RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

A company is currently marketing an implantable orthopedic medical device. The RandD department is planning to change the material used for the implant. The RandD department states that the change does not impact the safety and effectiveness of the product.

What action should the regulatory affairs professional take FIRST?

A. No action is needed in this situation.

B. Prepare regulatory submissions that detail the medical device\\'s change in materials.

C. Review the content of change and supporting data for the equivalency with the current material.

D. Write a memo to file since the change does not impact product safety and effectiveness.

Correct Answer: C

QUESTION 2

A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?

A. The ISO national member body

B. The ISO technical committee in charge of the area

C. The ISO Secretariat

D. The country\\'s regulatory authority

Correct Answer: AD

QUESTION 3

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 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

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 6

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 7

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 8

In preparation for the development of a new line of products, a regulatory affairs professional is asked to prepare a short presentation for senior management. Which of the following topics is MOST important to cover?

A. Potential clinical sites for the Phase III clinical trial

B. Regulatory requirements for labeling and packaging

C. Capacity of the manufacturing facilities to fully produce the new product

D. Previous actions taken by regulatory authorities on similar products

Correct Answer: D

QUESTION 9

A company is developing a device-drug combination product. Which of the following should be evaluated FIRST in order to determine the applicable guidance documents?

A. Approved indications of the drug

B. Determination of primary mode of action

C. Determination of product design deliverables

D. Guidance documents for the device

Correct Answer: C

QUESTION 10

Which of the following situations does NOT require rapid communication to regulatory authorities?

A. A clinically important increase in the rate of occurrence of an "expected." but serious ADR

B. A lack of efficacy with a medicinal product used in treating a life-threatening disease

C. A major safety finding from a newly completed animal carcinogenicity study

D. A statistically significant increase in the number of deaths in an animal dose finding study

Correct Answer: AD

QUESTION 11

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 12

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

Correct Answer: B

QUESTION 13

During the review of a design dossier, the reviewer asks why the company has only carried out a top-down risk approach. The reviewer is referring to which of the following?

A. ISO 14971 risk analysis

B. Failure mode and effect analysis

C. Fault tree analysis

D. Hazard and operability study

Correct Answer: A

QUESTION 14

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?

A. Local reimbursement requirements

B. Service operation procedures

C. Training program for sales people

D. Written procedure for product traceability

Correct Answer: C

QUESTION 15

According to ICH, how many stability time points are normally required to establish a two- year shelf life for a product?

A. 3

B. 5

C. 7

D. 9

Correct Answer: C