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 of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?

A. Proposed dose and volume of administration

B. Biological activity with species and/or tissue specificity

C. Immunochemical and functional tests

D. Proposed product route and frequency of administration

Correct Answer: B

QUESTION 3

Why is it necessary to run supplemental safety pharmacology studies?

A. To substitute the utilization of GLP

B. To comply with regulatory authority requirements related to clinical studies

C. To evaluate potential adverse pharmacodynamics effects not addressed by the core battery

D. To provide adverse reaction reports and the results of the statistical data to the regulatory authority

Correct Answer: C

QUESTION 4

A company is developing a novel drug to combat AIDS. The preliminary results are very promising and include instances of complete remission. The company has been granted patents in multiple countries for the drug. The regulatory affairs professional is asked to prepare a brief report concerning potential problems for marketing of the

product worldwide. Which of the following is the MOST important consideration to discuss?

A. Doha Declaration in the TRIPS Agreement

B. The stability of the drug in all zone conditions

C. The time frame in which the patent will expire

D. International import and export regulations

Correct Answer: B

QUESTION 5

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

A. To provide scientific evaluation of applications for international marketing authorization forsafe, 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, andhigh-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