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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

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 3

The requirements for document control are located in which of the following documents?

A. ICH guidelines

B. IEC 60601

C. ISO 13485

D. WHO guidelines

Correct Answer: C

QUESTION 4

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?

A. Fishbone analysis

B. Failure modes, effects, and criticality analysis

C. Fault tree analysis

D. Quality by design analysis

Correct Answer: B

QUESTION 5

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