RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

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 2

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

A. Stop product manufacturing.

B. Establish validation procedures.

C. Assess the impact of the changes.

D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 3

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 4

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 5

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