Vendor: ASQ

Exam Code: CPGP

Exam Name: Pharmaceutical GMP Professional Certification

Version: DEMO

QUESTION 1
What distinguishes a required compendial chapter from an informational ("general") compendial chapter?
Response:

A. Required chapters must be followed as a legal requirement, while informational chapters provide guidance.
B. Informational chapters are legally binding, whereas required chapters are optional.
C. Required chapters are specific to chemical tests only, while informational chapters cover physical tests.
D. Informational chapters are published more frequently than required chapters.

Answer: A

QUESTION 2
Critical considerations for infrastructure in product development include:
(Select two)
Response:

A. Aesthetic appeal of the facility
B. Equipment capability and cleanliness
C. Environmental control systems
D. Proximity to corporate headquarters

Answer: BC

QUESTION 3
When reviewing cleaning procedures, it is important to verify that they:
(Choose two)
Response:

A. Are aligned with the latest cleaning validation
B. Enhance the equipment's aesthetic features
C. Include details on cleaning schedules and methods
D. Focus on the use of environmentally friendly cleaning agents only

Answer: AC

QUESTION 4
Why are sterilization processes validated in a pharmaceutical facility? Response:

A. To ensure they are photogenic for promotional materials
B. To confirm their effectiveness and compliance with regulatory standards
C. To make the processes more appealing to facility tours
D. To reduce the time needed for sterilization

Answer: B

QUESTION 5

How often are European Product Quality Reviews (PQRs) typically conducted?
Response:

A. Bi-annually
B. Annually
C. Every two years
D. Quarterly

Answer: B

QUESTION 6
The necessity of equipment cleaning validation varies depending on:
Response:

A. The color and size of the equipment
B. Whether the equipment is single-use, multi-use, or dedicated
C. The personal preferences of the cleaning staff
D. The season in which the cleaning occurs

Answer: B

QUESTION 7
The effectiveness of a QMS is assessed through QMM to ensure:
Response:

A. Legal compliance
B. Process and product quality
C. Competitive pricing
D. Effective advertising

Answer: A

QUESTION 8
Risk management principles in ICH Q9 should be applied:
Response:

A. Only at the beginning of product development
B. Throughout the product lifecycle
C. Exclusively during clinical trials
D. Only post-market

Answer: B

QUESTION 9
CAPA feedback and trending are used to:
Response:

A. Justify budget increases
B. Modify quality system elements as appropriate

C. Allocate bonuses
D. Plan company events

Answer: B

QUESTION 10
When receiving incoming materials, why is it important to label and store them correctly?
Response:

A. To enhance the visual organization of the warehouse
B. To ensure traceability and proper handling throughout their lifecycle
C. To create more work for warehouse staff
D. To prepare for surprise inspections by celebrities

Answer: B

QUESTION 11
An effective post-change analysis should:
(Choose two)
Response:

A. Confirm alignment with initial objectives
B. Identify and evaluate any new risks or issues
C. Propose additional changes indiscriminately
D. Validate the change with external benchmarks

Answer: AB

QUESTION 12
What is the primary goal of conducting a pre-change analysis?
Response:

A. To reduce costs
B. To accelerate production
C. To minimize risk and ensure regulatory compliance
D. To simplify documentation

Answer: C

QUESTION 13
Batch release for commercial products requires rigorous _____ to ensure compliance with quality standards.
Response:

A. financial auditing
B. market analysis
C. quality control
D. personnel training

Answer: C

QUESTION 14
Unused labels and labeling materials must be:
Response:

A. Recycled within the facility
B. Controlled and documented
C. Used for training purposes
D. Discarded with general waste

Answer: B

QUESTION 15
Line clearance documentation is necessary to:Response:

A. Ensure the line is free from previous product remnants
B. Fulfill a regulatory formality
C. Keep employees busy
D. Increase paperwork

Answer: A

QUESTION 16
GMP requirements for clinical trials material focus on:
(Select two)
Response:

A. Ensuring patient safety
B. Guaranteeing the efficacy of the product
C. Enhancing the product's marketability
D. Simplifying production processes

Answer: AB

QUESTION 17
Line clearance operations must be:Response:

A. Performed and documented
B. Conducted biannually
C. Optional based on production schedules
D. Skipped to save time

Answer: A

QUESTION 18
The adoption of critical process parameters and specifications is crucial during:
Response:

A. The conceptual design phase
B. Phase II clinical trials
C. Marketing campaign development
D. All phases of development

Answer: D

QUESTION 19
Utilities design for production should prioritize:
Response:

A. The ability to be featured in company brochures
B. Compatibility with specific materials and production steps
C. The personal preferences of the CEO
D. The potential for utility systems to be multi-colored

Answer: B

QUESTION 20
When handling atypical results, the investigation must include a review of _____ to identify possible deviations or errors.
Response:

A. the cafeteria menu
B. test data and control samples
C. previous marketing campaigns
D. the annual holiday schedule

Answer: B

QUESTION 21
Utilities change control is vital for:
Response:

A. Keeping up with interior design trends
B. Maintaining the qualified state of affected utilities
C. Ensuring utilities are visible in promotional materials
D. Making utilities more user-friendly for new employees

Answer: B

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