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QUESTION 1

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 authority 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 2

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 Management System
- 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 3

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

- A. Intellectual property
- B. Clinical trial data
- C. Safety issues
- D. Marketing materials

Correct Answer: C

QUESTION 4

A company is developing a device-drug combination product. Which of the following should be evaluated FIRST in order to determine the applicable guidance documents?

- A. Approved indications of the drug
- B. Determination of primary mode of action
- C. Determination of product design deliverables
- D. Guidance documents for the device

Correct Answer: C

QUESTION 5

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

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