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QUESTION 1

In the process of obtaining a product approval, a regulatory affairs professional discovers that the product does not meet one of the specific technical requirements of the regulation. However, competitors with substantially similar products have claimed compliance with the requirement and received approval. Which action should the regulatory affairs professional take FIRST?

A. Discuss with the regulatory apriority and attempt to reach an acceptable solution.

B. Inform the internal departments to redesign the product to comply with this requirement.

C. Inform the regulatory authority that such a requirement is not applicable to the product.

D. Notify senior management that the product cannot be registered.

Correct Answer: A

QUESTION 2

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

QUESTION 3

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?

A. Specification

B. Formulation

C. Property

D. Justification

Correct Answer: D

QUESTION 4

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

QUESTION 5

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?

A. Allow doctors to use the product for the off-label indication.

B. Communicate with the sales department to stop using the promotional materials.

C. Contact the marketing department to recall the product.

D. Request that doctors stop using the product for the off-label indication.

Correct Answer: B