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ASQ Certified Pharmaceutical GMP Professional Sample Questions (Q415-Q420):

NEW QUESTION # 415

Critical Process Parameters (CPPs) are defined as:

Response:

- A. Parameters having an insignificant effect on CQAs
- B. Parameters that can be adjusted without impact on product quality
- C. Parameters only relevant during the initial stages of production
- D. Parameters that must be maintained to ensure CQAs are within specified limits

Answer: D

NEW QUESTION # 416

Which of the following are valid environmental monitoring tools?

(Select two)

Response:

- A. Viable particulate measuring instruments
- B. Employee satisfaction surveys
- C. Nonviable particulate measuring instruments
- D. Financial performance tracking software

Answer: A,C

NEW QUESTION # 417

Which of the following is an example of a critical quality attribute?

Response:

- A. The product name
- B. Sterility for injectable products
- C. The font used on the product label
- D. The color of the tablet coating

Answer: B

NEW QUESTION # 418

ICH Q7 provides guidance specifically for:

Response:

- A. Good Manufacturing Practice
- B. Good Distribution Practice
- C. Good Laboratory Practice
- D. Good Clinical Practice

Answer: A

NEW QUESTION # 419

What objectives are achieved through Performance Qualification (PQ) of equipment and utilities?

(Choose two)

Response:

- A. Ensuring equipment can be operated via remote control
- B. Demonstrating compliance with regulatory and user requirements over time

- Answer: B,D**

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- [illegible]

