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QUESTION 1

After numerous failed attempts to decrease an identified risk in a medical device to an acceptable level, the medical device continues to have unacceptable risks. However, the development team wants to continue development. Which is the BEST recommendation to make in this situation?

A. Add a warning in the IFU.

B. Discontinue the project.

C. Perform another risk-benefit analysis.

D. Redesign the device.

Correct Answer: D

QUESTION 2

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

QUESTION 3

During the review of a design dossier, the reviewer asks why the company has only carried out a top-down risk approach. The reviewer is referring to which of the following?

A. ISO 14971 risk analysis

B. Failure mode and effect analysis

C. Fault tree analysis

D. Hazard and operability study

Correct Answer: A

QUESTION 4

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D

QUESTION 5

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