RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

At a recent scientific meeting,Company Y had two booths:

At one booth,Company Y provided brochures on a completed Phase II study.

In an adjacent booth, Company Y\\'s sales professionals were promoting one of Company Y\\'s marketed products.

A regulatory affairs-professional at Company X sends a letter to a counterpart at Company Y requesting that Company Y stop this practice in the future and demanding a formal response to the letter. How should the regulatory affairs professional at Company Y BEST respond?

A. Acknowledge receipt of the letter in a written response but do nothing further.

B. Inform the legal department of the letter and discuss how to respond.

C. Inform Company X that it has no right to send such a letter and do nothing further.

D. Inform the local regulatory authority of the letter and discuss how to respond.

Correct Answer: BD

QUESTION 2

A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?

A. The ISO national member body

B. The ISO technical committee in charge of the area

C. The ISO Secretariat

D. The country\\'s regulatory authority

Correct Answer: AD

QUESTION 3

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

QUESTION 4

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 5

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