RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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

QUESTION 2

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

QUESTION 3

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 4

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 5

Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?

A. Before the enactment of the regulation, through the industry representative

B. Before the enactment of the regulation, through formal comments gathering process

C. After the enactment of the regulation, through the industry representative

D. After the enactment of the regulation, through a product-specific meeting

Correct Answer: B