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QUESTION 1

SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?

- A. Inadequate training
- B. Late and/or incorrect deliverables
- C. Causes of non-conformities
- D. Adverse environmental impacts

Correct Answer: C

QUESTION 2

Which of the following BEST describes the purpose of the ICH?

- A. To provide scientific evaluation of applications for international marketing authorization for safe, effective, and high-quality medicines for the ICH regions
- B. To protect and promote public health through the evaluation and supervision of safe, effective, and high-quality medicines for the ICH regions
- C. To lobby for improved industry standards for the development of new safe, effective, and high-quality medicines for the ICH regions
- D. To discuss and establish common guidelines for safe, effective, and high-quality medicines for the ICH regions

Correct Answer: D

QUESTION 3

During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product is distributed globally. Which of the following is the most appropriate action to take FIRST?

- A. Withdraw the affected product from the markets.
- B. Send a "Dear Dr." letter to customers.
- C. Notify the global regulatory authorities.
- D. Assess the potential safety risk.

Correct Answer: C

QUESTION 4



According to WHO, what are the temperature and humidity conditions for a Zone IVb long-term stability study?

- A. 25: C and 60% RH
- B. 30°C and 35% RH
- C. 30°C and 65% RH
- D. 30: C and 75% RH

Correct Answer: D

QUESTION 5

According to ICH, which of the following components of study information is NOT required in a clinical study report?

- A. Randomization scheme and codes
- B. Protocol and protocol amendments
- C. List of IECs or IRBs
- D. Detailed CV of all investigators

Correct Answer: D

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