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QUESTION 1

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?

A. Deleting an ingredient of the drug product

B. Deleting a drug substance

C. Introducing a new analytical method

D. Strengthening a precaution to the product labeling

Correct Answer: D

QUESTION 2

During routine surveillance, a regulatory authority sent a company the following communication: "Hepatotoxicity and suicidal behavior were identified as potential safety issues for the company\\'s product. The regulatory authority is evaluating these issues to determine the need for any regulatory action." Which action would be the most appropriate FIRST step for the company to take?

A. Contact the regulatory authority to argue that its conclusions are wrong.

B. Contact the regulatory authority to discuss its findings.

C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.

D. Wait for the regulatory authority\\'s final publication on its findings.

Correct Answer: B

QUESTION 3

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?

A. Fishbone analysis

B. Failure modes, effects, and criticality analysis

C. Fault tree analysis

D. Quality by design analysis

Correct Answer: B

QUESTION 4

Which of the following is the BEST approach for mitigating potential regulatory compliance issues at your company?

A. Document any failure to follow regulatory compliance processes in employee performancereviews.

B. Develop documented procedures for regulatory compliance processes and train personnel.

C. Train all new employees on regulatory compliance processes and assign a mentor to them.

D. Train employees on all regulatory compliance processes using state-of-the-art systems.

Correct Answer: B

QUESTION 5

The regulatory authority in Country X issued a request for a mandatory product recall in Country X due to serious injuries to patients. This product also is distributed in Country Y.

What should the regulatory affairs professional of the product\\'s manufacturer FIRST do in Country Y?

A. Draft a formal letter to customers in Country Y about this recall.

B. Initiate a mandatory recall of the product in Country Y.

C. Review alt distribution records and complaints reported in Country Y.

D. Prepare the legal team in Country Y for possible litigations.

Correct Answer: C