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QUESTION 1

Which of the following is the PRIMARY purpose of an audit report?

- A. To carry out a complete review of product applications
- B. To define how to prepare new product submissions
- C. To document compliance history
- D. To train sales representatives

Correct Answer: C

QUESTION 2

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

- A. "Product X is a guaranteed cure for arthritis."
- B. "Product X is effective for the treatment of arthritis."
- C. "Product X is safe for arthritis and without side effects."
- D. "Product X is effective in all patients with arthritis."

Correct Answer: B

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

During new drug development, a new impurity in the drug substance is detected at a level of 0.12%. The intended maximum daily dose is less than 2 g/day, and the drug is known generally not to be toxic.

What should be done in response to identifying the impurity?

- A. Perform either an identification study or a non-clinical qualification study.
- B. Perform both identification and non-clinical qualification studies concurrently.
- C. Perform an identification study, wait until the result is available, and then consider performing a nonclinical qualification study.
- D. Perform a non-clinical qualification study, wait until the result is available, and then consider performing an identification study.

Correct Answer: C

QUESTION 5

Company X has a patent for an anti-inflammatory drug that will expire in one year. In order to minimize the effect of the patent expiration, which is the BEST action for the company to take?

- A. Conduct a Phase III study for a new unrelated indication of the drug.
- B. Develop a generic version of the drug.
- C. Develop a better brand-name drug in the same class.
- D. Explore litigation strategy for patent infringements on the drug.

Correct Answer: B

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