FRA Sample Questions

What is typically considered a "combination product"?

a. A medical device that is used with a separate pharmaceutical product but sold independently.
b. A product that combines a medical device with a drug or biological product.
c. A medical device that can be used for different medical conditions.

In what way do Design Verification and Risk Management collectively contribute to the safety of medical devices?

a. Design Verification ensures that devices are produced as intended, while Risk Management identifies the conditions under which the device will fail.
b. Design Verification confirms that the device design meets specified requirements, while Risk Management identifies and mitigates potential hazards.
c. Both processes focus solely on the user acceptance of the device.

What are Active Pharmaceutical Ingredients?

a. The ingredients that are used to manufacture drug substances.
b. The ingredients that are responsible for the drug's therapeutic effect.
c. The ingredients that improve the effectiveness of the drug.

How does the New Drug Submission differ from an Abbreviated New Drug Submission?

a. Abbreviated New Drug Submission demonstrates bioequivalence to an approved product; a New Drug Submission applies to innovator products.
b. Abbreviated New Drug Submission allows for an abbreviated approval process; a New Drug Submission does not.
c. Abbreviated New Drug Submission is used for approval of orphan drugs; a New Drug Submission is used for other drugs.