



# RAC-GS<sup>Q&As</sup>

Regulatory Affairs Certification (RAC) Global Scope

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#### QUESTION 1

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

- A. Production
- B. Analytical
- C. Quality
- D. Regulatory

Correct Answer: CD

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#### QUESTION 2

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

- A. Subject is hospitalized due to complications of the product administration.
- B. Subject is hospitalized for the purpose of product administration.
- C. Subject's hospitalization is due to an unscheduled hip operation.
- D. Subject's hospitalization is prolonged during the clinical trial.

Correct Answer: BC

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#### QUESTION 3

During the review of a design dossier, the reviewer asks why the company has only carried out a top-down risk approach. The reviewer is referring to which of the following?

- A. ISO 14971 risk analysis
- B. Failure mode and effect analysis
- C. Fault tree analysis
- D. Hazard and operability study

Correct Answer: A

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#### 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

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#### QUESTION 5

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 performance reviews.
- 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

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