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QUESTION 1

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

Correct Answer: B

QUESTION 2

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 3

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

A. Stop product manufacturing.

B. Establish validation procedures.

C. Assess the impact of the changes.

D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 4

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

QUESTION 5

When applying for marketing approval of a drug for a rare disease, which requirement can be waived?

A. Pre-clinical studies

B. Phase I clinical trials

C. Phase I and II clinical trials

D. Phase III clinical trials

Correct Answer: D