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QUESTION 1

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 2

A global company is developing a sophisticated implantable medical device that is coated with antibiotics and biologics to enhance its efficacy. The product is marketed in Country X. where it is regulated as a medical device. The same product, without theantibiotics and biologics, is marketed as a medical device in Country Y. The company is proposing to start marketing the coated device in Country Y. Which regulatory approach should the company propose?

A. Submit the product for review as a pharmaceutical product in Country Y.

B. Submit the product as a medical device in Country Y as the product is already marketed in Country X as a medical device.

C. Apply for review of the additional part of the product as a pharmaceutical product in Country

D. Examine decisions made about similar products in Country Y to propose the classification ofthe product.

Correct Answer: CD

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

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

Correct Answer: B

QUESTION 5

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?

A. Local reimbursement requirements

B. Service operation procedures

C. Training program for sales people

D. Written procedure for product traceability

Correct Answer: C