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.passapply.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

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 2

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

QUESTION 3

A clinical study of a drug is completed to support a marketing approval application. According to ICH,how long should a sponsor retain the clinical study essential documents?

A. For at least two years after the last approval of an application in an ICH region

B. Fora minimum of 10 years after completion of the clinical study

C. Three years after the last clinical study site was supplied with investigational drugs

D. Until the product has been discontinued from marketing in all ICH regions

Correct Answer: AD

QUESTION 4

Which of the following is the PRIMARY purpose of an audit report?

A. To carry out a complete review of product applications

B. To define how to prepare new product submissions

C. Todocument compliance history

D. To train sales representatives

Correct Answer: C

QUESTION 5

A global company has obtained a patent in a specific country for a newly marketed product. What would be the BEST advice In order to protect the patent in other countries?

A. Use the Madrid system.

B. Use the community patent system.

C. File patents of interest in target countries.

D. File design patents in target countries.

Correct Answer: C