RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 3

In the process of obtaining a product approval, a regulatory affairs professional discovers that the product does not meet one of the specific technical requirements of the regulation. However, competitors with substantially similar products have claimed compliance with the requirement and received approval. Which action should the regulatory affairs professional take FIRST?

A. Discuss with the regulatory apriority and attempt to reach an acceptable solution.

B. Inform the internal departments to redesign the product to comply with this requirement.

C. Inform the regulatory authority that such a requirement is not applicable to the product.

D. Notify senior management that the product cannot be registered.

Correct Answer: A

QUESTION 4

During an audit of a contract manufacturing facility by a potential client, the auditor requested to be left alone in the records room. The records room contains information on all products produced by the contract manufacturer.

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

A. Allow the auditor access to the room and records due to the current audit.

B. Allow the auditor accompanied access to the room to retrieve the records.

C. Deny the auditor access to the room and retrieve only the requested records.

D. Deny the auditor access to the room and records due to confidentiality concerns.

Correct Answer: B

QUESTION 5

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