, which of the following topics is an advanced training element for current auditors?
   (A) Quality system principles
   (B) Process validation methods
   (C) Interviewing techniques
   (D) Auditing techniques

25. Which of the following is used to evaluate the adequacy of risk control requirements to ensure that the residual risk is as low as possible?
   (A) Severity cost
   (B) Risk severity
   (C) Business risk
   (D) Product analysis

26. Which of the following is a validation phase for sterilization by irradiation?
   (A) Installation qualification
   (B) Sterilizing dose audit
   (C) Challenge organism selection
   (D) Parametric release

27. When adverse events do not require remedial action, they must be reported according to which of the following timelines?
   (A) US 30 days; European community 10 days for incidents and 30 days for near incidents
   (B) US and European community 30 days regardless of the type of reportable event
   (C) US and European community 10 days regardless of the type of reportable event
   (D) US 10 days; European community 30 days regardless of the type of reportable event
28. According to ISO 14971, the risk management file is required to contain

(A) risk evaluations and mitigations
(B) the risk management plan
(C) the results of all risk management activities
(D) a risk/benefit analysis

29. Under the Medical Device Directive, a device is classified on the basis of the

(A) score from an essential requirements checklist for the device
(B) intended use of the device
(C) assessment of the device manufacturer’s quality system
(D) terminal sterilization method to be used on the device

30. When quality characteristics of a product cannot be described adequately in documented standards, the workmanship criteria must be established

(A) by the operator of the process
(B) by the quality inspector of the process
(C) in accordance with international standards
(D) through approved representative samples

END OF EXAM

IF YOU FINISH BEFORE TIME IS CALLED, YOU MAY GO BACK AND CHECK YOUR WORK ON THIS TEST.
APPENDIX A: Answer Sheet
For each sample test question, the correct answer is provided below along with the area of the body of knowledge (BOK) that the item is classified to. This sample examination is not intended to represent all areas of the BOK but to provide a sampling from each major topic area. All ASQ examinations are based on the BOK for that particular exam. To view the BOK for CBA, please go to http://www.asq.org/certification/biomedical-auditor/bok.html

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<th>Question</th>
<th>BOK</th>
<th>Correct Answer</th>
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<tr>
<td>2</td>
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<tr>
<td>3</td>
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<tr>
<td>4</td>
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<tr>
<td>5</td>
<td>III.C.</td>
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<td>7</td>
<td>II.A.2</td>
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<tr>
<td>8</td>
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<tr>
<td>9</td>
<td>IV.C.</td>
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<tr>
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<tr>
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<th>BOK</th>
<th>Correct Answer</th>
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</tbody>
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APPENDIX B: Analyzing Body of Knowledge (BOK) Content

The following worksheet can be used to help you analyze the results of your answers on this sample examination. It can be used to determine which areas of the body of knowledge (BOK) you may want to study.

After learning which sample test questions you had correct, total the number you had correct and enter that number into the 2nd column of the worksheet. The 3rd column provides the total number of test questions that are in this sample examination for that major area of the BOK. The last column provides the total number of test questions that appear in a formal ASQ examination for that area of the BOK.

<table>
<thead>
<tr>
<th>BOK Topic Area</th>
<th>Total You Had Correct on Sample Exam</th>
<th>Total in the Sample Exam</th>
<th>Total in Formal ASQ Exam</th>
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<tr>
<td>II. Auditing and Inspection Processes</td>
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<td>30</td>
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<tr>
<td>III. Biomedical Quality Management System Requirements</td>
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<tr>
<td>IV. Technical Biomedical Knowledge</td>
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<td>9</td>
<td>25</td>
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<tr>
<td>V. Quality Tools and Techniques</td>
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<td>15</td>
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<tr>
<td><strong>GRAND TOTAL</strong></td>
<td><strong>30</strong></td>
<td><strong>135</strong></td>
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