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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 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 3

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

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

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