Vendor:RAPS

Exam Code:RAC-GS

Exam Name: Regulatory Affairs Certification (RAC) Global Scope

Version: Demo

QUESTION 1

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 2

Which of the following claims would classify an apple as a drug?

A. "It will make you look younger."

B. "It will satisfy hunger."

C. "It will whiten teeth."

D. "It will prevent colds."

Correct Answer: D

QUESTION 3

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 4

A regulatory affairs professional has submitted a package for regulatory review. According to the regulation, the regulatory authority will need to respond within 90 days of submission. If there is no response after the deadline, what is the BEST approach?

A. Contact the regulatory authority, ask for clarification about the delay, and provide answers to any outstanding questions.

B. Contact the regulatory authority, ask for clarification about the delay, and demand a decision be made regarding the submission.

C. Contact the local political representative and ask for intervention with the regulatory authority to obtain a decision regarding the submission.

D. Contact the company legal representative in order to begin legal proceedings to enforce the regulatory authority\\'s response time.

Correct Answer: A

QUESTION 5

What is the LAST stage in the development of a quality risk management process for a medical device?

A. Risk analysis

B. Risk reduction

C. Risk acceptance

D. Risk evaluation

Correct Answer: C

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

A company is developing a new line of products in an area that is new to the company. What is the BEST approach?

A. Ask the trade association representative to provide an overview of the new product area to the marketing team.

B. Obtain competitor research and provide the information to the management team.

C. Obtain regulatory documents and history and provide the information to RandD.

D. Summarize regulatory documents and history and provide the information to the management team.

Correct Answer: D

QUESTION 8

Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?

A. Before the enactment of the regulation, through the industry representative

B. Before the enactment of the regulation, through formal comments gathering process

C. After the enactment of the regulation, through the industry representative

D. After the enactment of the regulation, through a product-specific meeting

Correct Answer: B

QUESTION 9

A superiority advertising claim for a product versus its competitor\\'s product can only be made under which of the following circumstances?

A. In vitro studies show the product to be superior.

B. Government survey data indicate the product is superior.

C. Results of a three-year, post-market patient survey indicate the product is superior.

D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Correct Answer: D

QUESTION 10

A materials supplier informs a company that it intends to stop supplying a material critical to the manufacture of the company\\'s products. What action should the company take FIRST?

A. Review the company\\'s existing Quality ManagementSystem

B. Reformulate the products with a replacement material.

C. Qualify another supplier and execute a supplier agreement.

D. Complete a gap analysis to identify options.

Correct Answer: CD

QUESTION 11

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 12

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