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Regulatory Affairs Certification (RAC) US

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### QUESTION 1

A company receives multiple complaints regarding the text included on a recently launched product's label. What action should the regulatory affairs professional take FIRST?

- A. Recommend an immediate product recall.
- B. Compare the approved text with the product label
- C. Notify the regulatory authority.
- D. Inform the production team.

Correct Answer: B

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### 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

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### QUESTION 3

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

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#### QUESTION 4

Which question is pertinent to demonstrate a new pharmaceutical's effectiveness during evaluation by a reimbursement agency?

- A. "Is the product profitable for the manufacturer?"
- B. "Is the product better than currently available alternatives?"
- C. "Has the product been approved for more than 10 years?"
- D. "Is the product an established gold standard?"

Correct Answer: B

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#### QUESTION 5

A company is developing a new line of products in an area that is new to the company. What is the BEST approach?

- A. Ask the trade association representative to provide an overview of the new product area to the marketing team.
- B. Obtain competitor research and provide the information to the management team.
- C. Obtain regulatory documents and history and provide the information to R&D.
- D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

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