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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 is the PRIMARY purpose of an audit report?

- A. To carry out a complete review of product applications
- B. To define how to prepare new product submissions
- C. To document compliance history
- D. To train sales representatives

Correct Answer: C

QUESTION 3

A superiority advertising claim for a product versus its competitor's product can only be made under which of the following circumstances?

- A. In vitro studies show the product to be superior.
- B. Government survey data indicate the product is superior.
- C. Results of a three-year, post-market patient survey indicate the product is superior.
- D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Correct Answer: D

QUESTION 4

You discover that your company's top selling product in the last two years has been used off-label. The off-label use is estimated to be about 70%, and it has been consistent since the product was first released to the market. Which of the following is MOST appropriate?



- A. Discuss with regulatory authorities to investigate how to have the off-label indication approved.
- B. No action is required since it is an off-label use.
- C. Advise the senior management to send a "Dear Dr." letter.
- D. File a report to regulatory authorities and advise the marketing department to prevent future off-label use.

Correct Answer: A

QUESTION 5

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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