

Regulatory Affairs Certification Practice Test Questions and Answers

1. What is the primary purpose of a 510(k) premarket notification submission to the FDA?

- A) To request clinical trial approval
- B) To demonstrate that a medical device is substantially equivalent to a legally marketed predicate device
- C) To register a manufacturing facility
- D) To report adverse events

2. Which ICH guideline addresses Good Clinical Practice (GCP) standards?

- A) ICH E2A
- B) ICH E6
- C) ICH Q1A
- D) ICH M4

3. What is the typical timeframe for FDA review of a New Drug Application (NDA)?

- A) 60 days
- B) 180 days
- C) 10-12 months (standard review)
- D) 24 months

4. What does the term "CAPA" stand for in regulatory affairs quality systems?

- A) Clinical Assessment and Product Analysis
- B) Corrective Action and Preventive Action
- C) Compliance Audit and Process Approval
- D) Chemical Analysis and Product Authorization

Answers: 1-B 2-B 3-C 4-B

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