



Sample Exam

Exam Name: ISO 13485 - Certified Lead Implementer

Exam Code: ISO-13485-CLI

1. What is the primary purpose of ISO 13485?

- A. To improve financial performance of organizations
- B. To define environmental management requirements
- C. To establish quality management system requirements for medical devices
- D. To regulate healthcare professionals

Correct Answer: C

2. Which key feature distinguishes ISO 13485 from other ISO management system standards?

- A. Focus on customer satisfaction only
- B. Strong alignment with medical device regulatory requirements
- C. Emphasis on information security
- D. Applicability to all industries

Correct Answer: B

3. Medical devices are classified into different classes primarily based on:

- A. Manufacturing cost
- B. Country of origin
- C. Level of risk to patients
- D. Market demand

Correct Answer: C

4. Which activity is a critical part of the ISO 13485 certification process after QMS implementation?

- A. Marketing analysis
- B. Internal audits
- C. Product promotion
- D. Financial review

Correct Answer: B

5. What is the main objective of risk management under ISO 13485?

- A. Reducing production costs
- B. Identifying and mitigating risks associated with medical devices
- C. Improving employee productivity
- D. Increasing sales volume

Correct Answer: B

6. Which principle of quality management emphasizes using data and analysis to support decisions?

- A. Leadership commitment
- B. Engagement of people
- C. Evidence-based decision making
- D. Continuous improvement

Correct Answer: C

7. What is the primary role of a Lead Implementer in ISO 13485?

- A. Conduct external certification audits
- B. Develop medical device designs
- C. Guide the organization through QMS implementation and compliance
- D. Approve regulatory submissions

Correct Answer: C
