RAC-GS Q&As

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QUESTION 1

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

QUESTION 2

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 3

What is the LAST stage in the development of a quality risk management process for a medical device?

A. Risk analysis

B. Risk reduction

C. Risk acceptance

D. Risk evaluation

Correct Answer: C

QUESTION 4

According to ISO 14971,what is the FIRST step when developing a risk management plan for a medical device?

A. Risk estimation

B. Risk analysis

C. Risk control

D. Risk management

Correct Answer: B

QUESTION 5

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