

# RAC-US<sup>Q&As</sup>

Regulatory Affairs Certification (RAC) US

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**QUESTION 1**

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

- A. Stop product manufacturing.
- B. Establish validation procedures.
- C. Assess the impact of the changes.
- D. Review the stability data for the changes.

Correct Answer: AC

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**QUESTION 2**

Which of the following claims would classify an apple as a drug?

- A. "It will make you look younger."
- B. "It will satisfy hunger."
- C. "It will whiten teeth."
- D. "It will prevent colds."

Correct Answer: D

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**QUESTION 3**

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

- A. Product stability
- B. Product registration
- C. Product formulation
- D. Product requirements

Correct Answer: A

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**QUESTION 4**

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 RandD.
- D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

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#### QUESTION 5

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?

- A. 100 patients for 12 months
- B. 200 patients for nine months
- C. 500 patients for three months
- D. 3.000 total patient exposures

Correct Answer: A

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