RAC-GS$^{Q\&As}$

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

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 3

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?

A. Allow doctors to use the product for the off-label indication.

B. Communicate with the sales department to stop using the promotional materials.

C. Contact the marketing department to recall the product.

D. Request that doctors stop using the product for the off-label indication.

Correct Answer: B

QUESTION 4

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 5

In the process of obtaining a product approval, a regulatory affairs professional discovers that the product does not meet one of the specific technical requirements of the regulation. However, competitors with substantially similar products have claimed compliance with the requirement and received approval. Which action should the regulatory affairs professional take FIRST?

A. Discuss with the regulatory apriority and attempt to reach an acceptable solution.

B. Inform the internal departments to redesign the product to comply with this requirement.

C. Inform the regulatory authority that such a requirement is not applicable to the product.

D. Notify senior management that the product cannot be registered.

Correct Answer: A

QUESTION 6

A process is ultimately validated to ensure which of the following?

A. The process meets the regulatory requirements.

B. The process meets the quality system requirements.

C. The process consistently produces the desired results.

D. The process consistently meets the desiredQuantity standards

Correct Answer: C

QUESTION 7

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?

A. Specification

B. Formulation

C. Property

D. Justification

Correct Answer: D

QUESTION 8

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

A. Safety and failure risk

B. Safety and effectiveness

C. Quality and failure risk

D. Quality and effectiveness

Correct Answer: B

QUESTION 9

According to ISO 14971,what is the FIRST step when developing a risk management plan for a medical device?

A. Risk estimation

B. Risk analysis

C. Risk control

D. Risk management

Correct Answer: B

QUESTION 10

A global company has obtained a patent in a specific country for a newly marketed product. What would be the BEST advice In order to protect the patent in other countries?

A. Use the Madrid system.

B. Use the community patent system.

C. File patents of interest in target countries.

D. File design patents in target countries.

Correct Answer: C

QUESTION 11

According to ICH, what is the MAXIMUM amount of timein calendar days that anorganizationhas from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?

A. 3

B. 5

C. 10

D. 15

Correct Answer: BCD

QUESTION 12

According to the ICH guideline on GMP for API,to which of the following is the MOST stringent requirement applied?

A. Physical processing and packaging

B. Isolation and purification

C. Production of Intermediate(s)

D. Introduction of the API starting material

Correct Answer: A

QUESTION 13

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

QUESTION 14

Under which of the following circumstances would a regulatory authority require a more detailed premarket submission, a more rigorous audit, and/or the provision of more performance evaluation data than would normally apply to an IVD device of that risk class?

A. The device is an updated version of a compliant device from the same manufacturer and contains no substantive

change.

B. Internationally recognized standards are available to cover the main aspects of the device and have been used by the manufacturer.

C. The manufacturer\\'s experience level with the type of IVD medical device is limited.

D. The device incorporates well-established technology that is already present in the market.

Correct Answer: C

QUESTION 15

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