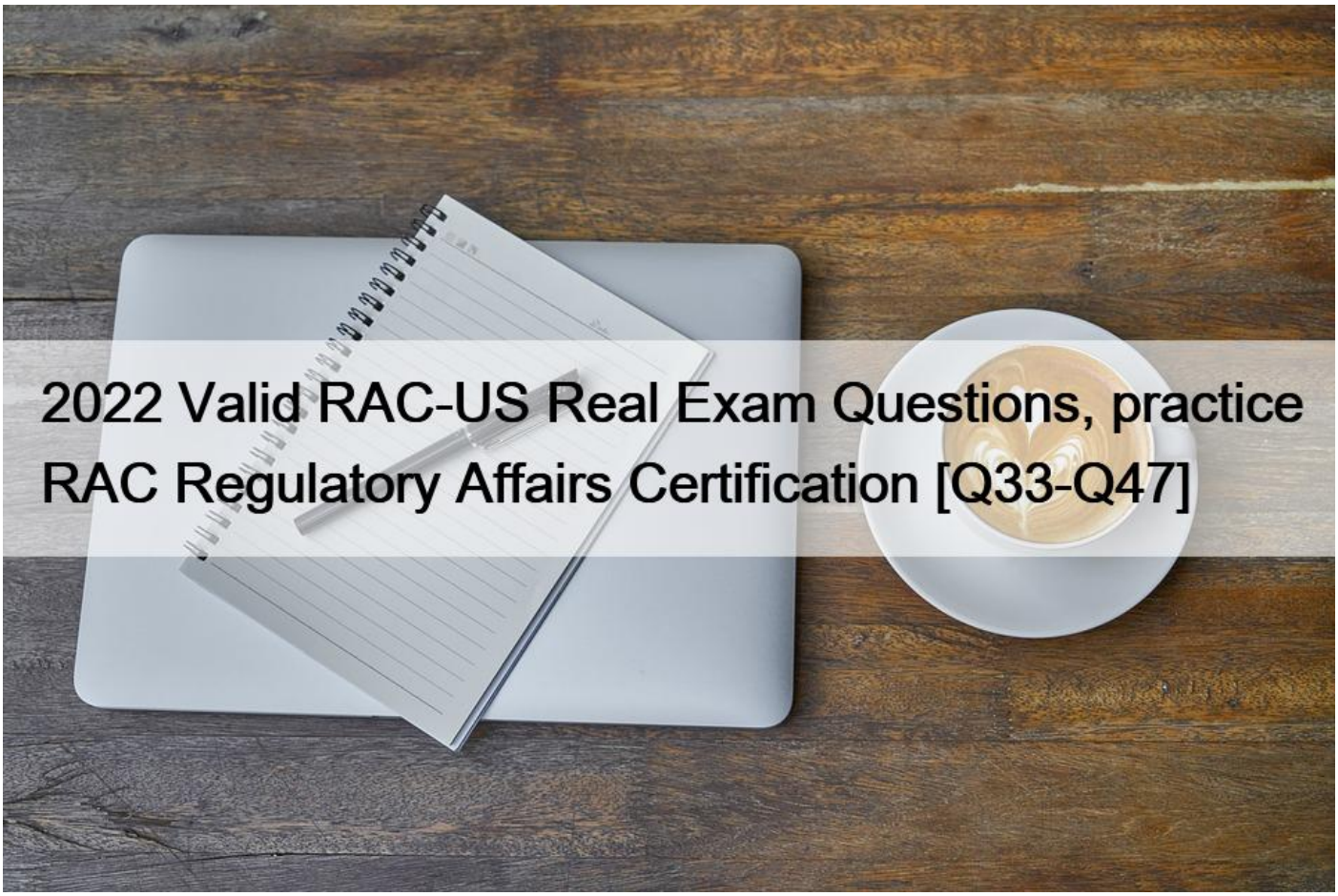
2022 Valid RAC-US Real Exam Questions, practice RAC Regulatory Affairs Certification [Q33-Q47



2022 Valid RAC-US Real Exam Questions, practice RAC Regulatory Affairs Certification Latest Success Metrics For Actual RAC-US Exam (Updated 100 Questions) NEW QUESTION 33

According to WHO, what are the temperature and humidity conditions for a Zone IVb long- term stability study?
* 25: C and 60% RH
* 30 C and 35% RH
* 30c C and 65% RH
* 30: C and 75% RH

NEW QUESTION 34

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?
* Stop product manufacturing.
* Establish validation procedures.
* Assess the impact of the changes.
* Review the stability data for the changes.

NEW QUESTION 35

During new drug development, a new impurity in the drug substance is detected at a level of 0.12%. The intended maximum daily dose Is less than 2 g/day, and the drug Is known generally not to be toxic.

What should be done in response to identifying the impurity?
* Perform either an identification study or a non-clinical qualification study.
* Perform both identification and non-clinical qualification studies concurrently.
* Perform an identification study, wait until the result is available, and then consider performing a non-clinical qualification study.
* Perform a non-clinical qualification study, wait until the result is available, and then consider performing an identification study.

NEW QUESTION 36

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?
* Utilize the STED template to complete global requirements.
* Initiate a global submission process after all submission data are finalized.
* Identify countries where special requirements exist during the product development phase.
* Plan regulatory approval update meetings with senior management and stakeholders.

NEW QUESTION 37

What is the LAST stage in the development of a quality risk management process for a medical device?
* Risk analysis
* Risk reduction
* Risk acceptance
* Risk evaluation

NEW QUESTION 38

A company is developing a new medical device using innovative technology. Which of the following is MOST critical in working with regulatory authorities?
* Documented agreement
* Frequent communication
* Early collaboration
* Follow-up meeting after submission

NEW QUESTION 39

A materials supplier informs a company that it intends to stop supplying a material critical to the manufacture of the company’s products. What action should the company take FIRST?
* Review the company’s existing Quality Management System
* Reformulate the products with a replacement material.
* Qualify another supplier and execute a supplier agreement.
* Complete a gap analysis to identify options.

NEW QUESTION 40

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

* To carry out a complete review of product applications
* To define how to prepare new product submissions
* To document compliance history
* To train sales representatives

NEW QUESTION 41

Which of the following BEST describes the content of the “Physical, Chemical, and

Pharmaceutical Properties and Formulation” section of an IB?
* A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation
* A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use
* A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product
* A brief summary of relevant physical, chemical, and pharmaceutical properties:

instructions for storage and handling of the dosage form: and a description of the formulation

NEW QUESTION 42

Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?
* Proposed dose and volume of administration
* Biological activity with species and/or tissue specificity
* Immunochemical and functional tests
* Proposed product route and frequency of administration

NEW QUESTION 43

Which of the following double-blind clinical trial designs would be MOST appropriate for a

Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?
* Active-controlled
* Cross-over
* Dose-ranging
* Placebo-controlled

NEW QUESTION 44

After numerous failed attempts to decrease an identified risk in a medical device to an acceptable level, the medical device continues to have unacceptable risks. However, the development team wants to continue development. Which is the BEST recommendation to make in this situation?
* Add a warning in the IFU.
* Discontinue the project.
* Perform another risk-benefit analysis.
* Redesign the device.

NEW QUESTION 45

Which of the following is MOST appropriate for the purpose of lot release of biologics?
* Inventory control
* Safety assurance
* Efficacy confirmation
* Quality verification

NEW QUESTION 46

As a member of the product launch review committee, a regulatory affairs professional discovers a major issue with the labeling of a product prior to production. In addition to informing the committee, which is the BEST approach to address the issue?
* Inform the regulatory authorities.
* Delay the start of product production.
* Correct the label text.
* Abort the product launch.

NEW QUESTION 47

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?
* Product stability
* Product registration
* Product formulation
* Product requirements

How to get prepared for the RAPS RAC-US Certification Exam?

There are many ways to prepare for the RAPS RAC-US Certification Exam. The candidate must make sure that he/she prepares well for the exam. Here are some of the ways to prepare for the RAPS RAC-US Certification Exam:

Take practice exams: The candidate must practice a lot and take practice exams on a regular basis. Candidates must ensure that they take practice exams regularly and prepare for the actual exam. Racadm exams help you to get familiar with the exam format and also help in building confidence.Read in a disciplined way: It is important for the candidate to read well and in a disciplined manner. The candidate must give time for studying each day and practice frequently to learn the concepts and techniques. Identification of the weak and strong areas will help the candidate to prepare well for the exam.Understand the topics well: It is important for the candidates to learn well the concepts related to the topics of the RAC-US Certification. The candidate must learn the concept thoroughly by referring to the course outline provided by RAPS.

You can also consider resources like guides, paid and free courses, books about Regulatory Affairs, concerning video tutorials for the prep of the RAPS RAC-US Certification Exam. But the most appropriate source for the preparation of the RAC-US Exam is the practice exams of the Actualtests4sure. These practice exams will provide you with an idea of what to expect from the RAC-US Certification exam. The **RAC-US exam dumps** will help you to determine your weaknesses and strengths as well as how much time to spend on each topic in a well-organized way. The practice exams will also help the candidates to understand how to approach questions in the exam in a smart way.

How to get ready for the RAPS RAC-US Certification Exam **The best prep guide for the RAPS RAC-US Certification Exam Read this if you don't have time to study the whole syllabus.**

The RAC certification exam is designed to test candidates on their knowledge and skills of drug regulation and medical device regulation. The exam covers the full range of topics from basic principles to advanced concepts in each of the two areas. Candidates are tested on the content of the Drug Regulation (RAC-DR) and Medical Device Regulation (RAC-MDR) domains.
In this article, we provide a brief introduction to the RAC exams and some details on the specific content of each exam. Here, we will also discuss the multiple resources which we can use for the preparation of the RAC-US Certification Exam, including **RAC-US exam dumps**. We also give an overview of the information about the registration process for the exams, the cost, the format of the exam, etc. So, without further ado, let's get started.

A quick overview of the RAPS RAC-US Certification Exam:

Regulatory Affairs Certification US is simply called RAC-US Certification Exam. It is a rigorous, technical exam consisting of questions across two disciplines - Pharmaceutical and Medical Devices. The exam is administered through the RAPS website which also serves as a platform for the RAC certification program. Candidates need to pass both the RAC-Drugs exam and RAC-Devices exam in order to achieve RAC-US Certification. Clinical qualification is not required for this exam. **RAC-US exam dumps** will help you to get prepared for the exam, with ease.

Genuine RAC-US Exam Dumps Free Demo Valid QA's: https://www.actualtests4sure.com/RAC-US-test-questions.html]