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QUESTION 1

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 2

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 3

Why is it necessary to run supplemental safety pharmacology studies?

A. To substitute the utilization of GLP

B. To comply with regulatory authority requirements related to clinical studies

C. To evaluate potential adverse pharmacodynamics effects not addressed by the core battery

D. To provide adverse reaction reports and the results of the statistical data to the regulatory authority

Correct Answer: C

QUESTION 4

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 5

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?

A. Expiration date

B. Relevance to regulations

C. Revision history

D. Scope and level of detail

Correct Answer: B