RAC-GS$^{Q\&As}$

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?

A. Deficiency of a device found by the user prior to patient use

B. Adverse event caused by patient conditions

C. Malfunction occurring before the end of service life of the medical device

D. Malfunction protection operated correctly

Correct Answer: BC

QUESTION 2

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 nonclinical 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 3

A process is ultimately validated to ensure which of the following?

A. The process meets the regulatory requirements.

B. The process meets the quality system requirements.

C. The process consistently produces the desired results.

D. The process consistently meets the desiredQuantity standards

Correct Answer: C

QUESTION 4

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 5

After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?

A. Resubmit the entire package.

B. Inform upper management immediately.

C. Contact the legal department and ask them how to proceed.

D. Verify the procedure in the regulation for the corrections.

Correct Answer: D