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QUESTION 1

According to ICH, how many stability time points are normally required to establish a two- year shelf life for a product?

- A. 3
- B. 5
- C. 7
- D. 9

Correct Answer: C

QUESTION 2

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?

- A. Local reimbursement requirements
- B. Service operation procedures
- C. Training program for sales people
- D. Written procedure for product traceability

Correct Answer: C

QUESTION 3

Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?

- A. Before the enactment of the regulation, through the industry representative
- B. Before the enactment of the regulation, through formal comments gathering process
- C. After the enactment of the regulation, through the industry representative
- D. After the enactment of the regulation, through a product-specific meeting

Correct Answer: B

QUESTION 4

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?



- A. Fishbone analysis
- B. Failure modes, effects, and criticality analysis
- C. Fault tree analysis
- D. Quality by design analysis

Correct Answer: B

QUESTION 5

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

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