

Certified Validation Manager Practice Test Questions and Answers

1. What is the primary purpose of validation in pharmaceutical and medical device manufacturing?

- A) Reducing manufacturing costs only
- B) Establishing documented evidence that systems and processes consistently produce results meeting predetermined specifications
- C) Speeding up production timelines
- D) Eliminating the need for quality control testing

2. Which validation approach is most appropriate for established manufacturing processes?

- A) No validation required
- B) Retrospective validation using historical data and process analysis
- C) Concurrent validation only
- D) Prospective validation exclusively

3. What is the most critical element of a validation master plan (VMP)?

- A) Cost reduction strategies
- B) Comprehensive strategy outlining validation approach, responsibilities, timelines, and acceptance criteria
- C) Marketing considerations only
- D) Staff scheduling requirements

4. How should validation managers handle change control in validated systems?

- A) Allow changes without documentation
- B) Implement formal change control procedures with impact assessment and re-validation as needed
- C) Make changes only during scheduled maintenance
- D) Avoid all changes to validated systems

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

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