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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 acounterfeit product.

D. Respond to the regulatory authority that the company will provide copies of the relevant QCrecords for batch release.

Correct Answer: A

QUESTION 2

Which of the following is the PRIMARY purpose of an audit report?

A. To carry out a complete review of product applications

B. To define how to prepare new product submissions

C. Todocument compliance history

D. To train sales representatives

Correct Answer: C

QUESTION 3

Why is it necessary to run supplemental safety pharmacology studies?

A. To substitute the utilization of GLP

B. To comply with regulatory authority requirements related to clinical studies

C. To evaluate potential adverse pharmacodynamics effects not addressed by the core battery

D. To provide adverse reaction reports and the results of the statistical data to the regulatory authority

Correct Answer: C

QUESTION 4

Following the introduction of a new regulation, an evaluation of the company\\'s products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?

A. Contact the trade association for advice.

B. Communicate with the relevant internal departments.

C. Prepare documents for the files.

D. Request a permanent waiver from the new regulation.

Correct Answer: B

QUESTION 5

A regulatory authority announces an inspection of a regulatory affairs professional\\'s facility during a holiday season when most of the staff Is not available. What is the MOST practical approach to this dilemma?

A. Negotiate with colleagues and the authority to find a better time.

B. Insist that key personnel be available for the inspection.

C. Inform the authority that the time is not suitable and request a new time

D. Arrange for an inspection without all intended personnel.

Correct Answer: A