RAC-GS Q&As

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QUESTION 1

During new drug development, a new impurity in the drug substance is detected at a level of 0.12%. The intended maximum daily dose Is less than 2 g/day, and the drug Is known generally not to be toxic.

What should be done in response to identifying the impurity?

A. Perform either an identification study or a non-clinical qualification study.

B. Perform both identification and non-clinical qualification studies concurrently.

C. Perform an identification study, wait until the result is available, and then consider performing a nonclinical qualification study.

D. Perform a non-clinical qualification study, wait until the result is available, and then consider performing an identification study.

Correct Answer: C

QUESTION 2

Which of the following is NOT required to be included in a marketing application?

A. Final printed label

B. Quality, safety, and efficacy Information

C. Administrative forms

D. Evidence of fee payment

Correct Answer: D

QUESTION 3

A superiority advertising claim for a product versus its competitor\\'s product can only be made under which of the following circumstances?

A. In vitro studies show the product to be superior.

B. Government survey data indicate the product is superior.

C. Results of a three-year, post-market patient survey indicate the product is superior.

D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Correct Answer: D

QUESTION 4

In addition to protection, what parameters MUST be considered when selecting the primary package (or a product?

A. Volume and material

B. Compatibility and safety

C. Safety and efficacy

D. Efficacy and material

Correct Answer: B

QUESTION 5

A company is developing a device-drug combination product. Which of the following should be evaluated FIRST in order to determine the applicable guidance documents?

A. Approved indications of the drug

B. Determination of primary mode of action

C. Determination of product design deliverables

D. Guidance documents for the device

Correct Answer: C