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QUESTION 1

SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?

A. Inadequate training

B. Late and/or incorrect deliverables

C. Causes of non-conformities

D. Adverse environmental impacts

Correct Answer: C

QUESTION 2

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

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

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

A. Product stability

B. Product registration

C. Product formulation

D. Product requirements

Correct Answer: A

QUESTION 5

Company X and Company Y both have products for the treatment of rare genetic diseases. Company X would like to acquire Company Y but does not know enough about Company Y to make an offer. What is the MOST appropriate approach that Company X should take to acquire more information about Company Y?

A. Enter into an agreement with Company Y to perform due diligence.

B. Recruit a professional to gather confidential intelligence on Company Y.

C. Request the needed information from the Board of Directors of Company Y.

D. Perform a thorough library search to gather detailed information on Company Y.

Correct Answer: A