RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

Pass RAPS RAC-GS Exam with 100% Guarantee

Free Download Real Questions & Answers **PDF** and **VCE** file from:

https://www.pass2lead.com/rac-gs.html

100% Passing Guarantee
100% Money Back Assurance

Following Questions and Answers are all new published by RAPS Official Exam Center

- **Instant Download** After Purchase
- **100% Money Back** Guarantee
- **365 Days** Free Update
- **800,000+** Satisfied Customers

QUESTION 1

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

A. A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation

B. A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use

C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product

D. A brief summary of relevant physical, chemical, and pharmaceutical properties: instructions for storage and handling of the dosage form: and a description of the formulation

Correct Answer: D

QUESTION 2

A company receives multiple complaints regarding the text included on a recently launched product\\'s label. What action should the regulatory affairs professional take FIRST?

A. Recommend an immediate product recall.

B. Compare the approved text with the product label

C. Notify the regulatory authority.

D. Inform the production team.

Correct Answer: B

QUESTION 3

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?

A. Specification

B. Formulation

C. Property

D. Justification

Correct Answer: D

QUESTION 4

The API used for an approved drug product conforms to international monograph specifications and local pharmacopeia; however, the international monograph specifications of the API will be changing soon.

Which is the most appropriate action for the regulatory affairs professional to take FIRST?

A. Transfer the notice of the upcoming international monograph change to QA for further processing.

B. Prepare the international monograph change submission first and then prepare the local change when required.

C. Confirm that the international monograph change is not related to local pharmacopeia.

D. Analyze the impact of the international monograph change on the local pharmacopeia.

Correct Answer: AB

QUESTION 5

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?

A. Deleting an ingredient of the drug product

B. Deleting a drug substance

C. Introducing a new analytical method

D. Strengthening a precaution to the product labeling

Correct Answer: D

RAC-GS Practice Test RAC-GS Study Guide RAC-GS Braindumps