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QUESTION 1

A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?

- A. The ISO national member body
- B. The ISO technical committee in charge of the area
- C. The ISO Secretariat
- D. The country's regulatory authority

Correct Answer: AD

QUESTION 2

According to ICH, what is the MAXIMUM amount of time in calendar days that an organization has from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?

- A. 3
- B. 5
- C. 10
- D. 15

Correct Answer: BCD

QUESTION 3

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2,000 patients. Which long-term ICH data requirement has NOT been met?

- A. 100 patients for 12 months
- B. 200 patients for nine months
- C. 500 patients for three months
- D. 3,000 total patient exposures

Correct Answer: A

QUESTION 4



A regulation change is imminent and may require further non-clinical testing on a product currently in Phase III clinical trials. What is the most appropriate action to take FIRST?

- A. Obtain a copy of the proposed regulation and analyze the impact.
- B. Inform the company's senior management and arrange an emergency meeting
- C. Consult with the company's legal department regarding options.
- D. Arrange for additional testing of the product at the testing facility.

Correct Answer: A

QUESTION 5

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

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