



# RAC-GS<sup>Q&As</sup>

Regulatory Affairs Certification (RAC) Global Scope

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### QUESTION 1

Which of the following statements regarding export regulations for an approved product is CORRECT?

- A. The product must not be in accord with the specifications of the foreign purchaser.
- B. The product must not be in conflict with the laws of the country to which it is intended for export.
- C. The product must not be labeled on the outside of the shipping package that it is intended for export.
- D. The product must not be sold or offered for sale in domestic commerce.

Correct Answer: B

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### QUESTION 2

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP is MOST important to consider?

- A. Expiration date
- B. Relevance to regulations
- C. Revision history
- D. Scope and level of detail

Correct Answer: B

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### QUESTION 3

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2,000 patients. Which long-term ICH data requirement has NOT been met?

- A. 100 patients for 12 months
- B. 200 patients for nine months
- C. 500 patients for three months
- D. 3,000 total patient exposures

Correct Answer: A

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### QUESTION 4

You discover that your company's top selling product in the last two years has been used off-label. The off-label use is estimated to be about 70%, and it has been consistent since the product was first released to the market. Which of the



following is MOST appropriate?

- A. Discuss with regulatory authorities to investigate how to have the off-label indication approved.
- B. No action is required since it is an off-label use.
- C. Advise the senior management to send a "Dear Dr." letter.
- D. File a report to regulatory authorities and advise the marketing department to prevent future off-label use.

Correct Answer: A

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#### QUESTION 5

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

- A. "Product X is a guaranteed cure for arthritis."
- B. "Product X is effective for the treatment of arthritis."
- C. "Product X is safe for arthritis and without side effects."
- D. "Product X is effective in all patients with arthritis."

Correct Answer: B

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