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QUESTION 1

According to ICH, what is the MAXIMUM amount of timein calendar days that anorganizationhas 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

QUESTION 2

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 3

Which of the following statements regarding the off-label use of drugs is CORRECT?

A. Although the regulatory authority reviews and approves drugs for specific indications, theapproval does not limit the use of those drugs in clinical practice.

B. The regulatory authority does not restrict physician prescribing for off-label indications orregulate the manufacturer\\'s promotion for such use.

C. Sponsors are allowed to distribute publications about unapproved uses of approved drugs and devices as long as the marketing application is under review by the regulatory authority.

D. The peer-reviewed literature can ensure high-quality off-label promotion of medications, thereby increasing accessto much needed drugs and devices.

Correct Answer: A

QUESTION 4

A company\\'s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product. To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 5

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