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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

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 3

Which of the following statements regarding export regulations for an approved product is CORRECT?

A. The product must not be in accord with the specifications of the foreign purchaser.

B. The product must not be in conflict with the laws of the country to which it is intended forexport.

C. The product must not be labeled on the outside of the shipping package that it is intendedfor export.

D. The product must not be sold or offered for sale in domestic commerce.

Correct Answer: B

QUESTION 4

A company is developing a new medical device using innovative technology. Which of the following is MOST critical in working with regulatory authorities?

A. Documented agreement

B. Frequent communication

C. Early collaboration

D. Follow-up meeting after submission

Correct Answer: B

QUESTION 5

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?

A. Plasma fractionation

B. Product distribution

C. Individual plasma donation

D. Plasma pooling

Correct Answer: B

QUESTION 6

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

QUESTION 7

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC

QUESTION 8

According to ICH, which of the following components of study information is NOT required in a clinical study report?

A. Randomization scheme and codes

B. Protocol and protocol amendments

C. ListoflECsorlRBs

D. Detailed CVofall investigators

Correct Answer: D

QUESTION 9

A protocol for a pivotal registration trial of a new product is submitted to a major regulatory authority for review and approval. The regulatory authority issues the company a written commitment that if the studies are completed as outlined in the protocol and the results meet the pre-specified criteria for efficacy and safety, the product will be approved.

During the final week of the review of the marketing application, which has fully met all pre- specified criteria, the company receives a letter from the regulatory authority stating that it no longer believes that

the product will be approved based on a recent withdrawal of a similar product in another country.

What is the BEST response?

A. Notify the regulatory authority regarding Its obligation to honor the commitment to approve the application.

B. Consult with the legal department to discuss the best course of action.

C. Review the regulatory guidelines to determine how to proceed.

D. Request a meeting with the regulatory authority to discuss the application.

Correct Answer: D

QUESTION 10

SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?

A. Inadequate training

B. Late and/or incorrect deliverables

C. Causes of non-conformities

D. Adverse environmental impacts

Correct Answer: C

QUESTION 11

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 12

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

QUESTION 13

After numerous failed attempts to decrease an identified risk in a medical device to an acceptable level, the medical device continues to have unacceptable risks. However, the development team wants to continue development. Which is the BEST recommendation to make in this situation?

A. Add a warning in the IFU.

B. Discontinue the project.

C. Perform another risk-benefit analysis.

D. Redesign the device.

Correct Answer: D

QUESTION 14

Company X and Company Y both have products for the treatment of rare genetic diseases. Company X would like to

acquire Company Y but does not know enough about Company Y to make an offer.

What is the MOST appropriate approach that Company X should take to acquire more information about Company Y?

A. Enter into an agreement with Company Y to perform due diligence.

B. Recruit a professional to gather confidential intelligence on Company Y.

C. Request the needed information from the Board of Directors of Company Y.

D. Perform a thorough library search to gather detailed information on Company Y.

Correct Answer: A

QUESTION 15

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