RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

Which of the following situations does NOT require rapid communication to regulatory authorities?

A. A clinically important increase in the rate of occurrence of an "expected." but serious ADR

B. A lack of efficacy with a medicinal product used in treating a life-threatening disease

C. A major safety finding from a newly completed animal carcinogenicity study

D. A statistically significant increase in the number of deaths in an animal dose finding study

Correct Answer: AD

QUESTION 2

A regulatory affairs professional has submitted a package for regulatory review. According to the regulation, the regulatory authority will need to respond within 90 days of submission. If there is no response after the deadline, what is the BEST approach?

A. Contact the regulatory authority, ask for clarification about the delay, and provide answers to any outstanding questions.

B. Contact the regulatory authority, ask for clarification about the delay, and demand a decision be made regarding the submission.

C. Contact the local political representative and ask for intervention with the regulatory authority to obtain a decision regarding the submission.

D. Contact the company legal representative in order to begin legal proceedings to enforce the regulatory authority\\'s response time.

Correct Answer: A

QUESTION 3

During several monitoring visits, a clinical trial monitor identifies serious and repeated noncompliance on the part of the PI. What action should the sponsor take?

A. Increase the frequency of monitoring visits.

B. Inform the institution that granted a medical license to the Pi.

C. Send a letter of complaint to the Ethics Committee that approved the site.

D. Terminate the PI and inform the regulatory authorities.

Correct Answer: D

QUESTION 4

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

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