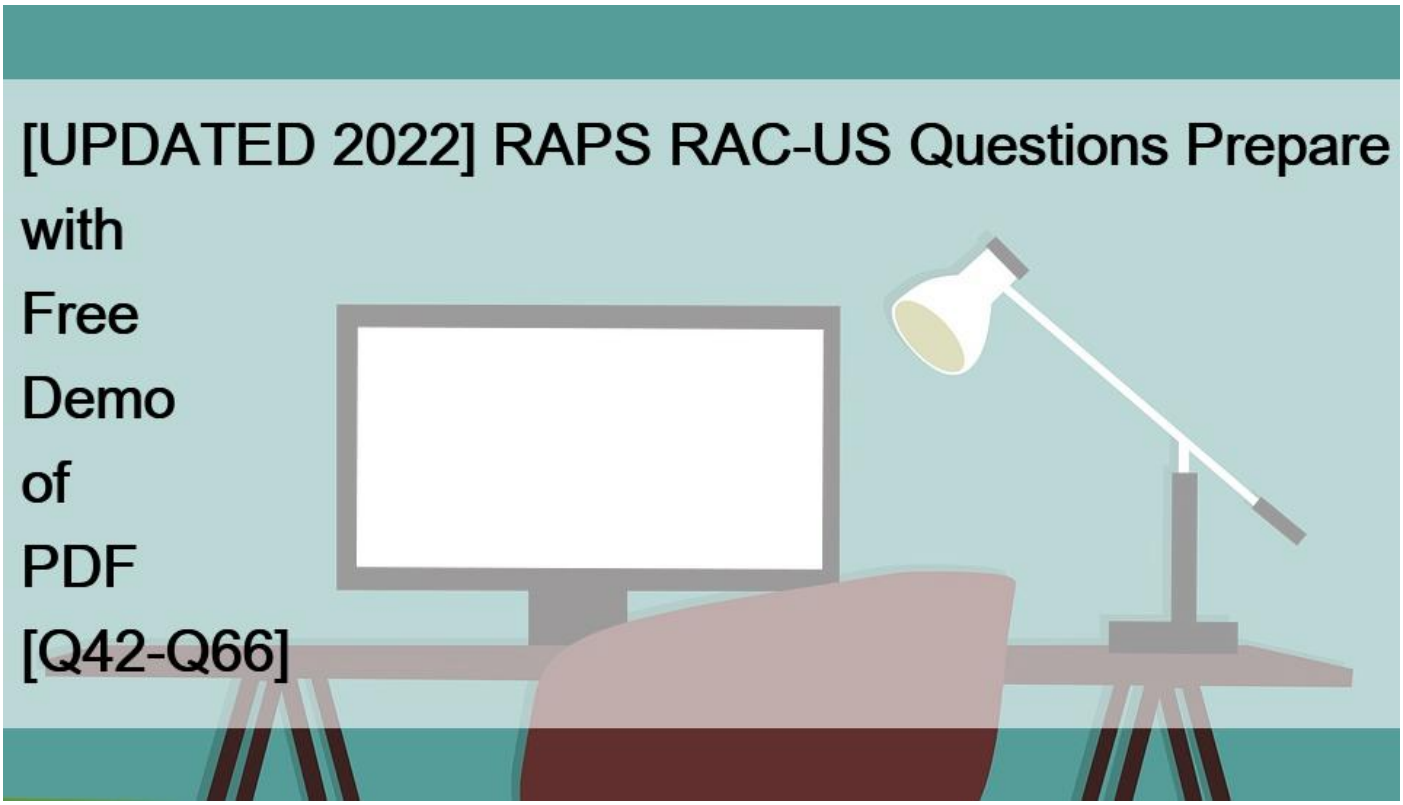
[UPDATED 2022 RAPS RAC-US Questions Prepare with Free Demo of PDF [Q42-Q66



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NEW 2022 Certification Sample Questions RAC-US Dumps & Practice Exam

QUESTION 42

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?
* Local reimbursement requirements
* Service operation procedures
* Training program for sales people
* Written procedure for product traceability

QUESTION 43

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.

QUESTION 44

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.

QUESTION 45

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.

QUESTION 46

During an audit of a contract manufacturing facility by a potential client, the auditor requested to be left alone in the records room. The records room contains information on all products produced by the contract manufacturer.

Which action is MOST appropriate for the regulatory affairs professional to take?
* Allow the auditor access to the room and records due to the current audit.
* Allow the auditor accompanied access to the room to retrieve the records.
* Deny the auditor access to the room and retrieve only the requested records.
* Deny the auditor access to the room and records due to confidentiality concerns.

QUESTION 47

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 48

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

QUESTION 49

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?
* For at least two years after the last approval of an application in an ICH region
* For a minimum of 10 years after completion of the clinical study
* Three years after the last clinical study site was supplied with investigational drugs
* Until the product has been discontinued from marketing in all ICH regions

QUESTION 50

A company is developing a new medical device.

During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?
* Concept development and validation
* Concept development and early technical design
* Early technical design and product release
* Product release and validation

QUESTION 51

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

QUESTION 52

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

QUESTION 53

Which of the following statements regarding the off-label use of drugs is CORRECT?
* Although the regulatory authority reviews and approves drugs for specific indications, the approval does not limit the use of those drugs in clinical practice.
* The regulatory authority does not restrict physician prescribing for off-label indications or regulate the manufacturer’s promotion for such use.
* Sponsors are allowed to distribute publications about unapproved uses of approved drugs and devices as long as the marketing application is under review by the regulatory authority.
* The peer-reviewed literature can ensure high-quality off-label promotion of medications, thereby increasing access to much

needed drugs and devices.

QUESTION 54

According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?
* Deficiency of a device found by the user prior to patient use
* Adverse event caused by patient conditions
* Malfunction occurring before the end of service life of the medical device
* Malfunction protection operated correctly

QUESTION 55

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

QUESTION 56

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 57

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

QUESTION 58

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?
* Specification
* Formulation
* Property
* Justification

QUESTION 59

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 60

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

QUESTION 61

A global company is developing a sophisticated implantable medical device that is coated with antibiotics and biologics to enhance its efficacy.

The product is marketed in Country X.

where it is regulated as a medical device.

The same product, without the antibiotics and biologics, is marketed as a medical device in Country Y.

The company is proposing to start marketing the coated device in Country Y.

Which regulatory approach should the company propose?
* Submit the product for review as a pharmaceutical product in Country Y.
* Submit the product as a medical device in Country Y as the product is already marketed in Country X as a medical device.
* Apply for review of the additional part of the product as a pharmaceutical product in Country
* Examine decisions made about similar products in Country Y to propose the classification of the product.

QUESTION 62

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.

QUESTION 63

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?
* Plasma fractionation
* Product distribution
* Individual plasma donation
* Plasma pooling

QUESTION 64

The safety database for an anti-hypertensive drug consists of the following:

* 461 patients exposed for three months

* 343 patients exposed for six months

* 112 patients exposed for nine months

* 74 patients exposed for 12 months

Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?
* 100 patients for 12 months
* 200 patients for nine months
* 500 patients for three months
* 3.000 total patient exposures

QUESTION 65

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 66

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.