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QUESTION 1

Which of the following situations does NOT require rapid communication to regulatory authorities?

- A. A clinically important increase in the rate of occurrence of an "expected." but serious ADR
- B. A lack of efficacy with a medicinal product used in treating a life-threatening disease
- C. A major safety finding from a newly completed animal carcinogenicity study
- D. A statistically significant increase in the number of deaths in an animal dose finding study

Correct Answer: AD

QUESTION 2

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

- A. Stop product manufacturing.
- B. Establish validation procedures.
- C. Assess the impact of the changes.
- D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 3

A regulatory authority announces an inspection of a regulatory affairs professional's facility during a holiday season when most of the staff is not available. What is the MOST practical approach to this dilemma?

- A. Negotiate with colleagues and the authority to find a better time.
- B. Insist that key personnel be available for the inspection.
- C. Inform the authority that the time is not suitable and request a new time
- D. Arrange for an inspection without all intended personnel.

Correct Answer: A



QUESTION 4

What is the LAST stage in the development of a quality risk management process for a medical device?

- A. Risk analysis
- B. Risk reduction
- C. Risk acceptance
- D. Risk evaluation

Correct Answer: C

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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