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**QUESTION 1**

During routine surveillance, a regulatory authority sent a company the following communication: "Hepatotoxicity and suicidal behavior were identified as potential safety issues for the company's product. The regulatory authority is evaluating these issues to determine the need for any regulatory action." Which action would be the most appropriate FIRST step for the company to take?

- A. Contact the regulatory authority to argue that its conclusions are wrong.
- B. Contact the regulatory authority to discuss its findings.
- C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.
- D. Wait for the regulatory authority's final publication on its findings.

Correct Answer: B

QUESTION 2

Under which of the following circumstances would a regulatory authority require a more detailed premarket submission, a more rigorous audit, and/or the provision of more performance evaluation data than would normally apply to an IVD device of that risk class?

- A. The device is an updated version of a compliant device from the same manufacturer and contains no substantive change.
- B. Internationally recognized standards are available to cover the main aspects of the device and have been used by the manufacturer.
- C. The manufacturer's experience level with the type of IVD medical device is limited.
- D. The device incorporates well-established technology that is already present in the market.

Correct Answer: C

QUESTION 3

What is the LAST stage in the development of a quality risk management process for a medical device?

- A. Risk analysis
- B. Risk reduction
- C. Risk acceptance
- D. Risk evaluation

Correct Answer: C



QUESTION 4

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

- A. Concept development and validation
- B. Concept development and early technical design
- C. Early technical design and product release
- D. Product release and validation

Correct Answer: B

QUESTION 5

Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?

- A. Before the enactment of the regulation, through the industry representative
- B. Before the enactment of the regulation, through formal comments gathering process
- C. After the enactment of the regulation, through the industry representative
- D. After the enactment of the regulation, through a product-specific meeting

Correct Answer: B

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