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Regulatory Affairs Certification (RAC) US

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#### QUESTION 1

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 2

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 3

When applying for marketing approval of a drug for a rare disease, which requirement can be waived?

- A. Pre-clinical studies
- B. Phase I clinical trials
- C. Phase I and II clinical trials
- D. Phase III clinical trials

Correct Answer: D

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#### QUESTION 4

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

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#### QUESTION 5

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?

- A. Deleting an ingredient of the drug product
- B. Deleting a drug substance
- C. Introducing a new analytical method
- D. Strengthening a precaution to the product labeling

Correct Answer: D

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