RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

A request was received from a regulatory authority asking the company to conduct product testing in compliance with a newly issued regulation.

What should be done. What action should the company take FIRST?

A. Initiate testing immediately to ensure compliance.

B. Consult with colleagues about the request.

C. Contact the regulatory authority that issued this request and discuss the requirement.

D. Send a letter back to the regulatory authority indicating why the regulation does not apply to the product.

Correct Answer: C

QUESTION 2

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 3

In preparation for the development of a new line of products, a regulatory affairs professional is asked to prepare a short presentation for senior management. Which of the following topics is MOST important to cover?

A. Potential clinical sites for the Phase III clinical trial

B. Regulatory requirements for labeling and packaging

C. Capacity of the manufacturing facilities to fully produce the new product

D. Previous actions taken by regulatory authorities on similar products

Correct Answer: D

QUESTION 4

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?

A. Review the company\\'s existing Quality ManagementSystem

B. Reformulate the products with a replacement material.

C. Qualify another supplier and execute a supplier agreement.

D. Complete a gap analysis to identify options.

Correct Answer: CD

QUESTION 5

Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?

A. Proposed dose and volume of administration

B. Biological activity with species and/or tissue specificity

C. Immunochemical and functional tests

D. Proposed product route and frequency of administration

Correct Answer: B