RAC-GS Q&As

Regulatory Affairs Certification (RAC) Global Scope

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QUESTION 1

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?

A. Allow doctors to use the product for the off-label indication.

B. Communicate with the sales department to stop using the promotional materials.

C. Contact the marketing department to recall the product.

D. Request that doctors stop using the product for the off-label indication.

Correct Answer: B

QUESTION 2

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 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

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 5

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