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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

Which of the following BEST describes the purpose of the ICH?

A. To provide scientific evaluation of applications for international marketing authorization forsafe, effective, and high-quality medicines for the ICH regions

B. To protect and promote public health through the evaluation and supervision of safe,effective, and high-quality medicines for the ICH regions

C. To lobby for improved industry standards for the development of new safe, effective, andhigh-quality medicines for the ICH regions

D. To discuss and establish common guidelines for safe, effective, and high-quality medicines for the ICH regions

Correct Answer: D

QUESTION 2

A company is developing a novel drug to combat AIDS. The preliminary results are very promising and include instances of complete remission. The company has been granted patents in multiple countries for the drug. The regulatory affairs professional is asked to prepare a brief report concerning potential problems for marketing of the product worldwide. Which of the following is the MOST important consideration to discuss?

A. Doha Declaration in the TRIPS Agreement

B. The stability of the drug in all zone conditions

C. The time frame in which the patent will expire

D. International import and export regulations

Correct Answer: B

QUESTION 3

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 4

According to the ICH guideline on GMP for API,to which of the following is the MOST stringent requirement applied?

A. Physical processing and packaging

B. Isolation and purification

C. Production of Intermediate(s)

D. Introduction of the API starting material

Correct Answer: A

QUESTION 5

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

Correct Answer: B

QUESTION 6

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.

Correct Answer: A

QUESTION 7

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D

QUESTION 8

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

QUESTION 9

According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?

A. Deficiency of a device found by the user prior to patient use

B. Adverse event caused by patient conditions

C. Malfunction occurring before the end of service life of the medical device

D. Malfunction protection operated correctly

Correct Answer: BC

QUESTION 10

GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?

A. Instructions for use

B. Risk analysis

C. Product literature

D. Essential principles

Correct Answer: BD

QUESTION 11

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

Correct Answer: C

QUESTION 12

A company is considering the development of a medical device similar to those already available. Which of the following should be evaluated FIRST when developing a clinical evaluation document?

A. Adverse event reports

B. Clinical experience

C. Clinical investigations

D. Literature search

Correct Answer: C

QUESTION 13

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?

A. Enter into an agreement with Company Y to perform due diligence.

B. Recruit a professional to gather confidential intelligence on Company Y.

C. Request the needed information from the Board of Directors of Company Y.

D. Perform a thorough library search to gather detailed information on Company Y.

Correct Answer: A

QUESTION 14

Company X encounters challenges in the global life cycle management of its medical devices. Which of the following Is MOST appropriate for improving product life cycle management?

A. Utilize the STED template to complete global requirements.

B. Initiate a global submission process after all submission data are finalized.

C. Identify countries where special requirements exist during the product development phase.

D. Plan regulatory approval update meetings with senior management and stakeholders.

Correct Answer: C

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