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QUESTION 1

A regulation change is imminent and may require further non-clinical testing on a product currently in Phase III clinical trials. What is the most appropriate action to take FIRST?

- A. Obtain a copy of the proposed regulation and analyze the impact.
- B. Inform the company's senior management and arrange an emergency meeting
- C. Consult with the company's legal department regarding options.
- D. Arrange for additional testing of the product at the testing facility.

Correct Answer: A

QUESTION 2

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?

- A. Plasma fractionation
- B. Product distribution
- C. Individual plasma donation
- D. Plasma pooling

Correct Answer: B

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

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

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

- A. Intellectual property
- B. Clinical trial data
- C. Safety issues
- D. Marketing materials

Correct Answer: C

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