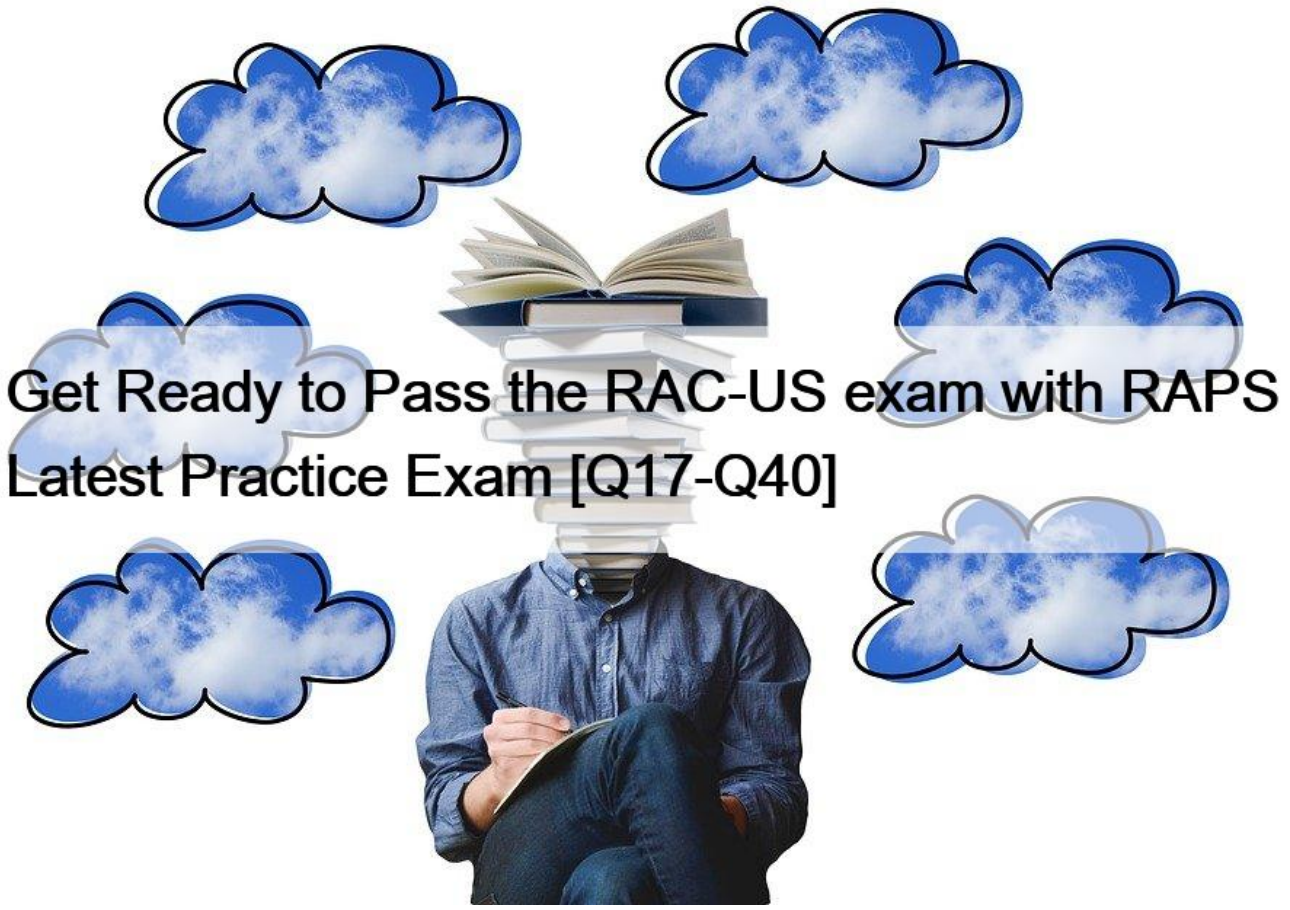
Get Ready to Pass the RAC-US exam with RAPS Latest Practice Exam [Q17-Q40



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Q17. 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

Q18. Company X acquires Company Y.

Both companies produce pharmaceuticals distributed globally. A regulatory authority requires that all labeling for Company Y’s products be converted to Company X within three months. The regulatory affairs professional at

Company X concludes that it is not feasible to meet this request within the time frame.

Which is the FIRST step that the regulatory affairs professional at Company X should take to address the situation?
* Develop a plan of action with tasks, timelines, and responsibilities and request an extension period from the regulatory authority.
* Request additional resources from senior management in order to complete the labeling conversion within the time frame given by the regulatory authority.
* Submit as many labeling conversion applications as possible within the time frame and request an extension for the remaining ones.
* Convene an urgent meeting with internal stakeholders to inform them of the regulatory authority requirement and assign responsibilities.

Q19. Why is it necessary to run supplemental safety pharmacology studies?
* To substitute the utilization of GLP
* To comply with regulatory authority requirements related to clinical studies
* To evaluate potential adverse pharmacodynamics effects not addressed by the core battery
* To provide adverse reaction reports and the results of the statistical data to the regulatory authority

Q20. A process is ultimately validated to ensure which of the following?
* The process meets the regulatory requirements.
* The process meets the quality system requirements.
* The process consistently produces the desired results.
* The process consistently meets the desired Quantity standards

Q21. 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

Q22. The API used for an approved drug product conforms to international monograph specifications and local pharmacopeia; however, the international monograph specifications of the API will be changing soon. Which is the most appropriate action for the regulatory affairs professional to take FIRST?
* Transfer the notice of the upcoming international monograph change to QA for further processing.
* Prepare the international monograph change submission first and then prepare the local change when required.
* Confirm that the international monograph change is not related to local pharmacopeia.
* Analyze the impact of the international monograph change on the local pharmacopeia.

Q23. As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?
* Site license

* Product license
* Import license
* Export license

Q24. Following the introduction of a new regulation, an evaluation of the company’s products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?
* Contact the trade association for advice.
* Communicate with the relevant internal departments.
* Prepare documents for the files.
* Request a permanent waiver from the new regulation.

Q25. Who has the PRIMARY responsibility for recall of products with quality defects?
* Consumer
* Distributor
* Manufacturer
* Regulatory authority

Q26. 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.

Q27. Which term does NOT describe the same concept as the others?
* Biosimilars
* Follow-on protein products
* Monoclonal antibody
* Subsequent entry biologics

Q28. A company is developing a new product for the global market. A new international guideline will recommend relevant studies in the pediatric population, and the guideline will be effective before the approval of the company’s new product.

What is the BEST advice the regulatory affairs professional can provide to minimize the impact of this guideline on the successful registration of the new product?
* The company should consult with relevant regulatory authorities to determine the potential impact on the current registration plan.
* The new guideline has no impact on the current registration plan, but the company must be prepared to defend its decision.
* The new guideline has no impact on the current registration plan since all relevant registration studies are almost completed.
* The company should initiate the required pediatric studies immediately to avoid costly delays to the current registration plan.

Q29. After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?
* Resubmit the entire package.
* Inform upper management immediately.
* Contact the legal department and ask them how to proceed.
* Verify the procedure in the regulation for the corrections.

Q30. 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.

Q31. During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product

Is distributed globally.

Which of the following is the most appropriate action to take FIRST?
* Withdraw the affected product from the markets.
* Send a “Dear Dr.” letter to customers.
* Notify the global regulatory authorities.
* Assess the potential safety risk.

Q32. During the review of a design dossier, the reviewer asks why the company has only carried out a top-down risk approach. The reviewer is referring to which of the following?
* ISO 14971 risk analysis
* Failure mode and effect analysis
* Fault tree analysis
* Hazard and operability study

Q33. Which of the following situations does NOT require rapid communication to regulatory authorities?
* A clinically important increase in the rate of occurrence of an “expected.” but serious

ADR
* A lack of efficacy with a medicinal product used in treating a life-threatening disease
* A major safety finding from a newly completed animal carcinogenicity study
* A statistically significant increase in the number of deaths in an animal dose finding study

Q34. 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

Q35. 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?
* Contact the regulatory authority to argue that its conclusions are wrong.
* Contact the regulatory authority to discuss its findings.
* Repeat the Hepatotoxicity tests and send the results to the regulatory authority.
* Wait for the regulatory authority’s final publication on its findings.

Q36. During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?
* The minimum number of attendees necessary to address the issues
* All senior management from the main office
* As many as government attendees
* As many as required by international standards

Q37. A regulatory affairs professional is asked to review and update regulatory affairs SOPs.

Which aspect of the SOP Is MOST important to consider?
* Expiration date
* Relevance to regulations
* Revision history
* Scope and level of detail

Q38. According to ICH, what is the MAXIMUM amount of time in calendar days that an organization has from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?
* 3
* 5
* 10
* 15

Q39. Company X and Company Y both have products for the treatment of rare genetic diseases.

Company X would like to acquire Company Y but does not know enough about Company Y to make an offer.

What is the MOST appropriate approach that Company X should take to acquire more information about Company Y?
* Enter into an agreement with Company Y to perform due diligence.
* Recruit a professional to gather confidential intelligence on Company Y.
* Request the needed information from the Board of Directors of Company Y.
* Perform a thorough library search to gather detailed information on Company Y.

Q40. A company is developing a device-drug combination product. Which of the following should be evaluated FIRST in order to determine the applicable guidance documents?
* Approved indications of the drug
* Determination of primary mode of action
* Determination of product design deliverables
* Guidance documents for the device

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.

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