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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

A company establishes a new medical device indication for its consumer disposable products. The regulatory affairs professional is asked to give a 30-minute training session on these products to sales representatives. Which of the following subjects is the MOST important to discuss?

A. Labeling

B. Regulatory application summary

C. Risk management process

D. Safety-related reporting

Correct Answer: A

QUESTION 2

Which of the following BEST describes the purpose of the ICH?

A. To provide scientific evaluation of applications for international marketing authorization forsafe, effective, and high-quality medicines for the ICH regions

B. To protect and promote public health through the evaluation and supervision of safe,effective, and high-quality medicines for the ICH regions

C. To lobby for improved industry standards for the development of new safe, effective, andhigh-quality medicines for the ICH regions

D. To discuss and establish common guidelines for safe, effective, and high-quality medicines for the ICH regions

Correct Answer: D

QUESTION 3

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

QUESTION 4

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 5

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