



Exam Name - ISO 13485:2016 - Certified Lead Auditor

Exam Code – ISO-QMS-13485

Sample Exam

According to ISO 13485, what is the minimum period of time that records relating to the manufacture of medical devices must be retained?

- A) 2 years
- B) Defined by national regulations
- C) Lifetime of device
- D) 2 years or the lifetime of the device

What phrase within ISO 13485 is associated with the use of risk based thinking?

- A) "establish and maintain"
- B) "proportionate to"
- C) "effectiveness"
- D) "as appropriate"

Answer: D



How often does a Management Review need to take place?

- A) Monthly
- B) At planned intervals
- C) Quarterly
- D) Annually

Answer: D

Is it sufficient for software used during measurement of a medical device to be verified, or does it also need to be validated?

- A) Verified
- B) Validated
- C) Both
- D) Neither

Answer: B



Which European Directives are referenced by ISO 13845?

- A) 90/385
- B) 93/42
- C) 98/79
- D) All of these

Answer: D

If an organization wished to indicate that some aspects of ISO 13485 were not applicable in their circumstances, where would this be stated?

- A) Quality Policy
- B) Scope statement
- C) Management review minutes
- D) External audit report