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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

QUESTION 2

According to ICH, which of the following components of study information is NOT required in a clinical study report?

A. Randomization scheme and codes

B. Protocol and protocol amendments

C. ListoflECsorlRBs

D. Detailed CVofall investigators

Correct Answer: D

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

Which of the following claims would classify an apple as a drug?

A. "It will make you look younger."

B. "It will satisfy hunger."

C. "It will whiten teeth."

D. "It will prevent colds."

Correct Answer: D

QUESTION 5

A company receives multiple complaints regarding the text included on a recently launched product\\'s label. What action should the regulatory affairs professional take FIRST?

A. Recommend an immediate product recall.

B. Compare the approved text with the product label

C. Notify the regulatory authority.

D. Inform the production team.

Correct Answer: B