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

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 3

Who has the PRIMARY responsibility for recall of products with quality defects?

A. Consumer

B. Distributor

C. Manufacturer

D. Regulatory authority

Correct Answer: C

QUESTION 4

A company\\'s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product.

To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 5

According to ISO 14971,what is the FIRST step when developing a risk management plan for a medical device?

A. Risk estimation

B. Risk analysis

C. Risk control

D. Risk management

Correct Answer: B