

ASQ CPGP

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Question: 1

The process of compendial methods review typically includes:
Response:

- A. Ignoring the method's relevance to the product being tested.
- B. Verifying the method's suitability and performance for the intended use.
- C. Using the method directly from the compendium without any verification.
- D. Choosing methods based on the shortest procedure.

Answer: B

Question: 2

The main reason for the traceability of intermediates in pharmaceutical manufacturing is to:
Response:

- A. Allow for creative marketing
- B. Ensure safety and efficacy through the supply chain
- C. Make the packaging more attractive
- D. Reduce the need for quality control

Answer: B

Question: 3

The design of water supply systems in pharmaceutical manufacturing should consider:
Response:

- A. The color of the water
- B. Taste preferences of the staff
- C. Unit operations like dechlorination and reverse osmosis
- D. The proximity to natural water bodies

Answer: C

Question: 4

Stability-indicating tests differ from release tests in that they:
Response:

- A. Are used to determine the product's color and texture
- B. Focus on the product's immediate quality upon release
- C. Are designed to predict the product's stability over time
- D. Assess the product's packaging integrity

Answer: C

Question: 5

The validation of sterilization processes is essential for:
(Choose two)
Response:

- A. Confirming the efficacy of sterilization methods
- B. Ensuring that product quality is not compromised
- C. Matching the sterilization process colors with the company logo
- D. Making the sterilization process more entertaining for employees

Answer: A,B

Question: 6

When should specifications be reviewed and updated?
Response:

- A. Only when the product formula changes
- B. Annually, as a standard procedure
- C. When methods are revised or compendia are changed
- D. When a new management team is appointed

Answer: C

Question: 7

The layout of pharmaceutical manufacturing equipment must be designed to:

Response:

- A. Allow for easy photography and videography
- B. Minimize errors and facilitate cleaning and maintenance
- C. Reflect the hierarchical structure of the company
- D. Ensure that all equipment is visible from the facility's entrance

Answer: B

Question: 8

The role of the supervisor in ensuring training effectiveness includes:

Response:

- A. Enhancing their own skills
- B. Ensuring staff understand and apply their training
- C. Investing in new technologies
- D. Networking with industry leaders

Answer: B

Question: 9

Remote audits are particularly useful when:

Response:

- A. In-person travel is restricted
- B. Auditors prefer not to travel
- C. The organization is too large for in-person audits
- D. The weather conditions are unfavorable

Answer: A

Question: 10

Calibration and engineering change control procedures are implemented to:

(Choose two)

Response:

- A. Guarantee that modifications do not affect the precision and accuracy of measurements
- B. Ensure equipment settings are optimized for the fastest production time
- C. Maintain the integrity of manufacturing processes

D. Facilitate the live streaming of equipment operations

Answer: A,C

Question: 11

Audit follow-up actions are necessary to:

Response:

- A. Check the effectiveness of implemented corrective actions
- B. Reward the audited team
- C. Finalize audit schedules for the next cycle
- D. Conduct team-building activities

Answer: A

Question: 12

What is a critical consideration when designing a sampling plan for bulk chemicals?

Response:

- A. The color of the chemicals
- B. The representative nature of the sample and appropriate sample size
- C. The preferences of the production department
- D. The current stock price of the chemicals

Answer: B

Question: 13

Mutual recognition agreements impact the import and export of pharmaceuticals by:

Response:

- A. Ensuring that product prices are consistent across borders.
- B. Requiring additional testing for all imported or exported products.
- C. Facilitating smoother regulatory approval processes between countries.
- D. Increasing the number of required inspections for each product.

Answer: C

Question: 14

In the context of APR and PQR, what is the significance of reviewing product complaints?

Response:

- A. To adjust the product price
- B. To assess the product's packaging design
- C. To evaluate and improve product quality and safety
- D. To measure consumer brand loyalty

Answer: C

Question: 15

Quality agreements are essential because they:

Response:

- A. Allow for the informal resolution of disputes
- B. Clearly define product and service quality requirements and responsibilities
- C. Serve as a formal record of the partnership for marketing purposes
- D. Provide a platform for socializing with suppliers

Answer: B

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