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QUESTION 1

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 2

A materials supplier informs a company that it intends to stop supplying a material critical to the manufacture of the company\\'s products. What action should the company take FIRST?

A. Review the company\\'s existing Quality ManagementSystem

B. Reformulate the products with a replacement material.

C. Qualify another supplier and execute a supplier agreement.

D. Complete a gap analysis to identify options.

Correct Answer: CD

QUESTION 3

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

Correct Answer: B

QUESTION 4

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC

QUESTION 5

The regulatory authority contacts the regulatory affairs professional regarding a complaint about a drug produced by the company. A consumer reported to the regulatory authority that the tablets have a slightly different color and break easily.

Which of the following actions should the regulatory affairs professional take?

A. Ask that the regulatory authority provide the batch number printed on the packaging of the affected product.

B. Ask that the regulatory authority provide the actual product subject to the complaint.

C. Respond to the regulatory authority that the product subject to the complaint is most likely acounterfeit product.

D. Respond to the regulatory authority that the company will provide copies of the relevant QCrecords for batch release.

Correct Answer: A

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