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QUESTION 1

Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?

A. Proposed dose and volume of administration

B. Biological activity with species and/or tissue specificity

C. Immunochemical and functional tests

D. Proposed product route and frequency of administration

Correct Answer: B

QUESTION 2

An inspection of a manufacturing site determines that a number of manufacturing changes have been implemented without obtaining the necessary regulatory clearance. Which of the following actions should the regulatory affairs professional complete FIRST?

A. Stop product manufacturing.

B. Establish validation procedures.

C. Assess the impact of the changes.

D. Review the stability data for the changes.

Correct Answer: AC

QUESTION 3

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 4

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

QUESTION 5

At a recent scientific meeting,Company Y had two booths:

At one booth,Company Y provided brochures on a completed Phase II study.

In an adjacent booth, Company Y\\'s sales professionals were promoting one of Company Y\\'s marketed products.

A regulatory affairs-professional at Company X sends a letter to a counterpart at Company Y requesting that Company Y stop this practice in the future and demanding a formal response to the letter. How should the regulatory affairs professional at Company Y BEST respond?

A. Acknowledge receipt of the letter in a written response but do nothing further.

B. Inform the legal department of the letter and discuss how to respond.

C. Inform Company X that it has no right to send such a letter and do nothing further.

D. Inform the local regulatory authority of the letter and discuss how to respond.

Correct Answer: BD