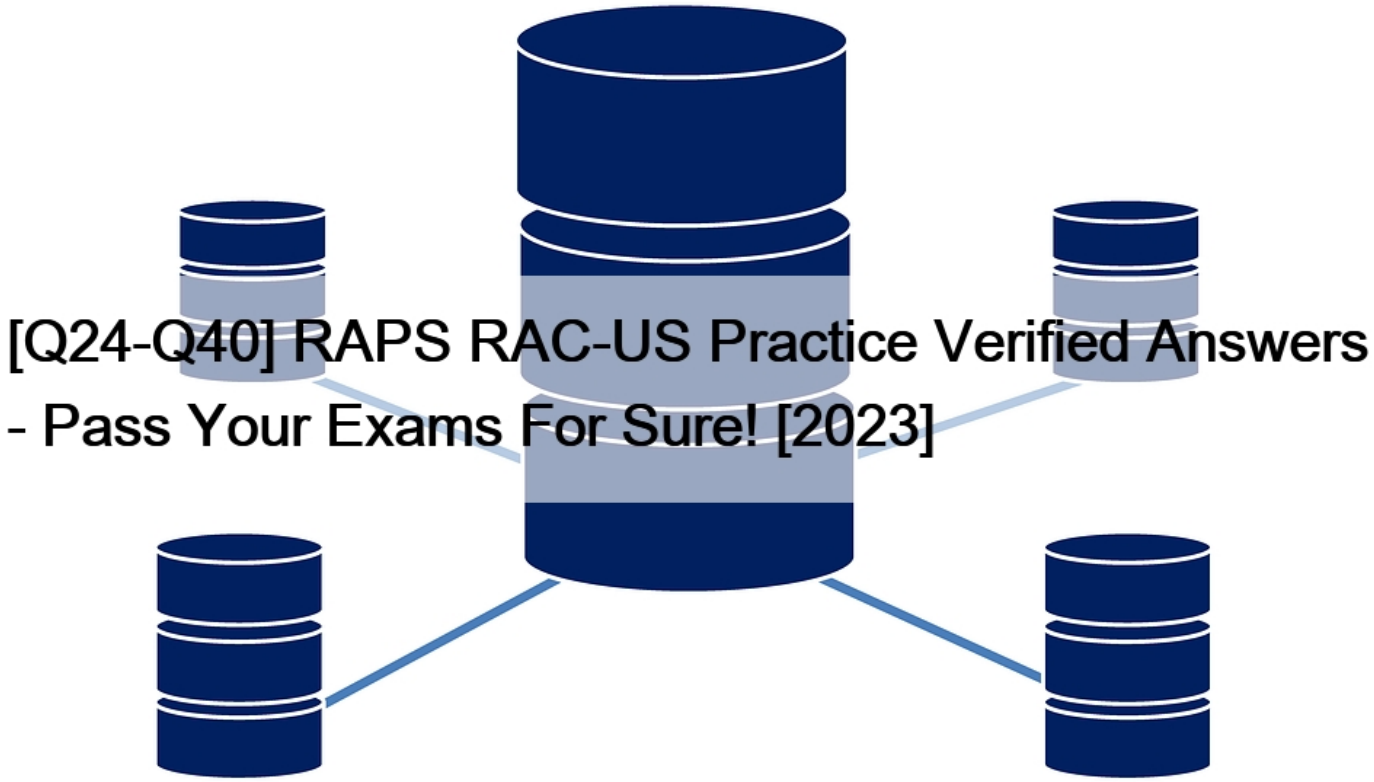
[Q24-Q40 RAPS RAC-US Practice Verified Answers - Pass Your Exams For Sure! [2023



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Valid Way To Pass RAC Regulatory Affairs Certification's RAC-US Exam

Here is the importance of the RAPS RAC-US Certification Exam:

Nowadays, the healthcare industry has undergone several changes. Regulatory agencies have been faced with a number of challenges which include an increase in the number of regulations, the rising cost of regulations, and the need to be more efficient and proactive in order to meet their goals. The RAC-US Certification can help healthcare regulatory professionals like you to prove that you are knowledgeable and competent in this rapidly changing and challenging environment. It is a great way to showcase your skills and show that you are a leader in the field. A free demo of the **RAC-US exam dumps** can help you to prepare for the real exam. The clinical trial is not required for the RAC-US Certification exam. Medication and medical device manufacturers can apply for registration on their own, the registration process for the RAC-US Exam is very simple and straightforward.

The RAC-US certification exam covers a wide range of regulatory topics, including product development, regulatory submissions, compliance, and post-market surveillance. The exam is divided into two parts, with the first part focusing on the fundamentals of regulatory affairs and the second part covering more advanced topics. The exam is designed to test the candidate's knowledge, skills, and abilities in regulatory affairs and to ensure that they meet the high standards set by the regulatory community.

Q24. Company X has a patent for an anti-inflammatory drug that will expire in one year. In order to minimize the effect of the patent expiration, which is the BEST action for the company to take?
* Conduct a Phase III study for a new unrelated indication of the drug.
* Develop a generic version of the drug.
* Develop a better brand-name drug in the same class.
* Explore litigation strategy for patent infringements on the drug.

Q25. A superiority advertising claim for a product versus its competitor’s product can only be made under which of the following circumstances?
* In vitro studies show the product to be superior.
* Government survey data indicate the product is superior.
* Results of a three-year, post-market patient survey indicate the product is superior.
* Results of adequate, well-controlled comparative clinical trial show the product is superior.

Q26. What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?
* Safety and failure risk
* Safety and effectiveness
* Quality and failure risk
* Quality and effectiveness

Q27. According to the GHTF IVD guidance, which of the following is the CORRECT classification for a blood glucose self-testing kit?
* Class A
* Class B
* Class C
* Class D

Q28. A company is currently marketing an implantable orthopedic medical device. The R&D department is planning to change the material used for the implant. The R&D department states that the change does not impact the safety and effectiveness of the product.

What action should the regulatory affairs professional take FIRST?
* No action is needed in this situation.
* Prepare regulatory submissions that detail the medical device’s change in materials.
* Review the content of change and supporting data for the equivalency with the current material.
* Write a memo to file since the change does not impact product safety and effectiveness.

Q29. What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?
* Ask the vendor to take responsibility.
* Document and perform audits.
* Request an inspection from a regulatory authority.
* Request documentation from the sub-contractor.

Q30. According to the ICH guideline on GMP for API, to which of the following is the MOST stringent requirement applied?
* Physical processing and packaging
* Isolation and purification
* Production of Intermediate(s)

* Introduction of the API starting material

Q31. The manufacturer of an API was changed from Company X to Company Y during the late stage of a new drug development. Despite differences in the manufacturing processes of the companies, both APIs meet the current specifications. Which is the MOST appropriate information to include in the final submission documents?
* The process information and analytical result of Company X API
* The process information and analytical result of Company Y API
* The process information and the comparative analytical result of APIs from both companies
* Information deemed appropriate by the regulatory authority

Q32. Which term does NOT describe the same concept as the others?
* Biosimilars
* Follow-on protein products
* Monoclonal antibody
* Subsequent entry biologics

Q33. A company is developing a new line of products in an area that is new to the company.

What is the BEST approach?
* Ask the trade association representative to provide an overview of the new product area to the marketing team.
* Obtain competitor research and provide the information to the management team.
* Obtain regulatory documents and history and provide the information to R&D.
* Summarize regulatory documents and history and provide the information to the management team.

Q34. Which of the following BEST describes the process of post-marketing surveillance for healthcare products?
* Systematic procedure to review published scientific journals
* Systematic procedure to review experiences with the products in use
* Vigilance procedure to ensure the full traceability of the products
* Vigilance procedure to notify the regulatory authorities about serious incidents

Q35. A regulation change is imminent and may require further non-clinical testing on a product currently in Phase III clinical trials. What is the most appropriate action to take FIRST?
* Obtain a copy of the proposed regulation and analyze the impact.
* Inform the company’s senior management and arrange an emergency meeting
* Consult with the company’s legal department regarding options.
* Arrange for additional testing of the product at the testing facility.

Q36. In addition to protection, what parameters MUST be considered when selecting the primary package (or a product?
* Volume and material
* Compatibility and safety
* Safety and efficacy
* Efficacy and material

Q37. The regulatory authority in Country X issued a request for a mandatory product recall in

Country X due to serious injuries to patients. This product also is distributed in Country Y.

What should the regulatory affairs professional of the product’s manufacturer FIRST do in

Country Y?

* Draft a formal letter to customers in Country Y about this recall.
* Initiate a mandatory recall of the product in Country Y.
* Review alt distribution records and complaints reported in Country Y.
* Prepare the legal team in Country Y for possible litigations.

Q38. 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

Q39. 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

Q40. 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?
* Quality improvement
* Quality assurance
* Clinical affairs
* Regulatory agency

The RAPS RAC-US certification exam is a comprehensive exam that covers all aspects of regulatory affairs in the healthcare industry. The exam covers topics such as regulatory strategy, product development, clinical trials, regulatory submissions, quality systems, and post-market activities. The exam is designed to test the candidate's knowledge of US regulations and regulatory requirements, as well as their ability to apply that knowledge in a practical setting.

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