RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

A. Stop product manufacturing.

B. Establish validation procedures.

C. Assess the impact of the changes.

D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 3

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

QUESTION 4

A company is developing a new line of products in an area that is new to the company. What is the BEST approach?

A. Ask the trade association representative to provide an overview of the new product area to the marketing team.

B. Obtain competitor research and provide the information to the management team.

C. Obtain regulatory documents and history and provide the information to RandD.

D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

QUESTION 5

According to ICH, what is the MAXIMUM amount of timein calendar days that anorganizationhas from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?

A. 3

B. 5

C. 10

D. 15

Correct Answer: BCD