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QUESTION 1

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

A. Safety and failure risk

B. Safety and effectiveness

C. Quality and failure risk

D. Quality and effectiveness

Correct Answer: B

QUESTION 2

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

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

QUESTION 4

A company is preparing the submission package for a drug to be registered in international markets. When preparing

the legal documentation, which document MUST comply with the WHO recommendations?

A. Certificate of GMP

B. Certificate of Free Sale

C. Certificate of Pharmaceutical Product

D. Certificate of Analysis for the finished product

Correct Answer: C

QUESTION 5

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