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QUESTION 1

Which question is pertinent to demonstrate a new pharmaceutical's effectiveness during evaluation by a reimbursement agency?

- A. "Is the product profitable for the manufacturer?"
- B. "Is the product better than currently available alternatives?"
- C. "Has the product been approved for more than 10 years?"
- D. "Is the product an established gold standard?"

Correct Answer: B

QUESTION 2

Which of the following is the BEST approach for mitigating potential regulatory compliance issues at your company?

- A. Document any failure to follow regulatory compliance processes in employee performance reviews.
- B. Develop documented procedures for regulatory compliance processes and train personnel.
- C. Train all new employees on regulatory compliance processes and assign a mentor to them.
- D. Train employees on all regulatory compliance processes using state-of-the-art systems.

Correct Answer: B

QUESTION 3

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 4

A company is developing a new medical device using innovative technology. Which of the following is MOST critical in working with regulatory authorities?

- A. Documented agreement



- B. Frequent communication
- C. Early collaboration
- D. Follow-up meeting after submission

Correct Answer: B

QUESTION 5

Which of the following double-blind clinical trial designs would be MOST appropriate for a Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?

- A. Active-controlled
- B. Cross-over
- C. Dose-ranging
- D. Placebo-controlled

Correct Answer: B

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