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QUESTION 1

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 2

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 3

GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?

A. Instructions for use

B. Risk analysis

C. Product literature

D. Essential principles

Correct Answer: BD

QUESTION 4

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 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