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QUESTION 1

A company is developing a device-drug combination product. Which of the following should be evaluated FIRST in order to determine the applicable guidance documents?

A. Approved indications of the drug

B. Determination of primary mode of action

C. Determination of product design deliverables

D. Guidance documents for the device

Correct Answer: C

QUESTION 2

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 3

According to the GHTF IVD guidance, which of the following is the CORRECT classification for a blood glucose self-testing kit?

A. Class A

B. Class B

C. Class C

D. Class D

Correct Answer: C

QUESTION 4

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 5

One month prior to the anticipated approval date for your product, the marketing application that you submitted to a major regulatory authority has become the subject of an advisory committee meeting of experts convened by the regulatory authority. The advisory committee members unanimously vote not to approve your product because of a safety concern. Two days after the advisory committee meeting, the regulatory authority requests additional information to support the safety of your product. Assuming you have no additional data to provide, which of the following would be your MOST appropriate response to the regulatory authority\\'s request?

A. "Given the advisory committee\\'s unanimous decision, we know that the product will not be approved, and additional data will not make any difference."

B. "We have no additional informationto provide at this time, but wecan perform an additional analysis for a specific safety concern, if necessary."

C. "We disagree with the advisory committee\\'s decision because the committee neglected the thorough safety analysis that we provided."

D. "We have no additional information to provide at this time because we have already provided everything needed to support our product\\'s approval."

Correct Answer: B