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QUESTION 1

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

QUESTION 2

A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?

A. Expiration date

B. Relevance to regulations

C. Revision history

D. Scope and level of detail

Correct Answer: B

QUESTION 3

A company is developing a novel drug to combat AIDS. The preliminary results are very promising and include instances of complete remission. The company has been granted patents in multiple countries for the drug. The regulatory affairs professional is asked to prepare a brief report concerning potential problems for marketing of the product worldwide. Which of the following is the MOST important consideration to discuss?

A. Doha Declaration in the TRIPS Agreement

B. The stability of the drug in all zone conditions

C. The time frame in which the patent will expire

D. International import and export regulations

Correct Answer: B

QUESTION 4

A company is developing a new product for the global market. A new international guideline will recommend relevant studies in the pediatric population, and the guideline will be effective before the approval of the company\\'s new product. What is the BEST advice the regulatory affairs professional can provide to minimize the impact of this guideline on the successful registration of the new product?

A. The company should consult with relevant regulatory authorities to determine the potential impact on the current registration plan.

B. The new guideline has no impact on the current registration plan, but the company must be prepared to defend its decision.

C. The new guideline has no impact on the current registration plan since all relevant registration studies are almost completed.

D. The company should initiate the required pediatric studies immediately to avoid costly delays to the current registration plan.

Correct Answer: AD

QUESTION 5

A regulation change is imminent and may require further non-clinical testing on a product currently in Phase III clinical trials. What is the most appropriate action to take FIRST?

A. Obtain a copy of the proposed regulation and analyze the impact.

B. Inform the company\\'s senior management and arrange an emergency meeting

C. Consult with the company\\'s legal department regarding options.

D. Arrange for additional testing of the product at the testing facility.

Correct Answer: A