RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

A company receives multiple complaints regarding the text included on a recently launched product\\'s label. What action should the regulatory affairs professional take FIRST?

A. Recommend an immediate product recall.

B. Compare the approved text with the product label

C. Notify the regulatory authority.

D. Inform the production team.

Correct Answer: B

QUESTION 2

A global company has obtained a patent in a specific country for a newly marketed product. What would be the BEST advice In order to protect the patent in other countries?

A. Use the Madrid system.

B. Use the community patent system.

C. File patents of interest in target countries.

D. File design patents in target countries.

Correct Answer: C

QUESTION 3

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

QUESTION 4

The requirements for document control are located in which of the following documents?

A. ICH guidelines

B. IEC 60601

C. ISO 13485

D. WHO guidelines

Correct Answer: C

QUESTION 5

In preparation for the development of a new line of products, a regulatory affairs professional is asked to prepare a short presentation for senior management. Which of the following topics is MOST important to cover?

A. Potential clinical sites for the Phase III clinical trial

B. Regulatory requirements for labeling and packaging

C. Capacity of the manufacturing facilities to fully produce the new product

D. Previous actions taken by regulatory authorities on similar products

Correct Answer: D