



RAC-GS^{Q&As}

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

The regulatory authority contacts the regulatory affairs professional regarding a complaint about a drug produced by the company. A consumer reported to the regulatory authority that the tablets have a slightly different color and break easily.

Which of the following actions should the regulatory affairs professional take?

- A. Ask that the regulatory authority provide the batch number printed on the packaging of the affected product.
- B. Ask that the regulatory authority provide the actual product subject to the complaint.
- C. Respond to the regulatory authority that the product subject to the complaint is most likely a counterfeit product.
- D. Respond to the regulatory authority that the company will provide copies of the relevant QC records for batch release.

Correct Answer: A

QUESTION 2

Which of the following is NOT required to be included in a marketing application?

- A. Final printed label
- B. Quality, safety, and efficacy information
- C. Administrative forms
- D. Evidence of fee payment

Correct Answer: D

QUESTION 3

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

- A. Safety and failure risk
- B. Safety and effectiveness
- C. Quality and failure risk
- D. Quality and effectiveness

Correct Answer: B

QUESTION 4



Which of the following BEST describes the purpose of the ICH?

- A. To provide scientific evaluation of applications for international marketing authorization for safe, effective, and high-quality medicines for the ICH regions
- B. To protect and promote public health through the evaluation and supervision of safe, effective, and high-quality medicines for the ICH regions
- C. To lobby for improved industry standards for the development of new safe, effective, and high-quality medicines for the ICH regions
- D. To discuss and establish common guidelines for safe, effective, and high-quality medicines for the ICH regions

Correct Answer: D

QUESTION 5

In addition to protection, what parameters MUST be considered when selecting the primary package (or a product)?

- A. Volume and material
- B. Compatibility and safety
- C. Safety and efficacy
- D. Efficacy and material

Correct Answer: B

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