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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 preparing the submission package for a drug to be registered in international markets. When preparing the legal documentation, which document MUST comply with the WHO recommendations?

A. Certificate of GMP

B. Certificate of Free Sale

C. Certificate of Pharmaceutical Product

D. Certificate of Analysis for the finished product

Correct Answer: C

QUESTION 3

According to ICH, how many stability time points are normally required to establish a two- year shelf life for a product?

A. 3

B. 5

C. 7

D. 9

Correct Answer: C

QUESTION 4

Which of the following is the BEST approach for mitigating potential regulatory compliance issues at your company?

A. Document any failure to follow regulatory compliance processes in employee performancereviews.

B. Develop documented procedures for regulatory compliance processes and train personnel.

C. Train all new employees on regulatory compliance processes and assign a mentor to them.

D. Train employees on all regulatory compliance processes using state-of-the-art systems.

Correct Answer: B

QUESTION 5

At a recent scientific meeting,Company Y had two booths:

At one booth,Company Y provided brochures on a completed Phase II study.

In an adjacent booth, Company Y\\'s sales professionals were promoting one of Company Y\\'s marketed products.

A regulatory affairs-professional at Company X sends a letter to a counterpart at Company Y requesting that Company Y stop this practice in the future and demanding a formal response to the letter. How should the regulatory affairs professional at Company Y BEST respond?

A. Acknowledge receipt of the letter in a written response but do nothing further.

B. Inform the legal department of the letter and discuss how to respond.

C. Inform Company X that it has no right to send such a letter and do nothing further.

D. Inform the local regulatory authority of the letter and discuss how to respond.

Correct Answer: BD

QUESTION 6

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 7

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?

A. 100 patients for 12 months

B. 200 patients for nine months

C. 500 patients for three months

D. 3.000 total patient exposures

Correct Answer: A

QUESTION 8

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?

A. Plasma fractionation

B. Product distribution

C. Individual plasma donation

D. Plasma pooling

Correct Answer: B

QUESTION 9

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 10

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 11

The API used for an approved drug product conforms to international monograph specifications and local pharmacopeia; however, the international monograph specifications of the API will be changing soon. Which is the most appropriate action for the regulatory affairs professional to take FIRST?

A. Transfer the notice of the upcoming international monograph change to QA for further processing.

B. Prepare the international monograph change submission first and then prepare the local change when required.

C. Confirm that the international monograph change is not related to local pharmacopeia.

D. Analyze the impact of the international monograph change on the local pharmacopeia.

Correct Answer: AB

QUESTION 12

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

A. "Product X is a guaranteed cure for arthritis."

B. "Product X is effective for the treatment of arthritis."

C. "Product X is safe for arthritis and without side effects."

D. "Product X is effective in all patients with arthritis."

Correct Answer: B

QUESTION 13

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 14

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 15

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

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