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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

Why is it necessary to run supplemental safety pharmacology studies?

A. To substitute the utilization of GLP

B. To comply with regulatory authority requirements related to clinical studies

C. To evaluate potential adverse pharmacodynamics effects not addressed by the core battery

D. To provide adverse reaction reports and the results of the statistical data to the regulatory authority

Correct Answer: C

QUESTION 3

A protocol for a pivotal registration trial of a new product is submitted to a major regulatory authority for review and approval. The regulatory authority issues the company a written commitment that if the studies are completed as outlined in the protocol and the results meet the pre-specified criteria for efficacy and safety, the product will be approved.

During the final week of the review of the marketing application, which has fully met all pre- specified criteria, the company receives a letter from the regulatory authority stating that it no longer believes that the product will be approved based on a recent withdrawal of a similar product in another country.

What is the BEST response?

A. Notify the regulatory authority regarding Its obligation to honor the commitment to approve the application.

B. Consult with the legal department to discuss the best course of action.

C. Review the regulatory guidelines to determine how to proceed.

D. Request a meeting with the regulatory authority to discuss the application.

Correct Answer: D

QUESTION 4

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 5

GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?

A. Instructions for use

B. Risk analysis

C. Product literature

D. Essential principles

Correct Answer: BD