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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

A clinical study of a drug is completed to support a marketing approval application. According to ICH,how long should a sponsor retain the clinical study essential documents?

A. For at least two years after the last approval of an application in an ICH region

B. Fora minimum of 10 years after completion of the clinical study

C. Three years after the last clinical study site was supplied with investigational drugs

D. Until the product has been discontinued from marketing in all ICH regions

Correct Answer: AD

QUESTION 3

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 4

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

A. Intellectual properly

B. Clinical trial data

C. Safety issues

D. Marketing materials

Correct Answer: C

QUESTION 5

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