RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

According to the ICH guideline on GMP for API,to which of the following is the MOST stringent requirement applied?

A. Physical processing and packaging

B. Isolation and purification

C. Production of Intermediate(s)

D. Introduction of the API starting material

Correct Answer: A

QUESTION 2

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

QUESTION 3

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

QUESTION 4

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for

the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 5

Which of the following statements regarding export regulations for an approved product is CORRECT?

A. The product must not be in accord with the specifications of the foreign purchaser.

B. The product must not be in conflict with the laws of the country to which it is intended forexport.

C. The product must not be labeled on the outside of the shipping package that it is intendedfor export.

D. The product must not be sold or offered for sale in domestic commerce.

Correct Answer: B