RAC-GS$^{Q\&As}$

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?

A. Proposed dose and volume of administration

B. Biological activity with species and/or tissue specificity

C. Immunochemical and functional tests

D. Proposed product route and frequency of administration

Correct Answer: B

QUESTION 2

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

QUESTION 3

A regulatory affairs professional has submitted a package for regulatory review. According to the regulation, the regulatory authority will need to respond within 90 days of submission. If there is no response after the deadline, what is the BEST approach?

A. Contact the regulatory authority, ask for clarification about the delay, and provide answers to any outstanding questions.

B. Contact the regulatory authority, ask for clarification about the delay, and demand a decision be made regarding the submission.

C. Contact the local political representative and ask for intervention with the regulatory authority to obtain a decision regarding the submission.

D. Contact the company legal representative in order to begin legal proceedings to enforce the regulatory authority\\'s response time.

Correct Answer: A

QUESTION 4

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

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