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Sample Exam

Exam Name: ISO 14971:2019 - Certified Lead Auditor

Exam Code: ISO-14971:2019-CLA

1. What is the primary objective of ISO 14971:2019?

a) To improve product quality

b) To manage risks associated with medical devices

c) To reduce manufacturing costs

d) To ensure compliance with environmental regulations

Answer: b) To manage risks associated with medical devices

2. Which of the following is NOT a step in the risk management process as defined by ISO 14971:2019?

a) Risk analysis

b) Risk control

c) Risk financing

d) Risk evaluation

Answer: c) Risk financing

3. In the context of ISO 14971:2019, what does the term "residual risk" refer to?

a) The risk that remains after all risk control measures have been implemented

b) The risk that is identified before risk control measures are applied

c) The risk associated with environmental factors

d) The risk that occurs during the production phase

Answer: a) The risk that remains after all risk control measures have been implemented

4. According to ISO 14971:2019, which of the following documents is crucial for maintaining an effective risk management process?

a) Marketing Plan

b) Risk Management File

c) Financial Report

d) Training Manual

Answer: b) Risk Management File

5. What is the role of a lead auditor in an ISO 14971:2019 audit?

a) To develop medical devices

b) To oversee the entire audit process, including planning, execution, and reporting

c) To conduct only the closing meeting of the audit

d) To ensure product design compliance with ISO 9001 standards

Answer: b) To oversee the entire audit process, including planning, execution, and reporting

6. During a risk assessment, if a hazard is identified but its associated risk is deemed acceptable, what should be done according to ISO 14971:2019?

a) Implement further risk control measures

b) No further action is required, but the risk should be documented and monitored

c) Discontinue the development of the device

d) Increase the frequency of risk assessment

Answer: b) No further action is required, but the risk should be documented and monitored

7. Which of the following best describes the relationship between ISO 14971:2019 and regulatory requirements?

a) ISO 14971:2019 is independent of any regulatory requirements

b) ISO 14971:2019 is designed to be compatible with global regulatory requirements

c) ISO 14971:2019 only applies to the European Union market

d) ISO 14971:2019 replaces all national regulations

Answer: b) ISO 14971:2019 is designed to be compatible with global regulatory requirements