Certified Pharmaceutical Good Manufacturing Practices Professional

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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.

Information

Certified Pharmaceutical Good Manufacturing Practices Professional

The Certified Pharmaceutical Good Manufacturing Practices Professional 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.

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. The Pharmaceutical GMP Professional examination is a one-part, 150 question, four-hour exam and is offered in English.

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/certification.

Minimum Expectations for a Certified Pharmaceutical GMP Professional

- Will have a fundamental understanding of regulatory agency governance, including global regulatory framework, relevant regulations and guidelines, and mutual recognition agreements.
- Will be able to develop and apply elements and requirements of a quality system, evaluate various types of audits and self-inspections, and analyze documents and record management systems.
- Will be able to distinguish between and verify suitability of factors relating to laboratory systems, including relevant compendia for the United States, Europe, and Japan, investigations of aberrant laboratory results, and instrument control and record-keeping.
- Will be able to determine requirements and specifications for construction of facilities, utilities and equipment, evaluate automated or computerized systems, and apply business continuity plans and disaster recovery techniques.
- Will be able to use sampling plans and apply 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 manufacturing systems and be able to analyze master and completed batch records, material control procedures, and contamination controls.
- Will have a thorough understanding of product design factors and phase-appropriate GMP requirements. Will be able to develop and evaluate filling and packaging operations and controls, and analyze 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, ectoparasitacides, and dietary supplements (alternatively called nutraceuticals where regulated as drug products), 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 comprehensive 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, directives, etc., 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 (EMEA), the Food & Drug Administration (FDA), the Therapeutic Goods Administration (TGA), USDA 9CFR, USDA Veterinary Service Memoranda, and the International Pharmaceutical Excipients Council (IPEC). (Understand)

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

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

E. Enforcement actions
Define and describe various enforcement actions and consequences (e.g., FDA 483s, warning letters, license withdrawals, product seizure). (Understand)

F. Regulatory agency reporting

1. **Post-marketing changes**
   Describe how post-marketing changes to specifications, processes, methods, etc., are assessed for impact to determine the appropriate reporting method. (Understand)
2. **Regulatory reporting requirements**
   Describe reporting requirements, including supplements, NDA Field Alerts, Biological Product Deviation Reports, annual reports, variations to dossiers and applications, etc. (Understand)

G. Site master file (SMF) and drug master file (DMF)
Describe the purpose and content of these files. (Understand)

II Quality Systems (30 Questions)

A. Quality management system (QMS)

1. **QMS elements**
   Describe key elements of the structure of a QMS, identify their interrelationships, and develop and describe their hierarchical positions. (Create)
2. **QMS requirements**
   Apply requirements related to QMS development and operations, as defined in ICH Q10, EU GMP, and other guidances. (Apply)

B. Quality unit (site) management
Describe quality management elements for individual sites or units, including responsibilities for company management, qualified persons, batch release requirements, the need for quality units to be independent from operations, etc. (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 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 (job titles, job descriptions, etc.). (Apply)

E. Change control and management

1. **Pre-change analysis**
   Assess the impact that proposed changes will have on products, processes, facilities, utilities, etc., to ensure risk minimization and ongoing 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 trigger events that necessitate investigation and the implications of the event elsewhere, and determine the underlying cause for the event. (Evaluate)
2. **Response actions**
   Define immediate action, corrective action, and preventive action, and explain their importance in terms of management responsibility, methods of implementing them, etc. (Evaluate)
3. **CAPA feedback and trending**
   Describe how trending is used in relation to CAPA data. Use investigation feedback and CAPA results to modify appropriate quality system elements. (Create)

G. Audits and self-inspections

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

2. **Audit follow-up**
   Use various methods to evaluate and verify the adequacy of corrective actions taken. (Evaluate)
3. **Ineffective corrective actions**
   Determine appropriate strategies to use when corrective actions are not implemented or are not effective. (Evaluate)

H. Documents and records management

1. **GMP document system**
   Examine the GMP document system, including corporate standards, master plans, procedures, manufacturing and test instructions, etc., to determine compliance to regulatory requirements. (Analyze)
2. **GMP compliance records**
   Review various records (log books, tags, training evidence, etc.) to confirm compliance to requirements. (Analyze)
3. **Record retention**
   Identify regulatory requirements for GMP compliance in record retention. (Understand)

I. Product quality complaints vs. adverse event reports

1. **Quality complaints**
   Describe and distinguish between product complaints and adverse events, and evaluate complaint-handling processes. (Evaluate)
2. **Adverse events and pharmacovigilance**
   Describe adverse events and identify the regulatory reports for these events and pharmacovigilance. (Understand)
3. **Problem response**
   Evaluate the level of action that needs to be taken in response to these types of events, including corrections, product removal, etc. (Evaluate)

J. Product trend requirements
Describe and distinguish between components of the U.S. annual product review (APR) and the European product quality review (PQR) with regard to data trends and other required review methods. (Understand)

K. Supplier and contractor quality management

1. **Supplier quality systems**
   Identify and interpret standards and regulations (e.g., ISO 17025) related to monitoring supplier and contractor quality management systems. (Analyze)
2. **Supplier controls**
   Assess the adequacy of controls over procurement and receipt of raw materials, components, and contract services. Determine the need for formal contracts. (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
(20 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 requirements review**
   Review test methods, qualifications, and validations against required compendial general chapters as well as against informational general compendial chapters whenever more specific tests are not prescribed in the product compendial monograph. (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 aberrant results

1. **Test data**
   Describe and distinguish among biological, microbiological, and chemical test data, and develop procedures for investigating each type. (Analyze)
2. **Aberrant results**
   Identify, analyze, and interpret data on processes or products that are out-of-specification ("no test" in USDA) or out-of-trend, and determine the outcome of the laboratory portion of the investigation and the criteria for further investigation. (Evaluate)

C. Instrument control and record-keeping

1. **Instrument control**
   Examine operating procedures for instrument identification, classification (e.g., GMP, for-information-only), and calibration, to meet requirements. (Apply)
2. **Instrument calibration**
   Determine whether instruments are calibrated within the specified range of operation, and whether they are accurate and precise. (Apply)

   [Note: Calibration of facilities equipment is covered in IV.E.]

D. Specifications

1. **Types of specifications**
   Determine whether approved specifications exist for raw materials, intermediates, packaging components, finished products, etc. (Analyze)
2. **Test data and specifications**
   Compare test data with specifications to determine whether raw materials, intermediates, packaging, or 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 review**
   Review laboratory records to detect errors or falsification and to prevent loss of data. (Apply)
2. **Record-keeping requirements**
   Identify and review record-keeping requirements for data acquisition systems. (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 identification**
   Determine whether samples are identified and handled in accordance with requirements, including name, sample identification, chains of custody, etc. (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, etc.) 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 and identify trends that can 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
(18 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. (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, etc.), delivery lines, back-flow or back-siphonage prevention, and drainage systems, as appropriate for the type of water (potable, purified, water for injection, etc.) 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, etc. (Apply)
3. **Utility design for production**
   Identify and select utility designs related to production steps (e.g., washing, sterilizing, depyrogenation, etc.) 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**
   Use various methods to 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, verification, or both. (Evaluate)
5. **Equipment change control**
   Use various methods to 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), installation, operational, and performance qualification (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 nonroutine maintenance of heating, ventilating, and air conditioning (HVAC) systems; air and water filters; and other GMP equipment and utilities; etc. (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) [Note: Calibration of instrumentation is covered in III.D.3.]

F. Cleaning, sanitization, and sterilization systems

1. **Washing facilities**
   Verify that washing facilities are adequate and properly located. (Apply)
2. **Cleaning procedures**
   Review cleaning procedures in accordance with prior cleaning validation, whenever validation is required and performed.
3. **Sanitization procedures**
   Review sanitization procedures for facilities and equipment, including details on cleaning schedules, methods, equipment, materials, etc., and verify that sanitizers, disinfectants, sporicides, and sterilants are used in accordance with marketing authorization and any required validation studies. (Apply)
4. **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, etc. (Apply)**
5. **Sterilization processes**
   Verify that appropriate sterilization processes are in place. (Apply)

G. Automated or computerized systems

1. **Validation procedures**
   Review procedures for validation of these systems, including building maintenance systems, utilities, and equipment. 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, change control, data archiving, maintenance, transcription, audit trail, periodic system monitoring, etc. (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 (15 Questions)

A. Receipt of materials

1. **Incoming materials**
   Describe and use processes to receive and store incoming materials, including raw materials, tank farm liquid chemicals or solvents, components, labels, etc., and take appropriate action on deviations, such as damaged materials, materials from unapproved suppliers, missing documentation, etc. (Apply)
2. **Inventory transactions**
   Describe and use procedures for documenting inventory transactions, such as material selection 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**
   Confirm that the storage environment is suitable, controlled, and monitored as required for the type of materials. (Analyze)
2. **Storage labels**
   Confirm that the identification label for stored materials contains the required information. (Analyze)
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**
   Describe potential sources of mix-up and identify methods to minimize their risk, including material segregation, labeling, special storage for rejects, control of material returns, lot-control methods, special process for materials with similar names, etc. (Analyze)

D. Shipping and distribution

1. **Temperature-sensitive requirements**
   Identify special requirements for temperature-sensitive products, including tertiary packaging design, monitoring devices, etc. (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, including tamper-evident seals, shipping manifests, verification of documentation, barcoding, radio frequency identification (RFID), etc. (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, etc., 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 whether qualified facilities and processes need to be used to destroy materials. (Apply)

VI Sterile and Nonsterile Manufacturing Systems
(25 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, hold times, etc. (Apply)
2. **Record processing requirements**
   Confirm that batch records meet requirements for execution, review, and disposition decisions. (Analyze)

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, combination products, etc. (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)**
   Identify and select appropriate 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 whether they meet requirements. (Analyze)
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. (Apply)

E. Requirements for critical unit processes

1. **Parameters for sterilization**
   Identify 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, etc. (Analyze)
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 required for aseptic processes including process simulations ("media fills"). (Evaluate)
3. **Unit processes**
   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. **Monitoring tools**
   Describe and use various monitoring tools to measure viable and nonviable particulates, pressure differentials, temperature, humidity, etc. (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 and equipment design, qualified disinfectants, operator training, validation, monitoring, etc. (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
(17 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, powders, etc.) 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, settle plates, nonviable particle counting, contact plates for surfaces and people, etc.) to determine that appropriate environmental conditions are maintained in various operations. (Apply)

C. In-process and finished goods inspections

1. **Finished goods inspections**
   Develop criteria for in-process and finished goods inspections of filled and packaged materials, including seal tests, torque testing, bottle rejection systems, etc. (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. Parenteral product inspection

1. **Staff evaluation**
   Ensure that staff who perform manual inspections are properly trained and that their inspections meet reproducibility requirements. (Apply)
2. **Automated inspection processes**
   Ensure that automated inspection processes are validated. (Apply)
3. **Defect library**
   Ensure that a defect library is available to confirm proper manual and automated inspection processes. (Apply)
4. **Inspector requirements**
   Establish requirements for inspectors to have periodic eye examinations. Confirm and document that they take frequent breaks from inspection. (Apply)

E. Packaging operations and controls

1. **Content protection**
   Develop and apply procedures to prevent the environment or events from altering the identity, strength, and purity 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, etc. (Apply)
6. **Hand-applied label procedures**
   Ensure that hand-applied labels are 100% inspected. (Apply)
7. **Production process controls**
   Distinguish between controls needed for different types of production processes. (Analyze)
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, etc.) on packaging materials is clear and resistant to fading, smudging, or erasure. (Apply)
3. **Label reconciliation**
   Confirm that label reconciliation is performed. (Apply)

4. **Label changes**
   Determine whether regulatory notification and approval is required for proposed label changes. (Apply)
5. **Unused labels**
   Confirm that procedures are in place and in use for destroying unused labels and labeling materials. (Apply)

G. Filling and packaging records

1. **Terms**
   Define terms related to these records, including evidence of line clearance, printed material reconciliation, yields, etc. (Understand)
2. **Setup instructions**
   Ensure that packaging line setup instructions are appropriate for all components. (Apply)

H. Artwork development and controls

1. **Terms**
   Define terms related to artwork/graphics, offline printing, roll label splicing, gang printing, secure storage and destruction, etc. (Understand)
2. **Access control**
   Ensure that controls are in place for the creation and use of artwork. (Apply)

VIII Product Development and Technology Transfer

(10 Questions)

A. Quality by design concepts

1. **Critical quality attributes (CQAs) and critical process parameters (CPPs)**
   Identify CQAs for products and CPPs for processes. (Understand)
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, etc., and describe their use in supporting the manufacture of quality products. (Remember)

B. Phase-appropriate GMP requirements

1. **ICH Q8**
   Identify recommendations contained in the ICH Q8 guidance for pharmaceutical development. (Understand)
2. **Development phases**
   Identify recommendations and requirements in relation to phases of development, including method qualification/validation, comparability protocols, adoption of critical process parameters and specifications, etc. (Understand)
3. **Combination products**
   Identify various studies required for combination drug-device or drug-delivery products. (Understand)
4. **Clinical trials material**
   Describe and apply requirements for packaging of clinical trials material/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, development reports, etc., to support product development and submissions. (Analyze)

E. Scale-up and transfer activities

1. **Development and validation reports**
   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, etc., and analyze inter-site comparison of results. (Analyze)
3. **Transfer efficiency**
   Define various studies, including ranging, capability, in-process control, hold times, shipping, etc., to improve transfer efficiency between development and commercial processes. (Apply)

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
(Also commonly referred to as recognition, recall, or rote knowledge.) Be able to remember or recognize terminology, definitions, facts, ideas, materials, patterns, sequences, methodologies, principles, etc.

Understand
Be able to read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply
Be able to apply ideas, procedures, methods, formulas, principles, theories, etc., in job-related situations.

Analyze
Break down information into its constituent Be able to break down information into its constituent parts and recognize the parts' relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate
Be able to make judgments regarding the value of proposed ideas, solutions, methodologies, etc., by using appropriate criteria or standards to estimate accuracy, effectiveness, economic benefits, etc.

Create
Be able to put parts or elements together in such a way as to show a pattern or structure not clearly there before; be able to identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

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