



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

Regulatory Affairs Certification (RAC) US

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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

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### QUESTION 2

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

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### QUESTION 3

Which of the following is NOT required to be included in a marketing application?

- A. Final printed label
- B. Quality, safety, and efficacy Information
- C. Administrative forms
- D. Evidence of fee payment

Correct Answer: D

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### QUESTION 4

According to ICH, what is the MAXIMUM amount of time in calendar days that an organization has from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?



A. 3

B. 5

C. 10

D. 15

Correct Answer: BCD

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#### QUESTION 5

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

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