



RAC-GS^{Q&As}

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

The manufacturer of an API was changed from Company X to Company Y during the late stage of a new drug development. Despite differences in the manufacturing processes of the companies, both APIs meet the current specifications. Which is the MOST appropriate information to include in the final submission documents?

- A. The process information and analytical result of Company X API
- B. The process information and analytical result of Company Y API
- C. The process information and the comparative analytical result of APIs from both companies
- D. Information deemed appropriate by the regulatory authority

Correct Answer: C

QUESTION 2

A regulatory authority announces an inspection of a regulatory affairs professional's facility during a holiday season when most of the staff is not available. What is the MOST practical approach to this dilemma?

- A. Negotiate with colleagues and the authority to find a better time.
- B. Insist that key personnel be available for the inspection.
- C. Inform the authority that the time is not suitable and request a new time
- D. Arrange for an inspection without all intended personnel.

Correct Answer: A

QUESTION 3

Which of the following is NOT required to be included in a marketing application?

- A. Final printed label
- B. Quality, safety, and efficacy information
- C. Administrative forms
- D. Evidence of fee payment

Correct Answer: D

QUESTION 4

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

QUESTION 5

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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