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QUESTION 1

Who has the PRIMARY responsibility for recall of products with quality defects?

A. Consumer

B. Distributor

C. Manufacturer

D. Regulatory authority

Correct Answer: C

QUESTION 2

A company\\'s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product. To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 3

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

QUESTION 4

During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product Is distributed globally. Which of the following is the most appropriate action to take FIRST?

A. Withdraw the affected product from the markets.

B. Send a "Dear Dr." letter to customers.

C. Notify the global regulatory authorities.

D. Assess the potential safety risk.

Correct Answer: C

QUESTION 5

Company X encounters challenges in the global life cycle management of its medical devices. Which of the following Is MOST appropriate for improving product life cycle management?

A. Utilize the STED template to complete global requirements.

B. Initiate a global submission process after all submission data are finalized.

C. Identify countries where special requirements exist during the product development phase.

D. Plan regulatory approval update meetings with senior management and stakeholders.

Correct Answer: C