

ASQ CMDA

ASQ Certified Medical Device Auditor (CMDA)

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Question: 1

Effective auditors should possess which of the following skills?

(Choose two)

Response:

- A. Ability to play a musical instrument
- B. Attention to detail
- C. Problem-solving skills
- D. Proficiency in video editing

Answer: B C

Question: 2

FDA CPG 7382.845 is critical for understanding the FDA's criteria for _____ based on quality system audit results.

Response:

- A. regulatory action
- B. market approval
- C. financial penalties
- D. product recalls

Answer: A

Question: 3

In preparing for an audit, which aspects are crucial?

(Choose two)

Response:

- A. Deciding on the lunch menu
- B. Choosing the color of the audit report cover
- C. Establishing the audit type
- D. Verifying audit authority

Answer: C D

Question: 4

When applying the elements of CAPA, which of the following is critical in ensuring the effectiveness of corrective actions?

Response:

- A. Prioritizing actions based on financial impact
- B. Focusing on actions with the easiest implementation
- C. Prioritizing actions based on risk
- D. Assigning responsibility based on department seniority

Answer: C

Question: 5

The impact of nonconformances in an audit report is significant. What is the primary purpose of detailing these impacts?

Response:

- A. To allocate blame to specific individuals
- B. To highlight areas for improvement
- C. To assess the financial loss only
- D. To promote alternative products

Answer: B

Question: 6

What are the benefits of including graphic presentation in an audit report?

(Select two)

Response:

- A. Simplifies complex data for better understanding
- B. Enhances the visual appeal of the report
- C. Replaces the need for written content
- D. Assists in highlighting key findings

Answer: A D

Question: 7

Monitoring of which elements is crucial in a controlled environment?

(Multiple correct answers)

Response:

- A. Bioburden
- B. Endotoxins
- C. Employee mood
- D. Color of the walls

Answer: A B

Question: 8

Auditor independence ensures that the audit is free from _____ bias.

Response:

- A. Technical
- B. Financial
- C. Personal
- D. Educational

Answer: C

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