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QUESTION 1

The regulatory authority contacts the regulatory affairs professional regarding a complaint about a drug produced by the company. A consumer reported to the regulatory authority that the tablets have a slightly different color and break easily.

Which of the following actions should the regulatory affairs professional take?

- A. Ask that the regulatory authority provide the batch number printed on the packaging of the affected product.
- B. Ask that the regulatory authority provide the actual product subject to the complaint.
- C. Respond to the regulatory authority that the product subject to the complaint is most likely a counterfeit product.
- D. Respond to the regulatory authority that the company will provide copies of the relevant QC records for batch release.

Correct Answer: A

QUESTION 2

As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?

- A. Site license
- B. Product license
- C. Import license
- D. Export license

Correct Answer: A

QUESTION 3

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

- A. "Product X is a guaranteed cure for arthritis."
- B. "Product X is effective for the treatment of arthritis."
- C. "Product X is safe for arthritis and without side effects."
- D. "Product X is effective in all patients with arthritis."

Correct Answer: B

**QUESTION 4**

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 5

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

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