
**Vendor:** RAPS

**Exam Code:** RAC-GS

**Exam Name:** Regulatory Affairs Certification (RAC) Global Scope

**Q&As:** Demo

**QUESTION 1**
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 2**
A global company is developing a sophisticated implantable medical device that is coated with antibiotics and biologics to enhance its efficacy. The product is marketed in Country X. where it is regulated as a medical device. The same product, without theantibiotics and biologics, is marketed as a medical device in Country Y. The company is proposing to start marketing the coated device in Country Y. Which regulatory approach should the company propose?

A. Submit the product for review as a pharmaceutical product in Country Y.
B. Submit the product as a medical device in Country Y as the product is already marketed in Country X as a medical device.
C. Apply for review of the additional part of the product as a pharmaceutical product in Country
D. Examine decisions made about similar products in Country Y to propose the classification ofthe product.

**Correct Answer:** CD

**QUESTION 3**
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 4**
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 5**
In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

A. Product stability
B. Product registration
C. Product formulation
D. Product requirements

**Correct Answer:** A

**QUESTION 6**
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 7**
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 8**
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 9**
Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

A. "Product X is a guaranteed cure for arthritis."
B. "Product X is effective for the treatment of arthritis."
C. "Product X is safe for arthritis and without side effects."
D. "Product X is effective in all patients with arthritis."

**Correct Answer:** B

**QUESTION 10**
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 11**
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 12**
A company receives multiple complaints regarding the text included on a recently launched product's label. What action should the regulatory affairs professional take FIRST?

A. Recommend an immediate product recall.
B. Compare the approved text with the product label
C. Notify the regulatory authority.
D. Inform the production team.

**Correct Answer:** B

**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**
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 15**
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 16**
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 17**
After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?

A. Resubmit the entire package.
B. Inform upper management immediately.
C. Contact the legal department and ask them how to proceed.
D. Verify the procedure in the regulation for the corrections.

**Correct Answer:** D

**QUESTION 18**
A company is developing a new product for the global market. A new international guideline will recommend relevant studies in the pediatric population, and the guideline will be effective before the approval of the company's new product.

What is the BEST advice the regulatory affairs professional can provide to minimize the impact of this guideline on the successful registration of the new product?

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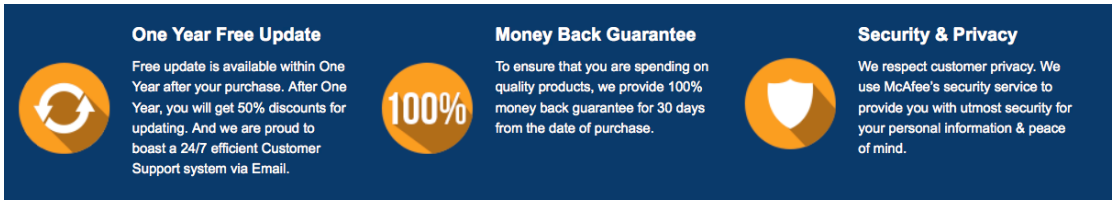


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