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QUESTION 1

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 2

Company X and Company Y both have products for the treatment of rare genetic diseases. Company X would like to acquire Company Y but does not know enough about Company Y to make an offer. What is the MOST appropriate approach that Company X should take to acquire more information about Company Y?

A. Enter into an agreement with Company Y to perform due diligence.

B. Recruit a professional to gather confidential intelligence on Company Y.

C. Request the needed information from the Board of Directors of Company Y.

D. Perform a thorough library search to gather detailed information on Company Y.

Correct Answer: A

QUESTION 3

GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?

A. Instructions for use

B. Risk analysis

C. Product literature

D. Essential principles

Correct Answer: BD

QUESTION 4

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 5

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 6

A regulatory affairs professional has submitted a package for regulatory review. According to the regulation, the regulatory authority will need to respond within 90 days of submission. If there is no response after the deadline, what is the BEST approach?

A. Contact the regulatory authority, ask for clarification about the delay, and provide answers to any outstanding questions.

B. Contact the regulatory authority, ask for clarification about the delay, and demand a decision be made regarding the submission.

C. Contact the local political representative and ask for intervention with the regulatory authority to obtain a decision regarding the submission.

D. Contact the company legal representative in order to begin legal proceedings to enforce the regulatory authority\\'s response time.

Correct Answer: A

QUESTION 7

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC

QUESTION 8

A global company is developing a sophisticated implantable medical device that is coated with antibiotics and biologics to enhance its efficacy. The product is marketed in Country X. where it is regulated as a medical device. The same product, without theantibiotics and biologics, is marketed as a medical device in Country Y. The company is proposing to start marketing the coated device in Country Y. Which regulatory approach should the company propose?

A. Submit the product for review as a pharmaceutical product in Country Y.

B. Submit the product as a medical device in Country Y as the product is already marketed in Country X as a medical device.

C. Apply for review of the additional part of the product as a pharmaceutical product in Country

D. Examine decisions made about similar products in Country Y to propose the classification ofthe product.

Correct Answer: CD

QUESTION 9

During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product Is distributed globally. Which of the following is the most appropriate action to take FIRST?

A. Withdraw the affected product from the markets.

B. Send a "Dear Dr." letter to customers.

C. Notify the global regulatory authorities.

D. Assess the potential safety risk.

Correct Answer: C

QUESTION 10

During several monitoring visits, a clinical trial monitor identifies serious and repeated noncompliance on the part of the PI. What action should the sponsor take?

A. Increase the frequency of monitoring visits.

B. Inform the institution that granted a medical license to the Pi.

C. Send a letter of complaint to the Ethics Committee that approved the site.

D. Terminate the PI and inform the regulatory authorities.

Correct Answer: D

QUESTION 11

You discover that your company\\'s top selling product in the last two years has been used off-label. The off-label use is estimated to be about 70%, and it has been consistent since the product was first released to the market. Which of the following is MOST appropriate?

A. Discuss with regulatory authorities to investigate how to have the off-label indication approved.

B. No action is required since it is an off-label use.

C. Advise the senior management to send a "Dear Dr." letter.

D. File a report to regulatory authorities and advise the marketing department to prevent future off-label use.

Correct Answer: A

QUESTION 12

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 13

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 14

Which analysis method is MOST appropriate to prioritize risk and monitor the effectiveness of risk control activities for a medical device?

A. Fishbone analysis

B. Failure modes, effects, and criticality analysis

C. Fault tree analysis

D. Quality by design analysis

Correct Answer: B

QUESTION 15

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D