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Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?

- A. 100 patients for 12 months
- B. 200 patients for nine months
- C. 500 patients for three months
- D. 3.000 total patient exposures

Correct Answer: A

QUESTION 2

According to ISO 14971, what is the FIRST step when developing a risk management plan for a medical device?

- A. Risk estimation
- B. Risk analysis
- C. Risk control
- D. Risk management

Correct Answer: B

QUESTION 3

As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?

- A. Site license
- B. Product license
- C. Import license
- D. Export license

Correct Answer: A

QUESTION 4

A company is currently marketing an implantable orthopedic medical device. The RandD department is planning to change the material used for the implant. The RandD department states that the change does not impact the safety and

effectiveness of the product.

What action should the regulatory affairs professional take FIRST?

- A. No action is needed in this situation.
- B. Prepare regulatory submissions that detail the medical device's change in materials.
- C. Review the content of change and supporting data for the equivalency with the current material.
- D. Write a memo to file since the change does not impact product safety and effectiveness.

Correct Answer: C

QUESTION 5

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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