RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 3

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 4

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors

comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

QUESTION 5

Company X has a patent for an anti-inflammatory drug that will expire in one year. In order to minimize the effect of the patent expiration, which is the BEST action for the company to take?

A. Conduct a Phase III study for a new unrelated indication of the drug.

B. Develop a generic version of the drug.

C. Develop a better brand-name drug in the same class.

D. Explore litigation strategy for patent infringements on the drug.

Correct Answer: B