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QUESTION 1

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 2

A company is developing a new medical device using innovative technology. Which of the following is MOST critical in working with regulatory authorities?

A. Documented agreement

B. Frequent communication

C. Early collaboration

D. Follow-up meeting after submission

Correct Answer: B

QUESTION 3

According to the ICH guideline on GMP for API,to which of the following is the MOST stringent requirement applied?

A. Physical processing and packaging

B. Isolation and purification

C. Production of Intermediate(s)

D. Introduction of the API starting material

Correct Answer: A

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

Which of the following situations does NOT require rapid communication to regulatory authorities?

A. A clinically important increase in the rate of occurrence of an "expected." but serious ADR

B. A lack of efficacy with a medicinal product used in treating a life-threatening disease

C. A major safety finding from a newly completed animal carcinogenicity study

D. A statistically significant increase in the number of deaths in an animal dose finding study

Correct Answer: AD

QUESTION 6

Company X encounters challenges in the global life cycle management of its medical devices. Which of the following Is MOST appropriate for improving product life cycle management?

A. Utilize the STED template to complete global requirements.

B. Initiate a global submission process after all submission data are finalized.

C. Identify countries where special requirements exist during the product development phase.

D. Plan regulatory approval update meetings with senior management and stakeholders.

Correct Answer: C

QUESTION 7

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 8

A company receives multiple complaints regarding the text included on a recently launched product\\'s label. What action should the regulatory affairs professional take FIRST?

A. Recommend an immediate product recall.

B. Compare the approved text with the product label

C. Notify the regulatory authority.

D. Inform the production team.

Correct Answer: B

QUESTION 9

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 10

A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?

A. The ISO national member body

B. The ISO technical committee in charge of the area

C. The ISO Secretariat

D. The country\\'s regulatory authority

Correct Answer: AD

QUESTION 11

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 12

Which of the following changes to a drug product is MOST likely to be implemented without prior regulatory authority approval?

A. Deleting an ingredient of the drug product

B. Deleting a drug substance

C. Introducing a new analytical method

D. Strengthening a precaution to the product labeling

Correct Answer: D

QUESTION 13

During face-to-face meetings with the regulatory authority to address submission issues, what is the BEST choice for the number of company representatives who should attend?

A. The minimum number of attendees necessary to address the issues

B. All senior management from the main office

C. As many as government attendees

D. As many as required by international standards

Correct Answer: A

QUESTION 14

Which of the following is the PRIMARY purpose of an audit report?

A. To carry out a complete review of product applications

B. To define how to prepare new product submissions

C. Todocument compliance history

D. To train sales representatives

Correct Answer: C

QUESTION 15

During routine surveillance, a regulatory authority sent a company the following communication: "Hepatotoxicity and suicidal behavior were identified as potential safety issues for the company\\'s product. The regulatory authority is evaluating these issues to determine the need for any regulatory action." Which action would be the most appropriate FIRST step for the company to take?

A. Contact the regulatory authority to argue that its conclusions are wrong.

B. Contact the regulatory authority to discuss its findings.

C. Repeat the Hepatotoxicity tests and send the results to the regulatory authority.

D. Wait for the regulatory authority\\'s final publication on its findings.

Correct Answer: B