Vendor:RAPS

Exam Code:RAC-US

Exam Name: Regulatory Affairs Certification (RAC) US

Version: Demo

QUESTION 1

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 2

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 3

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?

A. Fishbone analysis

B. Failure modes, effects, and criticality analysis

C. Fault tree analysis

D. Quality by design analysis

Correct Answer: B

QUESTION 4

According to the GHTF IVD guidance, which of the following is the CORRECT classification for a blood glucose self-testing kit?

A. Class A

B. Class B

C. Class C

D. Class D

Correct Answer: C

QUESTION 5

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 6

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 7

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?

A. The company should consult with relevant regulatory authorities to determine the potential impact on the current registration plan.

B. The new guideline has no impact on the current registration plan, but the company must be prepared to defend its decision.

C. The new guideline has no impact on the current registration plan since all relevant registration studies are almost completed.

D. The company should initiate the required pediatric studies immediately to avoid costly delays to the current registration plan.

Correct Answer: AD

QUESTION 8

The requirements for document control are located in which of the following documents?

A. ICH guidelines

B. IEC 60601

C. ISO 13485

D. WHO guidelines

Correct Answer: C

QUESTION 9

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 10

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D

QUESTION 11

The API used for an approved drug product conforms to international monograph specifications and local pharmacopeia; however, the international monograph specifications of the API will be changing soon. Which is the most appropriate action for the regulatory affairs professional to take FIRST?

A. Transfer the notice of the upcoming international monograph change to QA for further processing.

B. Prepare the international monograph change submission first and then prepare the local change when required.

C. Confirm that the international monograph change is not related to local pharmacopeia.

D. Analyze the impact of the international monograph change on the local pharmacopeia.

Correct Answer: AB

QUESTION 12

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