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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

According to ICH, which of the following components of study information is NOT required in a clinical study report?

A. Randomization scheme and codes

B. Protocol and protocol amendments

C. ListoflECsorlRBs

D. Detailed CVofall investigators

Correct Answer: D

QUESTION 3

A company is considering the development of a medical device similar to those already available. Which of the following should be evaluated FIRST when developing a clinical evaluation document?

A. Adverse event reports

B. Clinical experience

C. Clinical investigations

D. Literature search

Correct Answer: C

QUESTION 4

Which of the following is the BEST approach for mitigating potential regulatory compliance issues at your company?

A. Document any failure to follow regulatory compliance processes in employee performancereviews.

B. Develop documented procedures for regulatory compliance processes and train personnel.

C. Train all new employees on regulatory compliance processes and assign a mentor to them.

D. Train employees on all regulatory compliance processes using state-of-the-art systems.

Correct Answer: B

QUESTION 5

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC