RAC-US Q&As

Regulatory Affairs Certification (RAC) US

Pass RAPS RAC-US Exam with 100% Guarantee

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

https://www.leads4pass.com/rac-us.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

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 2

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 3

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

QUESTION 4

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented

without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

A. Stop product manufacturing.

B. Establish validation procedures.

C. Assess the impact of the changes.

D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 5

Which of the following statements regarding export regulations for an approved product is CORRECT?

A. The product must not be in accord with the specifications of the foreign purchaser.

B. The product must not be in conflict with the laws of the country to which it is intended forexport.

C. The product must not be labeled on the outside of the shipping package that it is intendedfor export.

D. The product must not be sold or offered for sale in domestic commerce.

Correct Answer: B