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Regulatory Affairs Certification (RAC) US

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#### QUESTION 1

According to ISO 14971, what is the FIRST step when developing a risk management plan for a medical device?

- A. Risk estimation
- B. Risk analysis
- C. Risk control
- D. Risk management

Correct Answer: B

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#### QUESTION 2

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

- A. "Product X is a guaranteed cure for arthritis."
- B. "Product X is effective for the treatment of arthritis."
- C. "Product X is safe for arthritis and without side effects."
- D. "Product X is effective in all patients with arthritis."

Correct Answer: B

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#### QUESTION 3

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

- A. Ask the vendor to take responsibility.
- B. Document and perform audits.
- C. Request an inspection from a regulatory authority.
- D. Request documentation from the sub-contractor.

Correct Answer: B

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#### QUESTION 4

Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?



- A. Proposed dose and volume of administration
- B. Biological activity with species and/or tissue specificity
- C. Immunochemical and functional tests
- D. Proposed product route and frequency of administration

Correct Answer: B

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#### QUESTION 5

During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product is distributed globally. Which of the following is the most appropriate action to take FIRST?

- A. Withdraw the affected product from the markets.
- B. Send a "Dear Dr." letter to customers.
- C. Notify the global regulatory authorities.
- D. Assess the potential safety risk.

Correct Answer: C

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