

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

Regulatory Affairs Certification (RAC) Global Scope

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**QUESTION 1**

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?

- A. Allow doctors to use the product for the off-label indication.
- B. Communicate with the sales department to stop using the promotional materials.
- C. Contact the marketing department to recall the product.
- D. Request that doctors stop using the product for the off-label indication.

Correct Answer: B

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**QUESTION 2**

According to WHO, what are the temperature and humidity conditions for a Zone IVb long-term stability study?

- A. 25: C and 60% RH
- B. 30°C and 35% RH
- C. 30°C and 65% RH
- D. 30: C and 75% RH

Correct Answer: D

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**QUESTION 3**

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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**QUESTION 4**

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

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#### QUESTION 5

The regulatory authority in Country X issued a request for a mandatory product recall in Country X due to serious injuries to patients. This product also is distributed in Country Y.

What should the regulatory affairs professional of the product's manufacturer FIRST do in Country Y?

- A. Draft a formal letter to customers in Country Y about this recall.
- B. Initiate a mandatory recall of the product in Country Y.
- C. Review all distribution records and complaints reported in Country Y.
- D. Prepare the legal team in Country Y for possible litigations.

Correct Answer: C

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