RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 2

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?

A. 100 patients for 12 months

B. 200 patients for nine months

C. 500 patients for three months

D. 3.000 total patient exposures

Correct Answer: A

QUESTION 3

Company X has a patent for an anti-inflammatory drug that will expire in one year. In order to minimize the effect of the patent expiration, which is the BEST action for the company to take?

A. Conduct a Phase III study for a new unrelated indication of the drug.

B. Develop a generic version of the drug.

C. Develop a better brand-name drug in the same class.

D. Explore litigation strategy for patent infringements on the drug.

Correct Answer: B

QUESTION 4

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 5

Company X acquires Company Y. Both companies produce pharmaceuticals distributed globally. A regulatory authority requires that all labeling for Company Y\\'s products be converted to Company X within three months. The regulatory affairs professional at Company X concludes that it is not feasible to meet this request within the time frame.

Which is the FIRST step that the regulatory affairs professional at Company X should take to address the situation?

A. Develop a plan of action with tasks, timelines, and responsibilities and request an extension period from the regulatory authority.

B. Request additional resources from senior management in order to complete the labeling conversion within the time frame given by the regulatory authority.

C. Submit as many labelingconversion applications as possible within the time frame and request an extension for the remaining ones.

D. Convene an urgent meeting with internal stakeholders to inform them of the regulatory authority requirement and assign responsibilities.

Correct Answer: A

QUESTION 6

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?

A. Expiration date

B. Relevance to regulations

C. Revision history

D. Scope and level of detail

Correct Answer: B

QUESTION 7

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 8

A company is preparing the submission package for a drug to be registered in international markets. When preparing the legal documentation, which document MUST comply with the WHO recommendations?

A. Certificate of GMP

B. Certificate of Free Sale

C. Certificate of Pharmaceutical Product

D. Certificate of Analysis for the finished product

Correct Answer: C

QUESTION 9

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 10

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

QUESTION 11

A company establishes a new medical device indication for its consumer disposable products. The regulatory affairs professional is asked to give a 30-minute training session on these products to sales representatives. Which of the following subjects is the MOST important to discuss?

A. Labeling

B. Regulatory application summary

C. Risk management process

D. Safety-related reporting

Correct Answer: A

QUESTION 12

Which of the following is the PRIMARY purpose of an audit report?

A. To carry out a complete review of product applications

B. To define how to prepare new product submissions

C. Todocument compliance history

D. To train sales representatives

Correct Answer: C

QUESTION 13

According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?

A. Deficiency of a device found by the user prior to patient use

B. Adverse event caused by patient conditions

C. Malfunction occurring before the end of service life of the medical device

D. Malfunction protection operated correctly

Correct Answer: BC

QUESTION 14

Following the introduction of a new regulation, an evaluation of the company\\'s products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?

A. Contact the trade association for advice.

B. Communicate with the relevant internal departments.

C. Prepare documents for the files.

D. Request a permanent waiver from the new regulation.

Correct Answer: B

QUESTION 15

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