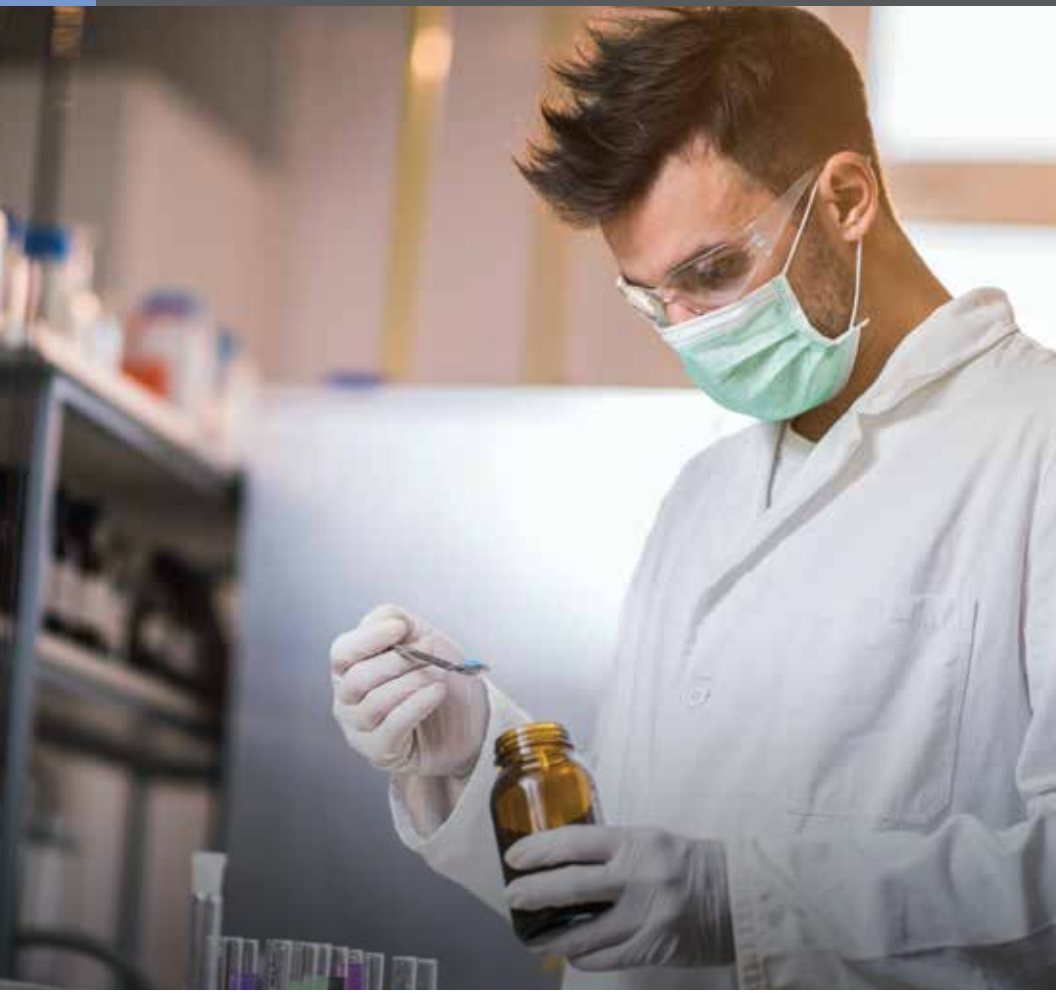
CPGP

CERTIFIED PHARMACEUTICAL GOOD MANUFACTURING PRACTICES PROFESSIONAL

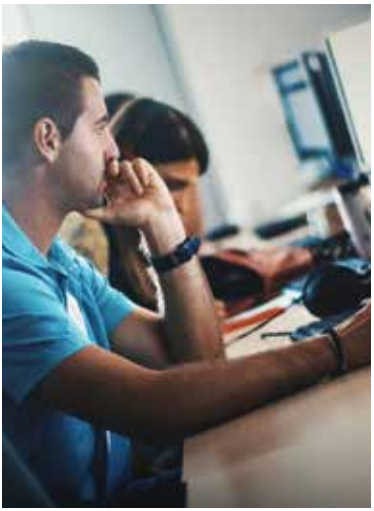


Quality excellence to enhance your career and boost your organization's bottom line

asq.org/cert

ASQ
The Global Voice of Quality®

Certification from ASQ is considered a mark of quality excellence in many industries. It helps you advance your career, and boosts your organization's bottom line through your mastery of quality skills. Becoming certified as a Pharmaceutical GMP Professional confirms your commitment to quality and the positive impact it will have on your organization.



Examination

Each certification candidate is required to pass a written examination that consists of multiple-choice questions that measure comprehension of the body of knowledge.

Certified Pharmaceutical Good Manufacturing Practices Professional

The Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) understands the GMP principles as regulated and guided by national and international agencies for the pharmaceutical industry. This covers finished human and veterinary drugs and biologics, ectoparasitacides, and dietary supplements (alternatively called nutraceuticals where regulated as drug products), as well as their component raw materials (includes active pharmaceutical ingredients (APIs) and excipients) and packaging and labeling operations.

CPGP

Computer Delivered – The CPGP examination is a one-part, 165 multiple-choice question, four-and-a-half-hour exam and is offered in English only. One hundred and fifty questions are scored and 15 are unscored.

Paper and Pencil – The CPGP examination is a one-part, 150 multiple-choice question, four-hour exam and is offered in English only.

Education and/or Experience

You must have five years of on-the-job experience in one or more of the areas of the Certified Pharmaceutical GMP Professional Body of Knowledge. A minimum of three years of this experience must be in a decision-making position. "Decision-making" is defined as the authority to define, execute, or control projects/processes and to be responsible for the outcome. This may or may not include management or supervisory positions. There are no education waivers for this exam.

For comprehensive exam information on the Pharmaceutical GMP Professional certification, visit **asq.org/cert**.

Minimum Expectations

- Will have a fundamental understanding of requirements and consequences of noncompliance of regulatory agency governance, including global regulatory framework, relevant regulations and guidelines, and mutual recognition agreements.
- Will be able to understand, apply, and evaluate elements and requirements of a quality system. Will be able to understand and evaluate self-inspection, audits, and supplier management. Will be able to evaluate records, documents, and reports created within these quality systems.
- Will be able to understand, apply, analyze, and evaluate requirements, specifications, and data relating to laboratory systems, including relevant compendia for the United States, Europe, and Japan, investigations of atypical laboratory results, and instrument control and record-keeping. Must be able to apply and evaluate stability and sample retain programs.
- Will be able to apply requirements, specifications, and qualification and validation for construction and maintenance of facilities, utilities, and equipment. Evaluate automated or computerized systems, and apply business continuity plans, disaster recovery techniques, and change management.
- Will be able to apply sampling plans and procedures for shipping and receiving materials, analyze in-house storage, identification, and rotation of materials, and meet requirements for materials traceability and sourcing, including returned goods.
- Will have a thorough understanding of sterile and nonsterile requirements of manufacturing systems and be able to analyze master and completed batch records, material control procedures, and contamination controls.
- Will be able to create and evaluate filling, packaging, and labeling operations and controls.
- Will have a fundamental understanding of product design factors and phase-appropriate GMP requirements. Will have a thorough understanding of technology transfer activities.

BODY OF KNOWLEDGE

Certified Pharmaceutical GMP Professional (CPGP)

Topics in this body of knowledge (BoK) cover compliance with good manufacturing practices (GMPs), as regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations.

This BoK includes subtext explanations and corresponding cognitive levels for each topic or subtopic. These details will be used by the Examination Development Committee as guidelines for writing test questions and are designed to help candidates prepare for the exam by identifying specific content that can be tested. The subtext is not intended to limit the subject matter or be all-inclusive of what might be covered in an exam but is intended to clarify how topics relate to the role of the Certified Pharmaceutical GMP Professional (CPGP). The descriptor in parentheses at the end of each subtext entry refers to the highest cognitive level at which the topic will be tested. A more complete description of cognitive levels is provided at the end of this document.

I. Regulatory Agency Governance (15 Questions)

A. Global Regulatory Framework
Identify the acts, statutes, and directives that apply to pharmaceuticals. (Understand)

B. Regulations and Guidances
Interpret frequently used regulations and guidelines/guidances, including those published or administered by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), Health Canada, the World Health Organization (WHO), the International Conference on Harmonization (ICH), the European Medicines Agency (EMA), the Food & Drug Administration (FDA), the USDA 9CFR, the International Pharmaceutical Excipients Council (IPEC), and Controlled Substance Act (CSA) 21 CFR 1300. (Understand)

C. Mutual Recognition Agreements
Interpret requirements that govern product registration, import or export of raw material or finished product, and the sharing of inspection findings. (Understand)

D. Regulatory Inspections

Define and describe various types of inspections including what triggers them, their frequency, and the inspection process used for inspections such as pre-approval, system-based, for-cause, and license renewal. (Understand)

E. Enforcement Actions

Define and describe various global enforcement actions and consequences (e.g., warning letters, consent decree, license withdrawals, product seizure, and import alerts). (Understand)

F. Regulatory Agency Reporting

1. **Post-marketing changes**

   Describe how post-marketing changes to specifications, processes, methods, are assessed for impact to determine the appropriate reporting method [e.g., scale up and post approval changes (SUPAC)]. (Understand)

2. **Regulatory reporting requirements**

   Describe global reporting requirements, including supplements, field alerts, biological product deviation reports, adverse events, product recalls, annual reports, and variations to dossiers and applications. (Understand)

3. **Product surveillance**

   Describe monitoring requirements for risk evaluation and mitigation strategy (REMS) and pharmacovigilance. (Understand)

G. Site Master File (SMF), Validation Master Plan (VMP) and Drug Master File (DMF) and Site Reference File (SRF)

Describe the purpose and content of these files. (Understand)

II. Quality Systems (27 Questions)

A. Quality Management System (QMS)

Describe key elements of the structure of a quality management system (QMS), the requirements for the development and operation and management review for suitability and effectiveness as defined in ICH Q10, EU GMP, and other guidances. (Evaluate)

B. Quality Unit (Site) Management

Describe quality management elements for individual sites or units, including responsibilities for the quality unit management such as qualified persons, batch release requirements, and the need for quality units to be independent from operations. (Understand)

C. Risk Management

Use various methods to apply risk management principles, as described in ICH Q9 and other guidance or regulatory documents. (Apply)

D. Training and Personnel Qualification

1. **Needs analysis**

   Identify the requirements for determining the type of training, qualification, and/or experience needed by quality staff members, operations personnel and related functions. (Understand)

2. **Staff development requirements**

   Determine proof of proficiency based on regulations, guidances, and directives including documented evidence and periodic reassessment. (Apply)

E. Change Control and Management

1. **Pre-change analysis**

   Assess the impact that proposed changes will have on products, processes, facilities, utilities, systems, to ensure risk minimization and regulatory compliance. (Analyze)

2. **Post-change analysis**

   Analyze data and other inputs to determine the results of a change, and evaluate any new risk factors created by the change. (Analyze)

F. Investigations and Corrective and Preventive Action (CAPA)

1. **Trigger events**
   Identify events that require: investigation, root cause analysis, and impact assessment both directly and indirectly related to the event. (Evaluate)

2. **Response actions**
   Define immediate action, corrective action, preventive action, management responsibility, and methods of implementing them. (Evaluate)

3. **CAPA feedback and trending**
   Describe how CAPA trending is used to modify appropriate quality system elements. (Create)

G. Audits and Self-inspections

1. **Audits processes and results**
   Differentiate between various audit types (systems, product, process) and analyze audit results to assess conformance to requirements. (Evaluate)

2. **Audit follow-up**
   Use various methods to evaluate and verify the effectiveness of corrective actions taken. (Evaluate)

H. Documents and Records Management

1. **GMP document system**
   Describe the GMP document system to determine compliance to regulatory requirements, including corporate standards, master plans, procedures, manufacturing and test instructions. (Analyze)

2. **Records**
   Review various records (log books, tags, training evidence) to confirm compliance to requirements. (Analyze)

3. **Record retention**
   Identify regulatory requirements for record retention. (Understand)

I. Product Complaints and Adverse Event Reports

1. **Product complaints**
   Describe and distinguish between product complaints and adverse events, and evaluate complaint-handling processes. (Evaluate)

2. **Adverse events**
   Describe regulatory requirements for the reporting of adverse events. (Analyze)

3. **Event response**
   Evaluate the level of action that needs to be taken in response to these types of events, including corrections, product removal. (Evaluate)

J. Product Trend Requirements

Describe and distinguish between components of periodic product assessment, such as the U.S. annual product review (APR) and the European product quality review (PQR), with regard to data trends and other required elements. (Understand)

K. Supplier and Contractor Quality Management

1. **Supplier quality systems**
   Identify and interpret standards and regulations related to monitoring supplier and contractor quality management systems. (Understand)

2. **Supplier controls**
   Assess the adequacy of controls over supplier selection and procurement and receipt of raw materials, components, and contract services. Determine the need for formal contracts/quality agreements. (Evaluate)

3. **Supplier evaluation**
   Assess the quality systems of suppliers and contractors using various methodologies, including supplier qualification, certification, evaluation, audit, as well as supplied product or service performance trending. (Evaluate)

III. Laboratory Systems (21 Questions)

A. Compendia (United States, Europe, and Japan)

1. **Required vs. informational compendia**
   Describe and distinguish between required and informational ("general") compendial chapters. (Apply)

2. **Marketing requirements vs. compendia**
   Distinguish among the U.S. Pharmacopoeia (USP), European Pharmacopoeia (PhEur or EP) and Japanese Pharmacopoeia (JP) in terms of requirements for marketing authorization. (Understand)

3. **Compendial methods review**
   Review compendial methods to ensure that they are verified as suitable for use in the testing lab. (Evaluate)

4. **Compendial or noncompendial requirements review**
   Review test methods, qualifications, validation and verification against required compendial chapters (general and informational as needed). (Analyze)

5. **Biological, microbiological, chemical, and physical test methods**
   Identify and interpret results from compendia identification tests, quantitative analysis, qualitative analysis, and other tests or studies for biological, microbiological, and chemical, and physical tests. (Apply)

B. Laboratory Investigations of Atypical Results

1. **Test data**
   Describe and develop procedures for investigating each type of test data including biological, microbiological, chemical test, and unknowns. (Analyze)

2. **Atypical results**
   Identify, analyze, and interpret data on processes or products that are out-of-specification or out-of-trend, and determine the outcome of the laboratory portion of the investigation and the criteria for further investigation. (Evaluate)

C. Instrument Management

1. **Instrument controls**
   Apply operating procedures for instrument identification, classification, qualification, calibration, and preventive maintenance. (Apply)

2. **Instrument calibration**
   Determine that instruments are calibrated within the specified range of operation, and they are accurate and precise. (Apply)

D. Specifications

1. **Types of specifications**
   Determine whether approved specifications exist for raw materials, intermediates, packaging components, labels, and finished products. (Analyze)

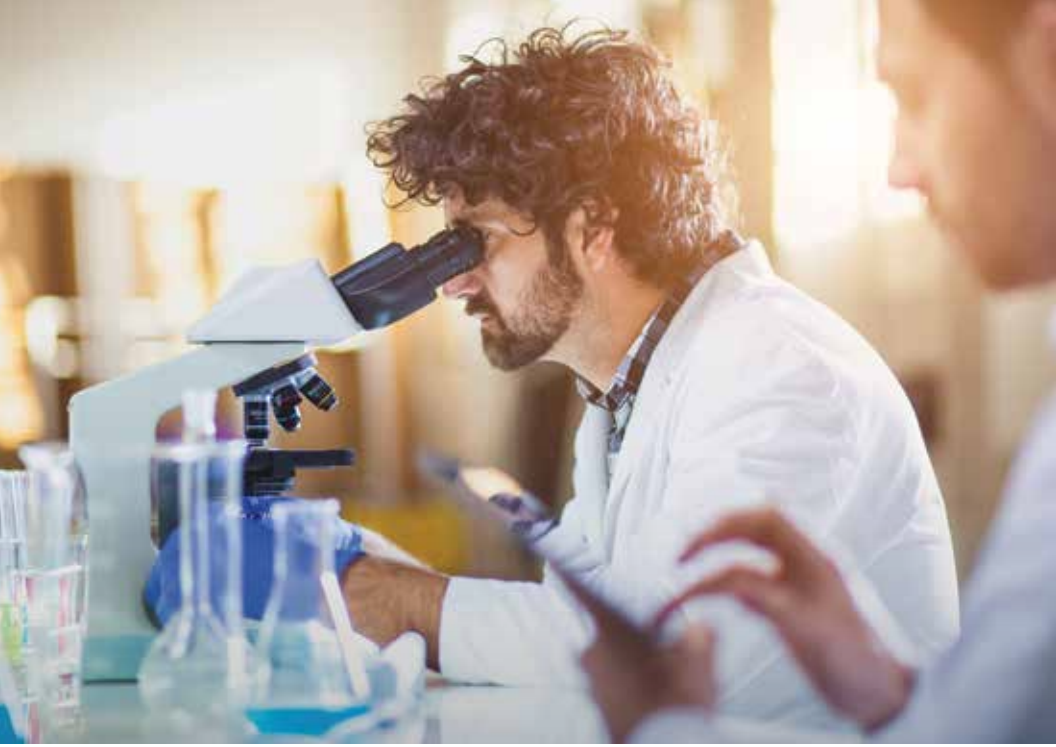
2. **Test data and specifications**
   Compare test data with specifications to determine whether raw materials, intermediates, packaging, labels, and finished products meet requirements. (Analyze)

3. **Specifications revision**
   Review and update specifications when methods are revised or compendia are changed. (Evaluate)

E. Laboratory Record-keeping and Data Requirements

1. **Record-keeping requirements**
   Identify and review record-keeping requirements for data acquisition systems to ensure data integrity. (Apply)

2. **Record review**
   Review laboratory records to detect errors or falsification, to prevent loss of data and ensure data integrity. (Apply)



3. **Certificates of analysis (COAs)**
   Review COAs to ensure they are complete, internally reviewed, and appropriately retained. (Apply)

F. Laboratory Handling Controls

1. **Sample handling**
   Determine whether samples are identified and handled in accordance with requirements, including name, sample identification, chain of custody. (Apply)

2. **Reagents, solutions, and standards identification**
   Determine whether reagents, solutions, and standards are identified and labeled in accordance with requirements, including opened-on, expiry, (validated) use-by, or recertify-by dates. (Apply)

3. **Storage requirements**
   Describe and use procedures to store samples, reagents, solutions, and standards in appropriate environmental conditions (e.g., temperature, humidity, light exposure, absence of oxygen) to maintain the material's characteristics for testing. (Apply)

G. Stability Programs

1. **Release tests vs. stability-indicating tests**
   Define and distinguish between these two types of tests. (Apply)

2. **Stability test data**
   Review stability data against specifications and identify trends that can establish, support, or challenge an expiry date. (Evaluate)

3. **Stability-point failure**
   Identify the stability-point failure of a product or material, and evaluate the implications for regulatory compliance. (Evaluate)

H. Reserve Samples and Retains

Describe the various regulatory requirements for retains and reserve samples. (Apply)

IV. Infrastructure: Facilities, Utilities, Equipment (17 Questions)

A. Facilities

1. **Buildings**
   Determine requirements for appropriate size and construction of buildings and areas as well as location of control systems. Ensure that construction and location facilitate proper operation and minimize the risk of error and cross contamination (including requirements to specify separation of antibiotics, hormones, toxins). (Apply)

2. **Manufacture and storage environment**
   Identify requirements for appropriate lighting, ventilation, and drainage to avoid adversely affecting product (either directly or indirectly) during manufacture and storage. (Apply)

3. **Facilities change control**
   Use various methods to verify that change control practices are in use to maintain the qualified state of the facilities. (Apply)

B. Utilities

1. **Water supply systems**
   Identify and interpret regulatory requirements for design of water supply systems, including various unit operations (e.g., dechlorination, reverse osmosis, deionization, distillation), delivery lines, back-flow or back-siphonage prevention, and drainage systems, as appropriate for the type of water (potable, purified, water for injection) needed in various processing steps. (Apply)

2. **Compressed air and gas systems**
   Identify and apply regulatory requirements related to compressed air and gas systems, including storage, flow regulation, filtration, venting, and purging. (Apply)

3. **Utility design for production**
   Identify and select utility designs related to production steps (e.g., washing, sterilizing, depyrogenation) for use with specific materials and processes. (Apply)

4. **Utilities design specifications**
   Review operations of utilities to ensure that they meet design specifications. (Apply)

5. **Utilities change control**
   Verify that change control practices are in use to maintain the qualified state of affected utilities. (Apply)

C. Equipment

1. **Equipment planning**
   Review equipment location, design, construction, installation, and maintenance based on the operations to be conducted. (Apply)

2. **Equipment layout**
   Determine the layout of equipment to minimize the risk of errors, to facilitate effective cleaning and maintenance, and to avoid contamination or any other undesired effect on product quality. (Apply)

3. **Equipment cleaning and maintenance**
   Review procedures and schedules for equipment cleaning, maintenance, and, where necessary, sanitization to ensure that they meet requirements. (Apply)

4. **Equipment cleaning validation or verification**
   Evaluate the need and methodology for product-contact cleaning validation and/or verification. (Evaluate)

5. **Equipment change control**
   Verify that change control has maintained the qualified state of equipment. (Apply)

D. Qualification and Validation

Verify that the qualifications and validations of facilities, equipment, and utilities are conducted in accordance with various requirements, including factory and site acceptance testing (FAT/SAT), design, installation, operational, and performance qualification (DQ/IQ/OQ/PQ) prior to process validation. (Analyze)

E. Maintenance and Metrology Systems

1. **Maintenance procedures**
   Verify that procedures are in use for routine and non-routine maintenance of heating, ventilation, air conditioning (HVAC) systems; air and water filters; and other equipment and utilities. (Analyze)

2. **Metrology change control**
   Verify that appropriate calibration and engineering/equipment change control procedures are in use, and that a metrology program exists for the calibration of instruments that control manufacturing facilities, utilities, and equipment. (Analyze)

F. General Cleaning, Sanitization, and Sterilization Systems

1. **Cleaning procedures**
   Review cleaning procedures in accordance with cleaning validation, whenever validation is required and performed. (Apply)

2. **Sanitization procedures**
   Review sanitization procedures for facilities and equipment, and ensure all are in accordance with any required validation studies, including details on cleaning schedules, methods, equipment, materials, sanitizers, disinfectants, sporicides, and sterilants. (Apply)

3. **Pest control**
   Review and verify that a pest control program is in place and that it uses authorized rodenticides, insecticides, fungicides, fumigating agents, and appropriate traps for pest elimination. (Apply)

4. **Sterilization processes**
   Verify that appropriate sterilization processes are in place and validated. (Apply)

G. Automated or Computerized Systems

1. **Validation procedures**
   Review procedures for validation of automated or computerized systems. Verify that critical parameters for their operation and maintenance are controlled and monitored. (Evaluate)

2. **Open and closed computerized systems**
   Distinguish between open and closed computerized systems. (Apply)

3. **Configuration control**
   Verify that version control and configuration are maintained and monitored. (Evaluate)

4. **Security requirements**
   Evaluate computerized systems to ensure they meet regulatory and guidance requirements for key elements, such as access control, data protection, electronic signature, change control, data archiving, maintenance, transcription, audit trail, and periodic system monitoring. (Evaluate)

H. Business Continuity and Disaster Recovery Planning

1. **Supply chain impact**
   Review plans and verify procedures for disaster recovery and business continuity that will guard operations from interruption to the supply chain. (Evaluate)

2. **Contingency plan**
   Verify the testing and effectiveness of contingency plans as required or proceduralized. (Apply)

V. Materials and Supply Chain Management (17 Questions)

A. Receipt of Materials

1. **Incoming materials**
   Describe and use processes to receive and store incoming materials (raw materials, bulk chemicals, components, labels) and take appropriate action on deviations (damaged materials, materials from unapproved suppliers, missing documentation). (Apply)

2. **Inventory controls**
   Describe and use procedures for documenting inventory transactions, material status, allocation, and "stop shipments" for quality holds. (Apply)

B. Sampling Processes

1. **Sampling plans**
   Review sampling plans for representative sampling, appropriate sample size, and test or inspection criteria. (Apply)

2. **Sampling environment**
   Differentiate and apply the requirements for sampling environment and utensils to the type of the material being sampled. (Apply)

3. **Cleaning**
   Ensure that the sampling environment is appropriately cleaned and monitored and that sampling utensils are appropriately cleaned or are single-use. (Apply)

C. Material Storage, Identification, and Rotation

1. **Storage suitability**
   Ensure that the storage environment is suitable, controlled, and monitored as required for the type of materials. (Apply)

2. **Storage labels**
   Confirm that the identification label for stored materials contains the required information. (Apply)

3. **Stock rotation**
   Define and use stock rotation requirements, such as first-in/first-out (FIFO) and first-expired/first out (FEFO). (Apply)

4. **Retest dates vs. expiration dates**
   Describe the difference between retest dates and expiration dates. (Understand)

5. **Mix-up risk**
   Identify potential sources of mix-up and identify methods to minimize their risk (material segregation, labeling, special storage for rejects, control of material returns, lot-control methods, special process for materials with similar names). (Analyze)

D. Shipping and Distribution

1. **Temperature-sensitive requirements**
   Identify special requirements for temperature-sensitive products, including tertiary packaging design, and monitoring devices. (Analyze)

2. **Special requirements**
   Determine specific product requirements and apply them to routine shipping processes. (Apply)

3. **Report requirements**
   Analyze shipping reports and transportation requirements in accordance with good distribution practices. (Analyze)

4. **Supply chain security**
   Identify and apply the various means to secure the supply chain (tamper-evident seals, shipping manifests, verification of documentation, barcoding, radio frequency identification (RFID), serialization). (Apply)

E. Traceability and Sourcing

1. **Traceability requirements**
   Define and differentiate the requirements for traceability of incoming materials, intermediates, and finished drugs. (Apply)

2. **Biological agent requirements**
   Identify and apply the requirements related to biological agents such as bovine and transmissible spongiform encephalopathy (BSE and TSE). (Apply)

3. **Pedigree and sourcing requirements**
   Identify and apply requirements for maintaining pedigree and sourcing details for active pharmaceutical ingredients (APIs), biological starting materials, excipients, intermediates, finished products and document the supply chain, from raw materials through wholesale or retail to end user. (Apply)

F. Salvaged/Returned Goods and Destruction

1. **Disposition**
   Review salvaged and returned goods and evaluate them for disposition. (Evaluate)

2. **Destruction facilities and processes**
   Determine the destruction requirements for materials including suitable facilities and processes. (Apply)

VI. Sterile and Nonsterile Manufacturing Systems (22 Questions)

A. Master Batch and Completed Batch Records

1. **Required elements**
   Review batch records for required elements, including proper issuance, sections on yields, critical manufacturing step verification, processing instructions, and hold times. (Apply)

2. **Record processing requirements**
   Confirm that batch records meet requirements for execution, review, and disposition decisions. (Apply)

B. Production Operations

1. **Application factors**
   Describe and differentiate the requirements for manufacturing processes according to their application: human or veterinary drugs or biologics. (Apply)

2. **Utility requirements**
   Identify the facility and utility requirements that are appropriate for different production environments and product types, including sterile vs. nonsterile manufacturing, solid and semisolid dosage forms, liquids, creams, ointments, and combination products. (Analyze)

3. **Sanitization and protection**
   Identify various production operations that require gowning, sanitization, hygiene, and other product-protective steps. (Apply)

C. In-process Controls

1. **In-process testing**
   Identify appropriate tests for each step in the manufacturing process and review results. (Analyze)

2. **Critical process parameters (CPPs)**
   Monitor CPPs. (Analyze)

3. **Process capability studies**
   Review process capability studies, and calculate Cp and Cpk. (Apply)

4. **Specification limits**
   Assess specification limits in relation to registration or compendial requirements. (Evaluate)

D. Dispensing and Weighing Controls

1. **Staging areas**
   Review product dispensing and after-dispensing staging areas to determine if they meet requirements. (Apply)

2. **Dispensing materials**
   Identify the requirements for using weighing equipment and handling utensils for dispensing raw materials or intermediates, including proper cleaning, labeling, and environmental controls, based on the type of material and manufacturing process being used. (Analyze)

E. Requirements for Critical Unit Processes

1. **Process parameters**
   Use required CPPs for such unit processes as sterilization or sterilizing filtration, aseptic filling, depyrogenation, lyophilization, other drying processes, tablet granulation and compression, terminal sterilization, cream or ointment emulsification. (Apply)

2. **Validation studies**
   Explain and evaluate the validation studies, specifically the methodologies and acceptance criteria, required before implementing critical unit processes. Explain and evaluate validation studies such as requirements for aseptic processes including process simulations ("media fills"), and temperature controls. (Evaluate)

3. **Unit operations**
   Assess unit processes or their validations for deviations requiring investigation. (Analyze)

4. **Operating procedures**
   Review qualification and validation results and confirm that they are reflected in operating procedures. (Analyze)

5. **Re-evaluation and revalidation**
   Determine appropriate criteria and frequency for re-evaluation and revalidation of unit processes. (Evaluate)

6. **Environmental monitoring requirements**
   Differentiate between environmental monitoring requirements for different manufacturing area classifications. (Apply)

7. **Environmental monitoring tools**
   Describe and use various monitoring tools to measure viable and nonviable particulates, pressure differentials, temperature, and humidity. (Apply)

F. Contamination and Cross-contamination

1. **Sources**
   Identify potential sources for these events. (Apply)

2. **Risk mitigation**
   Describe and apply various techniques for mitigating the risk of these events, including cleaning, facility, utility and equipment design, material and personnel flow, qualified disinfectants, operator training, validation, and monitoring. (Apply)

G. Reprocessed and Reworked Materials

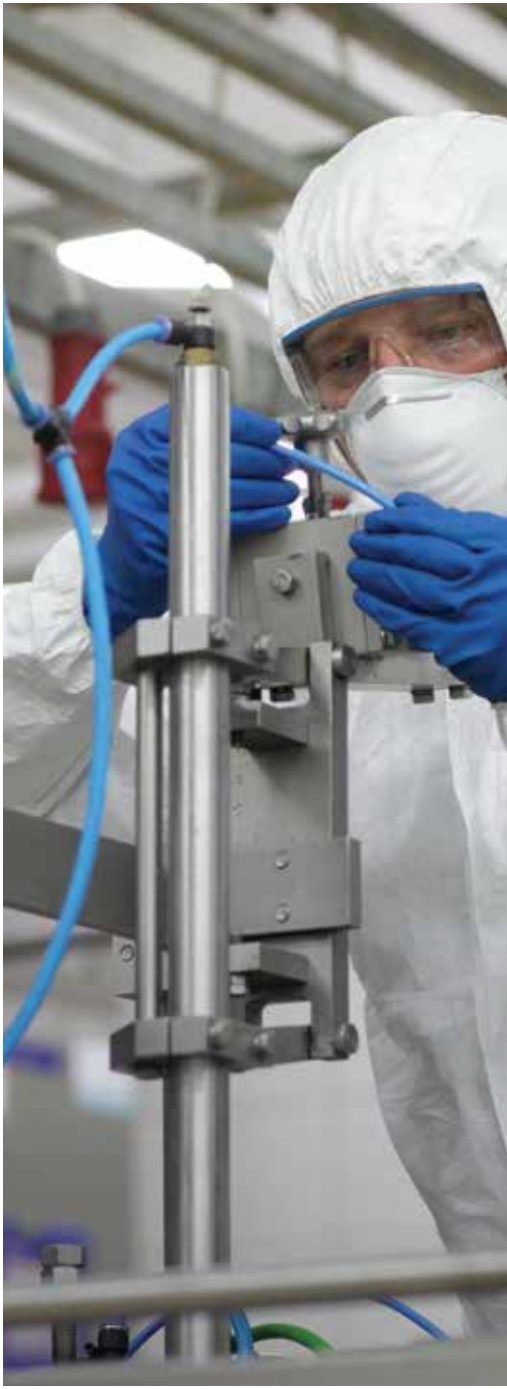
1. **Disposition process**
   Distinguish reprocessing from reworking and apply appropriate documentation, approval, and disposition methods for these materials. (Apply)

2. **Storage**
   Describe and apply requirements for segregation and secure storage of these materials. (Apply)

VII. Filling, Packaging, Labeling (18 Questions)

A. Filling Operations and Controls

1. **Materials control**
   Develop and review procedures to ensure the identity, strength, and purity of specified materials (e.g., liquids, powders, ointments, tablets, capsules, suspensions) and to prevent them from being altered. (Create)



2. **Filling equipment control**
   Analyze the controls needed for various types of production equipment and processes and ensure that the appropriate controls are in place to verify filling criteria. (Analyze)

3. **Contamination controls**
   Identify controls to prevent microbial and other contamination at all stages of filling. (Apply)

4. **Staged materials**
   Review staged materials and confirm that they are approved for use. (Apply)

5. **Status labeling**
   Identify and apply proper status labeling throughout the process. (Apply)

B. Environmental Monitoring

Use various monitoring techniques (active air sampling, settling plates, swab sampling, nonviable particle counting, contact plates for surfaces and people) to determine that appropriate environmental conditions are maintained during production operations. (Apply)

C. In-process and Finished Goods Inspections

1. **Inspections**
   Develop criteria for in-process and finished goods inspections of filled and packaged materials, including seal tests, torque testing, and bottle rejection systems. (Create)

2. **Vision and detection systems**
   Ensure that vision and detection systems are qualified, calibrated, and challenged as required for the system. (Apply)

3. **Defect characterizations**
   Ensure that defect characterizations are identified for each product and can be detected by inspection or test. (Apply)

4. **Equipment failure detection**
   Confirm by inspection or test that equipment failures can be detected. (Apply)

D. Product Inspection

1. **Staff evaluation**
   Ensure that staff who perform manual and semi-automatic inspections are properly trained and that their inspections meet reproducibility requirements. (Apply)

2. **Inspector requirements**
   Establish requirements for inspectors to have periodic eye examinations. Confirm and document that they take frequent breaks from inspection. (Apply)

3. **Automated inspection processes**
   Ensure that automated inspection processes are validated. (Apply)

E. Packaging Operations and Controls

1. **Content protection**
   Develop and apply procedures to prevent the environment or events from altering the identity, strength, purity and quality of the package content. (Create)

2. **Qualification and maintenance of equipment**
   Ensure that equipment used in packaging operations is qualified and maintained. (Apply)

3. **Line clearance operations**
   Determine that line clearance is performed and documented. (Apply)

4. **Quality check criteria**
   Identify and apply specified criteria when quality checks are performed. (Apply)

5. **Cut-label procedures**
   Apply appropriate procedures for cut labels, splices. (Apply)

6. **Hand-applied label procedures**
   Ensure that hand-applied labels are 100% inspected. (Apply)

7. **Packaging controls**
   Distinguish between controls needed for different types of packaging processes.

8. **Contamination controls**
   Identify controls to prevent microbial and other contamination at all stages of packaging. (Apply)

9. **Tamper-evident packaging**
   Ensure that tamper-evident and child-proof packaging requirements are in place for required products. (Apply)

F. Labeling Operations and Controls

1. **Label printing in packaging**
   Confirm and document that any printing done separately or in the course of packaging is performed correctly. (Apply)

2. **Quality of print used**
   Ensure that any type of print information (engraved, embossed) on packaging materials is clear and resistant to fading, smudging, or erasure. (Apply)

3. **Label changes**
   Determine whether regulatory notification and approval is required for proposed label changes. (Analyze)

4. **Label reconciliation**
   Confirm that label reconciliation is performed and documented and discrepancies are investigated. (Analyze)

5. **Unused labels**
   Confirm that procedures are in place and in use for controlled, unused batch-coded labels and labeling materials. (Apply)

6. **Label production**
   Define terms related to offline printing, roll label splicing, gang printing, secure storage and destruction, (Understand)

7. **Access control**
   Ensure that controls are in place for the creation, storage, and issuance of labels. (Apply)

G. Filling and Packaging Records

1. **Terms**
   Define terms related to these records, including evidence of line clearance, printed material reconciliation, and yields. (Understand)

2. **Setup instructions**
   Ensure that packaging line setup instructions are appropriate for all components. (Apply)

VIII. Product Development and Technology Transfer (13 Questions)

A. Quality by Design Concepts

1. **Critical quality attributes (CQAs) and critical process parameters (CPPs)**
   Identify CQAs for products and CPPs for processes. (Evaluate)

2. **Design space**
   Define the concept of design space as it is used throughout the product life cycle. (Understand)

3. **Process analytical technology (PAT) tools**
   Identify PAT tools, including multivariate data analysis, process analyzers, process and endpoint controls, and describe their use in supporting the manufacture of quality products. (Remember)

B. Phase-appropriate GMP Requirements

1. **Product life cycle development**
   Apply phase appropriate GMPs throughout the product life cycle. (Understand)

2. **Development phases**
   Identify recommendations and requirements in relation to phases of development, including method qualification/validation, comparability protocols, and adoption of critical process parameters and specifications. (Understand)

3. **Combination products**
   Identify GMP requirements and various studies required for combination drug-device or drug-delivery products. (Understand)

4. **Clinical trials material**
   Describe and apply requirements for production and packaging of clinical trials material/investigational medicinal products (IMPs). (Apply)

C. Raw Materials, Packaging, and Infrastructure for Product Development

Select appropriate development studies for raw material selection and evaluate the results to determine their critical quality attributes. (Analyze)

D. New Product Development Studies and Reports

Analyze studies and reports, including stability reports, material compatibility, method development, and development reports to support product development and submissions. (Evaluate)

E. Scale-up and Transfer Activities

1. **Development and validation principles**
   Identify and distinguish development and validation studies. (Understand)

2. **Technology transfer types**
   Define different types of technology transfer, including manufacturing site change, analytical laboratory site change, and analyze inter-site comparison of results. (Analyze)

3. **Successful technology transfer**
   Define various studies, including ranging, capability, in-process control, hold times, and shipping to ensure successful transfer between development and commercial processes. (Evaluate)

LEVELS OF COGNITION

Based on Bloom's Taxonomy—Revised (2001)

In addition to **content** specifics, the subtext for each topic in this BoK also indicates the intended **complexity level** of the test questions for that topic. These levels are based on "Levels of Cognition" (from Bloom's Taxonomy—Revised, 2001) and are presented below in rank order, from least complex to most complex.

REMEMBER | Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

UNDERSTAND | Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

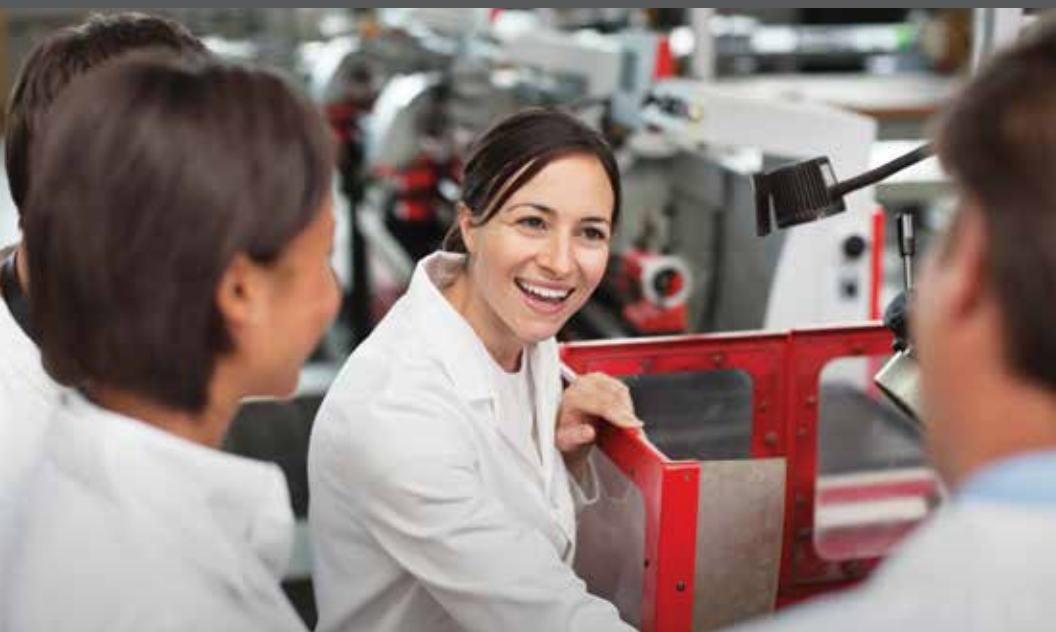
APPLY | Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

ANALYZE | Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

EVALUATE | Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

CREATE | Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

Visit **asq.org/cert** for comprehensive exam information.



Enhance your career with ASQ certification today!

Visit **asq.org/cert** for additional certification information including:

- Applications
- Available certifications and international language options
- Reference materials
- Study guides and test-taking tips
- Comprehensive exam information
- ASQ sections
- International contacts
- Endorsements

Item B1638

600 N. Plankinton Ave.
Milwaukee, WI 53203-2914

ASQ

The Global Voice of Quality®