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QUESTION 1

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D

QUESTION 2

A request was received from a regulatory authority asking the company to conduct product testing in compliance with a newly issued regulation.

What should be done. What action should the company take FIRST?

A. Initiate testing immediately to ensure compliance.

B. Consult with colleagues about the request.

C. Contact the regulatory authority that issued this request and discuss the requirement.

D. Send a letter back to the regulatory authority indicating why the regulation does not apply to the product.

Correct Answer: C

QUESTION 3

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 4

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 morand4nan 10 years?"

D. "Is the product an established gold standard?"

Correct Answer: B

QUESTION 5

Which of the following claims would classify an apple as a drug?

A. "It will make you look younger."

B. "It will satisfy hunger."

C. "It will whiten teeth."

D. "It will prevent colds."

Correct Answer: D