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Regulatory Affairs Certification (RAC) US

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**QUESTION 1**

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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**QUESTION 2**

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

- A. A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation
- B. A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use
- C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product
- D. A brief summary of relevant physical, chemical, and pharmaceutical properties: instructions for storage and handling of the dosage form: and a description of the formulation

Correct Answer: D

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**QUESTION 3**

After numerous failed attempts to decrease an identified risk in a medical device to an acceptable level, the medical device continues to have unacceptable risks. However, the development team wants to continue development. Which is the BEST recommendation to make in this situation?

- A. Add a warning in the IFU.
- B. Discontinue the project.
- C. Perform another risk-benefit analysis.
- D. Redesign the device.

Correct Answer: D

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## QUESTION 4

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 5

A company's product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product. To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

- A. Label the product for use in appropriate populations.
- B. Educate patients and healthcare providers on how to use the product
- C. Delay product launch until required studies are completed.
- D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

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