RAPS

Exam RAC-GS

Regulatory Affairs Certification (RAC) Global Scope

Version: 6.1

[Total Questions: 100]

Question No : 1

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?

A. Acknowledge receipt of the letter in a written response but do nothing further.
B. Inform the legal department of the letter and discuss how to respond.
C. Inform Company X that it has no right to send such a letter and do nothing further.
D. Inform the local regulatory authority of the letter and discuss how to respond.

Answer: B

Question No : 2

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1
B. Module 2
C. Module 3
D. Module 4

Answer: B

Question No : 3

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.

Answer: D

Question No : 4

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?

A. Contact the regulatory authority to argue that its conclusions are wrong.
B. Contact the regulatory authority to discuss its findings.
C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.
D. Wait for the regulatory authority's final publication on its findings.

Answer: B

Question No : 5

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?

A. Plasma fractionation
B. Product distribution
C. Individual plasma donation
D. Plasma pooling

Answer: B

Question No : 6

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

Answer: B

Question No : 7

In the process of obtaining a product approval, a regulatory affairs professional discovers that the product does not meet one of the specific technical requirements of the regulation. However, competitors with substantially similar products have claimed compliance with the requirement and received approval. Which action should the regulatory affairs professional take FIRST?

A. Discuss with the regulatory apriority and attempt to reach an acceptable solution.
B. Inform the internal departments to redesign the product to comply with this requirement.
C. Inform the regulatory authority that such a requirement is not applicable to the product.
D. Notify senior management that the product cannot be registered.

Answer: A

Question No : 8

Who has the PRIMARY responsibility for recall of products with quality defects?

A. Consumer
B. Distributor
C. Manufacturer
D. Regulatory authority

Answer: C

Question No : 9

Which of the following is NOT required to be included in a marketing application?

A. Final printed label
B. Quality, safety, and efficacy Information
C. Administrative forms
D. Evidence of fee payment

Answer: D

Question No : 10

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?

A. Perform either an identification study or a non-clinical qualification study.
B. Perform both identification and non-clinical qualification studies concurrently.
C. Perform an identification study, wait until the result is available, and then consider performing a non-clinical qualification study.
D. Perform a non-clinical qualification study, wait until the result is available, and then consider performing an identification study.

Answer: C

Question No : 11

A superiority advertising claim for a product versus its competitor's product can only be made under which of the following circumstances?

A. In vitro studies show the product to be superior.
B. Government survey data indicate the product is superior.
C. Results of a three-year, post-market patient survey indicate the product is superior.
D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Answer: D

Question No : 12

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.

Answer: C

Question No : 13

A company establishes a new medical device indication for its consumer disposable products. The regulatory affairs professional is asked to give a 30-minute training session on these products to sales representatives. Which of the following subjects is the MOST important to discuss?

A. Labeling
B. Regulatory application summary
C. Risk management process
D. Safety-related reporting

Answer: A

Question No : 14

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?

A. Local reimbursement requirements
B. Service operation procedures
C. Training program for sales people
D. Written procedure for product traceability

Answer: C

Question No : 15

Which of the following double-blind clinical trial designs would be MOST appropriate for a Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?

A. Active-controlled
B. Cross-over
C. Dose-ranging
D. Placebo-controlled

Answer: B

Question No : 16

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?

A. ISO 14971 risk analysis
B. Failure mode and effect analysis
C. Fault tree analysis
D. Hazard and operability study

Answer: A

Question No : 17

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?

A. The company should consult with relevant regulatory authorities to determine the potential impact on the current registration plan.
B. The new guideline has no impact on the current registration plan, but the company must be prepared to defend its decision.
C. The new guideline has no impact on the current registration plan since all relevant