RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

During routine surveillance, a regulatory authority sent a company the following communication: "Hepatotoxicity and suicidal behavior were identified as potential safety issues for the company\\'s product. The regulatory authority is evaluating these issues to determine the need for any regulatory action." Which action would be the most appropriate FIRST step for the company to take?

A. Contact the regulatory authority to argue that its conclusions are wrong.

B. Contact the regulatory authority to discuss its findings.

C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.

D. Wait for the regulatory authority\\'s final publication on its findings.

Correct Answer: B

QUESTION 3

The manufacturer of an API was changed from Company X to Company Y during the late stage of a new drug development. Despite differences in the manufacturing processes of the companies, both APIs meet the current specifications. Which is the MOST appropriate information to include in the final submission documents?

A. The process information and analytical result of Company X API

B. The process information and analytical result of Company Y API

C. The process information and the comparative analytical result of APIs from both companies

D. Information deemed appropriate by the regulatory authority

Correct Answer: C

QUESTION 4

A regulatory authority announces an inspection of a regulatory affairs professional\\'s facility during a holiday season when most of the staff Is not available. What is the MOST practical approach to this dilemma?

A. Negotiate with colleagues and the authority to find a better time.

B. Insist that key personnel be available for the inspection.

C. Inform the authority that the time is not suitable and request a new time

D. Arrange for an inspection without all intended personnel.

Correct Answer: A

QUESTION 5

Which of the following statements regarding the off-label use of drugs is CORRECT?

A. Although the regulatory authority reviews and approves drugs for specific indications, theapproval does not limit the use of those drugs in clinical practice.

B. The regulatory authority does not restrict physician prescribing for off-label indications orregulate the manufacturer\\'s promotion for such use.

C. Sponsors are allowed to distribute publications about unapproved uses of approved drugs and devices as long as the marketing application is under review by the regulatory authority.

D. The peer-reviewed literature can ensure high-quality off-label promotion of medications, thereby increasing accessto much needed drugs and devices.

Correct Answer: A