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QUESTION 1

A company is considering the development of a medical device similar to those already available. Which of the following should be evaluated FIRST when developing a clinical evaluation document?

- A. Adverse event reports
- B. Clinical experience
- C. Clinical investigations
- D. Literature search

Correct Answer: C

QUESTION 2

A company's product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product.

To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

- A. Label the product for use in appropriate populations.
- B. Educate patients and healthcare providers on how to use the product
- C. Delay product launch until required studies are completed.
- D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 3

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

- A. A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation
- B. A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use
- C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product
- D. A brief summary of relevant physical, chemical, and pharmaceutical properties: instructions for storage and handling of the dosage form: and a description of the formulation

Correct Answer: D



QUESTION 4

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?

- A. Deleting an ingredient of the drug product
- B. Deleting a drug substance
- C. Introducing a new analytical method
- D. Strengthening a precaution to the product labeling

Correct Answer: D

QUESTION 5

Which of the following is NOT required to be included in a marketing application?

- A. Final printed label
- B. Quality, safety, and efficacy Information
- C. Administrative forms
- D. Evidence of fee payment

Correct Answer: D

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