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QUESTION 1

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 2

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 3

A materials supplier informs a company that it intends to stop supplying a material critical to the manufacture of the company\\'s products. What action should the company take FIRST?

A. Review the company\\'s existing Quality ManagementSystem

B. Reformulate the products with a replacement material.

C. Qualify another supplier and execute a supplier agreement.

D. Complete a gap analysis to identify options.

Correct Answer: CD

QUESTION 4

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

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