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QUESTION 1

A regulatory authority announces an inspection of a regulatory affairs professional\\'s facility during a holiday season when most of the staff Is not available. What is the MOST practical approach to this dilemma?

A. Negotiate with colleagues and the authority to find a better time.

B. Insist that key personnel be available for the inspection.

C. Inform the authority that the time is not suitable and request a new time

D. Arrange for an inspection without all intended personnel.

Correct Answer: A

QUESTION 2

Which of the following double-blind clinical trial designs would be MOST appropriate for a Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?

A. Active-controlled

B. Cross-over

C. Dose-ranging

D. Placebo-controlled

Correct Answer: B

QUESTION 3

During new drug development, a new impurity in the drug substance is detected at a level of 0.12%. The intended maximum daily dose Is less than 2 g/day, and the drug Is known generally not to be toxic.

What should be done in response to identifying the impurity?

A. Perform either an identification study or a non-clinical qualification study.

B. Perform both identification and non-clinical qualification studies concurrently.

C. Perform an identification study, wait until the result is available, and then consider performing a non-clinical qualification study.

D. Perform a non-clinical qualification study, wait until the result is available, and then consider performing an identification study.

Correct Answer: C

QUESTION 4

Following the introduction of a new regulation, an evaluation of the company\\'s products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?

A. Contact the trade association for advice.

B. Communicate with the relevant internal departments.

C. Prepare documents for the files.

D. Request a permanent waiver from the new regulation.

Correct Answer: B

QUESTION 5

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