RAC-GS Q&As

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QUESTION 1

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC

QUESTION 2

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 3

According to ISO 14971,what is the FIRST step when developing a risk management plan for a medical device?

A. Risk estimation

B. Risk analysis

C. Risk control

D. Risk management

Correct Answer: B

QUESTION 4

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 5

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?

A. Specification

B. Formulation

C. Property

D. Justification

Correct Answer: D