[Nov 06, 2023 Updates Up to 365 days On Valid RAC-US Braindumps [Q19-Q42

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Best QualityRAC-US Exam Questions RAPS Test To Gain Brilliante Result

The RAC-US certification exam covers a broad range of topics including regulatory strategy, clinical trials, post-market surveillance, quality control, and compliance. RAC-US exam is divided into two parts: a multiple-choice section and a case study section. The multiple-choice section consists of 125 questions that cover general regulatory affairs knowledge, while the case study section consists of 25 questions that test the candidate's ability to apply their knowledge to real-world scenarios.

The RAC-US exam is an important certification for regulatory professionals who want to demonstrate their expertise in regulatory affairs. RAC-US exam is designed to test the knowledge and skills of regulatory professionals and to ensure that they have a thorough understanding of the regulatory landscape. The RAC-US exam is recognized globally and is a symbol of excellence in the regulatory affairs profession.

QUESTION 19

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

QUESTION 20

Which of the following claims would classify an apple as a drug?
* “It will make you look younger.”
* “It will satisfy hunger.”
* “It will whiten teeth.”
* “It will prevent colds.”

QUESTION 21

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.

QUESTION 22

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.

QUESTION 23

One month prior to the anticipated approval date for your product, the marketing application that you submitted to a major regulatory authority has become the subject of an advisory committee meeting of experts convened by the regulatory authority. The advisory committee members unanimously vote not to approve your product because of a safety concern. Two days after the advisory committee meeting, the regulatory authority requests additional information to support the safety of your product. Assuming you have no additional data to provide, which of the following would be your MOST appropriate response to the regulatory authority’s request?
* “Given the advisory committee’s unanimous decision, we know that the product will not be approved, and additional data will not make any difference.”
* “We have no additional information to provide at this time, but we can perform an additional analysis for a specific safety concern, if necessary.”
* “We disagree with the advisory committee’s decision because the committee neglected the thorough safety analysis that we provided.”
* “We have no additional information to provide at this time because we have already provided everything needed to support our product’s approval.”

QUESTION 24

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

QUESTION 25

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.

QUESTION 26

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?
* Deleting an ingredient of the drug product
* Deleting a drug substance
* Introducing a new analytical method
* Strengthening a precaution to the product labeling

QUESTION 27

At a recent scientific meeting, Company Y had two booths:

* At one booth, Company Y provided brochures on a completed Phase II study.

* In an adjacent booth, Company Y’s sales professionals were promoting one of Company

Y’s marketed products.

A regulatory affairs-professional at Company X sends a letter to a counterpart at Company

Y requesting that Company Y stop this practice in the future and demanding a formal response to the letter. How should the regulatory affairs professional at Company Y BEST respond?
* Acknowledge receipt of the letter in a written response but do nothing further.
* Inform the legal department of the letter and discuss how to respond.
* Inform Company X that it has no right to send such a letter and do nothing further.
* Inform the local regulatory authority of the letter and discuss how to respond.

QUESTION 28

When applying for marketing approval of a drug for a rare disease, which requirement can be waived?
* Pre-clinical studies
* Phase I clinical trials
* Phase I and II clinical trials
* Phase III clinical trials

QUESTION 29

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

QUESTION 30

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?
* Subject is hospitalized due to complications of the product administration.
* Subject is hospitalized for the purpose of product administration.
* Subject’s hospitalization is due to an unscheduled hip operation.
* Subject’s hospitalization is prolonged during the clinical trial.

QUESTION 31

You discover that your company’s top selling product in the last two years has been used off-label.

The off-label use is estimated to be about 70%, and it has been consistent since the product was first released to the market. Which of the following is MOST appropriate?
* Discuss with regulatory authorities to investigate how to have the off-label indication approved.
* No action is required since it is an off-label use.
* Advise the senior management to send a “Dear Dr.” letter.
* File a report to regulatory authorities and advise the marketing department to prevent future off-label use.

QUESTION 32

According to ICH, which of the following components of study information is NOT required in a clinical study report?
* Randomization scheme and codes
* Protocol and protocol amendments
* List of lECs or lRBs
* Detailed CV of all investigators

QUESTION 33

The regulatory authority contacts the regulatory affairs professional regarding a complaint about a drug produced by the company. A consumer reported to the regulatory authority that the tablets have a slightly different color and break easily.

Which of the following actions should the regulatory affairs professional take?

* Ask that the regulatory authority provide the batch number printed on the packaging of the affected product.
* Ask that the regulatory authority provide the actual product subject to the complaint.
* Respond to the regulatory authority that the product subject to the complaint is most likely a counterfeit product.
* Respond to the regulatory authority that the company will provide copies of the relevant

QC records for batch release.

QUESTION 34

A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?
* The ISO national member body
* The ISO technical committee in charge of the area
* The ISO Secretariat
* The country’s regulatory authority

QUESTION 35

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

QUESTION 36

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

QUESTION 37

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

QUESTION 38

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

QUESTION 39

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?
* “Product X is a guaranteed cure for arthritis.”
* “Product X is effective for the treatment of arthritis.”
* “Product X is safe for arthritis and without side effects.”
* “Product X is effective in all patients with arthritis.”

QUESTION 40

A company’s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product.

To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?
* Label the product for use in appropriate populations.
* Educate patients and healthcare providers on how to use the product
* Delay product launch until required studies are completed.
* Promote off-label use to a carefully selected patient population.

QUESTION 41

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?
* Allow doctors to use the product for the off-label indication.
* Communicate with the sales department to stop using the promotional materials.
* Contact the marketing department to recall the product.
* Request that doctors stop using the product for the off-label indication.

QUESTION 42

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

Who can take the RAPS RAC-US Certification Exam?

The targeted audience for the RAPS RAC-US certification exam is regulatory professionals involved in the pharmaceutical and medical device industries. However, candidates from any related field can take the RAPS RAC-US exam provided that they have sufficient knowledge in the area of medical devices and pharmaceuticals regulations. Individuals having designations like Pharmacist, Regulatory Scientist, Medical Device Regulatory Specialist, etc. may also apply. The **RAC-US exam dumps** say that

Senior managers with the ability to make recommendations for a particular company's products and services are also eligible to take the exam. Chat with us now to learn more about the eligibility requirements and other requirements for this certification exam.

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