RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?

A. Plasma fractionation

B. Product distribution

C. Individual plasma donation

D. Plasma pooling

Correct Answer: B

QUESTION 2

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 3

In the process of obtaining a product approval, a regulatory affairs professional discovers that the product does not meet one of the specific technical requirements of the regulation. However, competitors with substantially similar products have claimed compliance with the requirement and received approval. Which action should the regulatory affairs professional take FIRST?

A. Discuss with the regulatory apriority and attempt to reach an acceptable solution.

B. Inform the internal departments to redesign the product to comply with this requirement.

C. Inform the regulatory authority that such a requirement is not applicable to the product.

D. Notify senior management that the product cannot be registered.

Correct Answer: A

QUESTION 4

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 5

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