RAC-GS Q&As

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QUESTION 1

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 2

A company is currently marketing an implantable orthopedic medical device. The RandD department is planning to change the material used for the implant. The RandD department states that the change does not impact the safety and effectiveness of the product.

What action should the regulatory affairs professional take FIRST?

A. No action is needed in this situation.

B. Prepare regulatory submissions that detail the medical device\\'s change in materials.

C. Review the content of change and supporting data for the equivalency with the current material.

D. Write a memo to file since the change does not impact product safety and effectiveness.

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

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 5

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