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QUESTION 1

Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?

A. Before the enactment of the regulation, through the industry representative

B. Before the enactment of the regulation, through formal comments gathering process

C. After the enactment of the regulation, through the industry representative

D. After the enactment of the regulation, through a product-specific meeting

Correct Answer: B

QUESTION 2

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 3

The API used for an approved drug product conforms to international monograph specifications and local pharmacopeia; however, the international monograph specifications of the API will be changing soon. Which is the most appropriate action for the regulatory affairs professional to take FIRST?

A. Transfer the notice of the upcoming international monograph change to QA for further processing.

B. Prepare the international monograph change submission first and then prepare the local change when required.

C. Confirm that the international monograph change is not related to local pharmacopeia.

D. Analyze the impact of the international monograph change on the local pharmacopeia.

Correct Answer: AB

QUESTION 4

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors

comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

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