RAC-GS$^{Q\&As}$

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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

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 3

SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?

A. Inadequate training

B. Late and/or incorrect deliverables

C. Causes of non-conformities

D. Adverse environmental impacts

Correct Answer: C

QUESTION 4

GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?

A. Instructions for use

B. Risk analysis

C. Product literature

D. Essential principles

Correct Answer: BD

QUESTION 5

During several monitoring visits, a clinical trial monitor identifies serious and repeated noncompliance on the part of the PI. What action should the sponsor take?

A. Increase the frequency of monitoring visits.

B. Inform the institution that granted a medical license to the Pi.

C. Send a letter of complaint to the Ethics Committee that approved the site.

D. Terminate the PI and inform the regulatory authorities.

Correct Answer: D