RAC-GS$^{Q\&As}$

Regulatory Affairs Certification (RAC) Global Scope

Pass RAPS RAC-GS Exam with 100% Guarantee

Free Download Real Questions & Answers **PDF** and **VCE** file from:

https://www.passapply.com/rac-gs.html

100% Passing Guarantee
100% Money Back Assurance

Following Questions and Answers are all new published by RAPS Official Exam Center

QUESTION 1

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?

A. Add a warning in the IFU.

B. Discontinue the project.

C. Perform another risk-benefit analysis.

D. Redesign the device.

Correct Answer: D

QUESTION 2

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?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 3

According to ISO 14971,what is the FIRST step when developing a risk management plan for a medical device?

A. Risk estimation

B. Risk analysis

C. Risk control

D. Risk management

Correct Answer: B

QUESTION 4

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 5

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?

A. 100 patients for 12 months

B. 200 patients for nine months

C. 500 patients for three months

D. 3.000 total patient exposures

Correct Answer: A

QUESTION 6

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

A. 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

B. 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

C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product

D. 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

Correct Answer: D

QUESTION 7

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?

A. Draft a formal letter to customers in Country Y about this recall.

B. Initiate a mandatory recall of the product in Country Y.

C. Review alt distribution records and complaints reported in Country Y.

D. Prepare the legal team in Country Y for possible litigations.

Correct Answer: C

QUESTION 8

A protocol for a pivotal registration trial of a new product is submitted to a major regulatory authority for review and approval. The regulatory authority issues the company a written commitment that if the studies are completed as outlined in the protocol and the results meet the pre-specified criteria for efficacy and safety, the product will be approved.

During the final week of the review of the marketing application, which has fully met all pre- specified criteria, the company receives a letter from the regulatory authority stating that it no longer believes that

the product will be approved based on a recent withdrawal of a similar product in another country.

What is the BEST response?

A. Notify the regulatory authority regarding Its obligation to honor the commitment to approve the application.

B. Consult with the legal department to discuss the best course of action.

C. Review the regulatory guidelines to determine how to proceed.

D. Request a meeting with the regulatory authority to discuss the application.

Correct Answer: D

QUESTION 9

During several monitoring visits, a clinical trial monitor identifies serious and repeated noncompliance on the part of the PI. What action should the sponsor take?

A. Increase the frequency of monitoring visits.

B. Inform the institution that granted a medical license to the Pi.

C. Send a letter of complaint to the Ethics Committee that approved the site.

D. Terminate the PI and inform the regulatory authorities.

Correct Answer: D

QUESTION 10

SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?

A. Inadequate training

B. Late and/or incorrect deliverables

C. Causes of non-conformities

D. Adverse environmental impacts

Correct Answer: C

QUESTION 11

Which of the following statements regarding export regulations for an approved product is CORRECT?

A. The product must not be in accord with the specifications of the foreign purchaser.

B. The product must not be in conflict with the laws of the country to which it is intended forexport.

C. The product must not be labeled on the outside of the shipping package that it is intendedfor export.

D. The product must not be sold or offered for sale in domestic commerce.

Correct Answer: B

QUESTION 12

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?

A. Fishbone analysis

B. Failure modes, effects, and criticality analysis

C. Fault tree analysis

D. Quality by design analysis

Correct Answer: B

QUESTION 13

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

A. Site license

B. Product license

C. Import license

D. Export license

Correct Answer: A

QUESTION 14

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?

A. Expiration date

B. Relevance to regulations

C. Revision history

D. Scope and level of detail

Correct Answer: B

QUESTION 15

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?

A. Obtain a copy of the proposed regulation and analyze the impact.

B. Inform the company\\'s senior management and arrange an emergency meeting

C. Consult with the company\\'s legal department regarding options.

D. Arrange for additional testing of the product at the testing facility.

Correct Answer: A