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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, the approval does not limit the use of those drugs in clinical practice.
- B. The regulatory authority does not restrict physician prescribing for off-label indications or regulate 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 access to much needed drugs and devices.

Correct Answer: A

QUESTION 2

After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?

- A. Resubmit the entire package.
- B. Inform upper management immediately.
- C. Contact the legal department and ask them how to proceed.
- D. Verify the procedure in the regulation for the corrections.

Correct Answer: D

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



In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

- A. Product stability
- B. Product registration
- C. Product formulation
- D. Product requirements

Correct Answer: A

QUESTION 5

As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?

- A. Site license
- B. Product license
- C. Import license
- D. Export license

Correct Answer: A

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