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QUESTION 1

As a member of the product launch review committee, a regulatory affairs professional discovers a major issue with the labeling of a product prior to production. In addition to informing the committee, which is the BEST approach to address the issue?

- A. Inform the regulatory authorities.
- B. Delay the start of product production.
- C. Correct the label text.
- D. Abort the product launch.

Correct Answer: A

QUESTION 2

Which of the following is NOT required to be included in a marketing application?

- A. Final printed label
- B. Quality, safety, and efficacy Information
- C. Administrative forms
- D. Evidence of fee payment

Correct Answer: D

QUESTION 3

A company is developing a new line of products in an area that is new to the company. What is the BEST approach?

- A. Ask the trade association representative to provide an overview of the new product area to the marketing team.
- B. Obtain competitor research and provide the information to the management team.
- C. Obtain regulatory documents and history and provide the information to RandD.
- D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

QUESTION 4

According to the ICH guideline on GMP for API, to which of the following is the MOST stringent requirement applied?

- A. Physical processing and packaging



- B. Isolation and purification
- C. Production of Intermediate(s)
- D. Introduction of the API starting material

Correct Answer: A

QUESTION 5

A regulatory affairs professional has submitted a package for regulatory review. According to the regulation, the regulatory authority will need to respond within 90 days of submission. If there is no response after the deadline, what is the BEST approach?

- A. Contact the regulatory authority, ask for clarification about the delay, and provide answers to any outstanding questions.
- B. Contact the regulatory authority, ask for clarification about the delay, and demand a decision be made regarding the submission.
- C. Contact the local political representative and ask for intervention with the regulatory authority to obtain a decision regarding the submission.
- D. Contact the company legal representative in order to begin legal proceedings to enforce the regulatory authority's response time.

Correct Answer: A

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