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QUESTION 1

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 2

Company X acquires Company Y. Both companies produce pharmaceuticals distributed globally. A regulatory authority requires that all labeling for Company Y\\'s products be converted to Company X within three months. The regulatory affairs professional at Company X concludes that it is not feasible to meet this request within the time frame.

Which is the FIRST step that the regulatory affairs professional at Company X should take to address the situation?

A. Develop a plan of action with tasks, timelines, and responsibilities and request an extension period from the regulatory authority.

B. Request additional resources from senior management in order to complete the labeling conversion within the time frame given by the regulatory authority.

C. Submit as many labelingconversion applications as possible within the time frame and request an extension for the remaining ones.

D. Convene an urgent meeting with internal stakeholders to inform them of the regulatory authority requirement and assign responsibilities.

Correct Answer: A

QUESTION 3

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 4

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

A. Safety and failure risk

B. Safety and effectiveness

C. Quality and failure risk

D. Quality and effectiveness

Correct Answer: B

QUESTION 5

The manufacturer of an API was changed from Company X to Company Y during the late stage of a new drug development. Despite differences in the manufacturing processes of the companies, both APIs meet the current specifications. Which is the MOST appropriate information to include in the final submission documents?

A. The process information and analytical result of Company X API

B. The process information and analytical result of Company Y API

C. The process information and the comparative analytical result of APIs from both companies

D. Information deemed appropriate by the regulatory authority

Correct Answer: C