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ASQ Certified Pharmaceutical GMP Professional Sample Questions (Q11-Q16):

NEW QUESTION # 11

Audit evidence should be _____ to confirm audit completion and findings.

Response:

- A. estimated
- B. deleted
- C. documented
- D. ignored

Answer: C

NEW QUESTION # 12

Biological product deviation reports are crucial for:

Response:

- A. Cataloging cafeteria incidents
- B. Logging daily employee attendance
- C. Reporting changes in executive leadership
- D. Tracking deviations in biological product manufacturing or handling

Answer: D

NEW QUESTION # 13

Product seizure is a regulatory enforcement action used to:

Response:

- A. Reward companies for outstanding compliance records.
- B. Encourage voluntary compliance with marketing guidelines.
- C. Compel a company to relocate its manufacturing facilities.
- D. Address serious violations by removing products from the market.

Answer: D

NEW QUESTION # 14

An effective REMS program is designed to:

Response:

- A. Enhance the marketing potential of a drug
- B. Provide competitive intelligence
- C. Increase shareholder value
- D. Ensure that the benefits of a drug outweigh its risks

Answer: D

NEW QUESTION # 15

Critical considerations for infrastructure in product development include:

(Select two)

Response:

- A. Aesthetic appeal of the facility
- B. Environmental control systems
- C. Proximity to corporate headquarters
- D. Equipment capability and cleanliness

Answer: B,D

NEW QUESTION # 16

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- [illegible]