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.pass4itsure.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

At the last internal audit, a regulatory affairs professional identified a need for a corrective action for the manufacturing process. Which of the following stakeholders should be notified FIRST?

A. Quality improvement

B. Quality assurance

C. Clinical affairs

D. Regulatory agency

Correct Answer: B

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

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

A. Intellectual properly

B. Clinical trial data

C. Safety issues

D. Marketing materials

Correct Answer: C

QUESTION 4

Company X encounters challenges in the global life cycle management of its medical devices. Which of the following Is

MOST appropriate for improving product life cycle management?

A. Utilize the STED template to complete global requirements.

B. Initiate a global submission process after all submission data are finalized.

C. Identify countries where special requirements exist during the product development phase.

D. Plan regulatory approval update meetings with senior management and stakeholders.

Correct Answer: C

QUESTION 5

During routine surveillance, a regulatory authority sent a company the following communication: "Hepatotoxicity and suicidal behavior were identified as potential safety issues for the company\\'s product. The regulatory authority is evaluating these issues to determine the need for any regulatory action." Which action would be the most appropriate FIRST step for the company to take?

A. Contact the regulatory authority to argue that its conclusions are wrong.

B. Contact the regulatory authority to discuss its findings.

C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.

D. Wait for the regulatory authority\\'s final publication on its findings.

Correct Answer: B

RAC-US VCE Dumps RAC-US Practice Test RAC-US Study Guide