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QUESTION 1

According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?

A. Deficiency of a device found by the user prior to patient use

B. Adverse event caused by patient conditions

C. Malfunction occurring before the end of service life of the medical device

D. Malfunction protection operated correctly

Correct Answer: BC

QUESTION 2

As a member of the product launch review committee, a regulatory affairs professional discovers a major issue with the labeling of a product prior to production. In addition to informing the committee, which is the BEST approach to address the issue?

A. Inform the regulatory authorities.

B. Delay the start of product production.

C. Correct the label text.

D. Abort the product launch.

Correct Answer: A

QUESTION 3

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 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 NOT required to be included in a marketing application?

A. Final printed label

B. Quality, safety, and efficacy Information

C. Administrative forms

D. Evidence of fee payment

Correct Answer: D

QUESTION 6

Following the introduction of a new regulation, an evaluation of the company\\'s products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?

A. Contact the trade association for advice.

B. Communicate with the relevant internal departments.

C. Prepare documents for the files.

D. Request a permanent waiver from the new regulation.

Correct Answer: B

QUESTION 7

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

A. Intellectual properly

B. Clinical trial data

C. Safety issues

D. Marketing materials

Correct Answer: C

QUESTION 8

A company is currently marketing an implantable orthopedic medical device. The RandD department is planning to change the material used for the implant. The RandD department states that the change does not impact the safety and effectiveness of the product.

What action should the regulatory affairs professional take FIRST?

A. No action is needed in this situation.

B. Prepare regulatory submissions that detail the medical device\\'s change in materials.

C. Review the content of change and supporting data for the equivalency with the current material.

D. Write a memo to file since the change does not impact product safety and effectiveness.

Correct Answer: C

QUESTION 9

Which question is pertinent to demonstrate a new pharmaceutical\\'s effectiveness during evaluation by a reimbursement agency?

A. "Is the product profitable for the manufacturer?"

B. "Is the product better than currently available alternatives?"

C. "Has the product been approved for morand4nan 10 years?"

D. "Is the product an established gold standard?"

Correct Answer: B

QUESTION 10

A regulatory authority announces an inspection of a regulatory affairs professional\\'s facility during a holiday season when most of the staff Is not available. What is the MOST practical approach to this dilemma?

A. Negotiate with colleagues and the authority to find a better time.

B. Insist that key personnel be available for the inspection.

C. Inform the authority that the time is not suitable and request a new time

D. Arrange for an inspection without all intended personnel.

Correct Answer: A

QUESTION 11

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 12

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

QUESTION 13

Which of the following double-blind clinical trial designs would be MOST appropriate for a Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?

A. Active-controlled

B. Cross-over

C. Dose-ranging

D. Placebo-controlled

Correct Answer: B

QUESTION 14

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 15

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

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