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FAQ #13

What recommendations do the Exam Champions have for the people studying for and taking the CPGP Exam?

Obtain and study from the reference documents. The following 10 references are the most important:

- 1) 21CFR 211
- 2) EC GMPs Annex 1
- 3) ICH Q10--Quality Systems
- 4) FDA 2004 Guidance "Changes to an NDA/ANDA"
- 5) ICH Q7
- 6) USP General Notices
- 7) USP <1058>
- 8) World Health Organization GMPs
- 9) FDA Guide on Inspection of Water Systems
- 10) FDA Guidance on Aseptic Processing



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ASQ Certified Pharmaceutical GMP Professional Sample Questions (Q127-Q132):

NEW QUESTION # 127

Specification limits should be:Response:

- A. Tailored to meet registration or compendial requirements
- B. Determined by the marketing department
- C. The same for every product, regardless of its use
- D. Based on historical sales data

Answer: A

NEW QUESTION # 128

In the context of sampling processes, why is it necessary to ensure sampling utensils are appropriately cleaned or are single-use?
Response:

- A. To make the cleaning process more challenging
- **B. To prevent cross-contamination and ensure accurate sampling results**
- C. To comply with employee preferences
- D. To increase the aesthetic appeal of the sampling process

Answer: B

NEW QUESTION # 129

Terminal sterilization CPPs include:Response:

- A. The design of the product label
- B. The brand of equipment used
- C. The music played in the production area
- **D. Time, temperature, and sterilant concentration**

Answer: D

NEW QUESTION # 130

Which stock rotation methods are used to minimize the risk of using expired or outdated materials?
(Choose two)

Response:

- **A. First-in/first-out (FIFO)**
- B. Last-in/first-out (LIFO)
- C. Most-expensive/first-out (MEFO)
- **D. First-expired/first-out (FEFO)**

Answer: A,D

NEW QUESTION # 131

Reviewing compendial or non-compendial requirements is critical for ensuring:(Choose two) Response:

- **A. Procedures are in place for both qualification and validation.**
- **B. Test methods are aligned with required compendial chapters.**
- C. The laboratory's social media presence is enhanced.
- D. Tests are chosen based on the laboratory's location.

Answer: A,B

NEW QUESTION # 132

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