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QUESTION 1

When applying for marketing approval of a drug for a rare disease, which requirement can be waived?

A. Pre-clinical studies

B. Phase I clinical trials

C. Phase I and II clinical trials

D. Phase III clinical trials

Correct Answer: D

QUESTION 2

During the review of a design dossier, the reviewer asks why the company has only carried out a top-down risk approach. The reviewer is referring to which of the following?

A. ISO 14971 risk analysis

B. Failure mode and effect analysis

C. Fault tree analysis

D. Hazard and operability study

Correct Answer: A

QUESTION 3

Company X acquires Company Y. Both companies produce pharmaceuticals distributed globally. A regulatory authority requires that all labeling for Company Y\\'s products be converted to Company X within three months. The regulatory affairs professional at Company X concludes that it is not feasible to meet this request within the time frame.

Which is the FIRST step that the regulatory affairs professional at Company X should take to address the situation?

A. Develop a plan of action with tasks, timelines, and responsibilities and request an extension period from the regulatory authority.

B. Request additional resources from senior management in order to complete the labeling conversion within the time frame given by the regulatory authority.

C. Submit as many labelingconversion applications as possible within the time frame and request an extension for the remaining ones.

D. Convene an urgent meeting with internal stakeholders to inform them of the regulatory authority requirement and assign responsibilities.

Correct Answer: A

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

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