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

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

During an audit of a contract manufacturing facility by a potential client, the auditor requested to be left alone in the records room. The records room contains information on all products produced by the contract manufacturer.

Which action is MOST appropriate for the regulatory affairs professional to take?

A. Allow the auditor access to the room and records due to the current audit.

B. Allow the auditor accompanied access to the room to retrieve the records.

C. Deny the auditor access to the room and retrieve only the requested records.

D. Deny the auditor access to the room and records due to confidentiality concerns.

Correct Answer: B

QUESTION 2

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 3

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

A. A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation

B. A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use

C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product

D. A brief summary of relevant physical, chemical, and pharmaceutical properties: instructions for storage and handling of the dosage form: and a description of the formulation

Correct Answer: D

QUESTION 4

Which of the following is the BEST approach for mitigating potential regulatory compliance issues at your company?

A. Document any failure to follow regulatory compliance processes in employee performancereviews.

B. Develop documented procedures for regulatory compliance processes and train personnel.

C. Train all new employees on regulatory compliance processes and assign a mentor to them.

D. Train employees on all regulatory compliance processes using state-of-the-art systems.

Correct Answer: B

QUESTION 5

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?

A. Expiration date

B. Relevance to regulations

C. Revision history

D. Scope and level of detail

Correct Answer: B