Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

The Certified Pharmaceutical Good Manufacturing Practices (CPGP) Body of Knowledge (BoK) has been updated to ensure that the most current state of practice is being tested in the examination. If you would like more information on how a BoK is updated, see a description of the process at https://asq.org/cert/exam-development.

To update the CPGP BoK, ASQ first conducted a job analysis survey to determine whether the topics in the 2016 BoK are still relevant to the job role of CPGPs and to identify any new topics that have emerged since that BoK was developed. The results of the CPGP job analysis survey showed that all but two topics that were in the previous BoK are still relevant to the job roles of software quality engineers currently. However, several new topics were added to the previous BoK because of changing industry needs. As indicated in Table 2: six new subtopics were added (II.C.2, II.D.3, II.E.2, II.K.4, II.K.5, VI.B.2).

The 2023 CPGP BoK will be introduced at the **October 2023** administration. Both BoKs will be available online until December 1, 2023 when the 2016 BoK will be removed.

General comments about ASQ Body of Knowledge updates
When the BoK is updated for an ASQ exam, most of the material covered in the BoK remains the same. There are very few programs that change significantly over 5-7 years. ASQ informs all the exam development committees that ASQ Certification exams must reflect "the state of practice" not "the state of the art." This helps to keep the programs grounded in what people currently do rather than being driven by the latest hot-topic improvement idea or trend. Typically, the biggest change in any updated BoK is in how the content is organized. When a new BoK is announced and posted on the ASQ website, we also include a "BoK Map" that highlights the changes between the two BoKs: old and new. The BoK Map also clearly identifies any new content that has been added to the exam and any content that has been removed from the exam.

Regarding exam preparation materials, you are able to use any of the reference books that are currently listed on the bibliography for the exam program. These are the source materials that the exam development committees use to write questions and verify answers.

Specific comments about the 2023 CPGP Body of Knowledge updates
The CPGP BoK mostly stayed the same with the 2023 update. In Sections I, III, IV, V, and VIII, no new subtopics were added. In Section II, five new subtopics were added: Risk assessment (II.C.2), Training effectiveness and role of supervisor (II.D.3), Change implementation (II.E.2), Quality agreements (II.K.4), and Outsource processes (II.K.5). In Section VI, one new subtopic was added: Process operations (VI.B.2). There were several revisions made to the subtext including adding new pieces of knowledge. There were sixteen subtopics that increased in cognitive level: II.D.1,III.E.2, III.G.1, VI.F.1, VII.B, VII.C.3, VII.D.1, VII.E.3, VII.E.4, VII.E.8, VII.F.1, VII.F.3, VII.F.5, VII.F.7, VIII.A.3, and VIII.B.1. There were two subtopics that decreased in cognitive level: III.A.3 and VII.A.1. For each of these subtopics, the subtext was revised to reflect the new cognitive level.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

Table 1 (below) portrays the change in items allocated to each section of the BoK. All the section names remained the same. Table II presents the 2023 CPGP BoK and maps the topics to the 2016 BoK. Table 3 presents the 2016 CPGP BoK and maps the topics to the 2023 BoK. Details on changes between the two can be found below.

Table 1. CPGP BoK Section Item Allocation

BoK Section	2016 BoK	2023 BoK	Difference
I. Regulatory Agency Governance	15	17	**+2**
II. Quality Systems	27	26	**-1**
III. Laboratory Systems	21	20	**-1**
IV. Infrastructure: Facilities, Utilities, and Equipment	17	17	**0**
V. Materials and Supply Chain Management	17	17	**0**
VI. Sterile and Nonsterile Manufacturing Systems	22	22	**0**
VII. Filling, Packaging, and Labeling	18	18	**0**
VIII. Product Development and Technology Transfer	13	13	**0**

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

Table 2. 2023 CPGP BoK mapped to 2016 CPGP BoK

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	I. Regulatory Agency Governance (17 Questions)	Increased number of questions from 15 to 17
I A	**A. Global regulatory framework** Identify the acts, statutes, and directives that apply to pharmaceuticals. (Understand)	
I B	**B. Regulations and guidances** Interpret frequently used regulations and guidelines/guidances/drafts including those published or administered by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), the International Conference on Harmonization (ICH), the World Health Organization (WHO), the European Medicines Agency (EMA), the Food & Drug Administration (FDA), Health Canada, USDA 9CFR, and other national regulatory agencies and international standards (e.g., ISOs). (Understand)	Reorganized subtext, removed IPEC and CSA, and added international standards and drafts.
I C	**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)	
I D	**D. Regulatory inspections** Define and describe various types of inspections including pre-approval, system-based, for-cause, and license renewal and describe the frequency for each. Describe how to prepare for and host in-person and remote evaluations and how to accommodate record requests and digital reporting. (Understand)	Reorganized subtext and added preparing for and hosting in-person and remote evaluations, and how to accommodate record requests and digital reporting.
I E	**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)	
I F	**F. Regulatory agency reporting**	
I F 1	**1. Post-marketing changes** Describe how post-marketing changes to specifications, processes, and methods are	

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	assessed for impact to determine the appropriate reporting method [e.g., scale up and post-approval changes (SUPAC)]. (Understand)	
I F 2	**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)	
I F 3	**3. Product surveillance** Describe monitoring requirements for risk evaluation and mitigation strategy (REMS) and pharmacovigilance. (Understand)	
I G	**G. Site Master File (SMF), Validation Master Plan (VMP), Drug Master File (DMF), and Site Reference File (SRF)** Describe the purpose and content of Site Master Files (SMFs), Validation Master Plans (VMPs), Drug Master Files (DMFs), and Site Reference Files (SRFs). (Understand)	Expanded subtext to include more context.
	II. Quality Systems (26 Questions)	Decreased number of questions from 27 to 26
II A	**A. Quality management system (QMS)** Describe key elements of the structure of a Quality Management System (QMS). Outline the requirements for the development, operation, and management review for suitability and effectiveness as defined in ICH Q7, ICH Q10, EU GMP, and other guidances. (Evaluate)	Added ICH Q7
II B	**B. Quality unit (site) management** Describe quality management elements for individual sites or units including responsibilities for the quality unit management such as Qualified Person, Management Representative, batch release (disposition) requirements for investigational and commercial products, and the need for quality units to be independent from operations. (Understand)	Expanded subtext to include more context and added Management Representative.
II C	**C. Risk management and assessment**	Revised title of subtopic and split topic into two subtopics: 2.C.1 and 2.C.2.
II C	**1. Risk management**	Added ICH Q12

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	Use various methods to apply risk management principles as described in ICH Q9, ICH Q12, and other guidance and regulatory documents. (Apply)	
New	**2. Risk assessment** Use the Quality Management Maturity (QMM) assessment program to assess the effectiveness of the Quality Management System to ensure process and product quality. (Apply)	
II D	**D. Training and personnel qualification**	
II D 1	**1. Needs analysis** Identify the requirements for determining the type of training, qualification, and experience needed by quality staff members, operations personnel, and related functions. (Apply)	Increased cognitive level from Understand to Apply.
II D 2	**2. Staff development requirements** Determine proof of proficiency based on regulations, guidances, and directives including documented evidence and periodic reassessment. (Apply)	
New	**3. Training effectiveness and role of supervisor** Apply various methods for testing and evaluating training effectiveness. Identify the role and responsibilities of supervisors including ensuring staff are adequately trained to perform their assigned functions. (Apply)	
II E	**E. Change control and management**	
II E 1	**1. Pre-change analysis** Assess the impact that proposed changes will have on products, processes, facilities, utilities, and systems to minimize risk and ensure regulatory compliance. (Analyze)	Reworded subtext.
New	**2. Change implementation** Implement and document the change following a change implementation plan. (Create)	
II E 2	**3. 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)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
II F	**F. Investigations and corrective and preventive action (CAPA)**	
II F 1	**1. Trigger events** Identify events that require investigation, root cause analysis, and impact assessment both directly and indirectly related to the event. (Evaluate)	
II F 2	**2. Response actions** Define immediate action, corrective action, preventive action, management responsibility and identify methods for implementing them. (Evaluate)	
II F 3	**3. CAPA feedback and trending** Describe how CAPA trending is used to modify appropriate quality system elements. (Create)	
II G	**G. Audits and self-inspections**	
II G 1	**1. Audits processes and results** Develop audit schedules, differentiate between various audit types (systems, product, and process) conducted either remotely or on-site, document evidence of audit completion, and analyze audit results to assess conformance to requirements. (Evaluate)	Added audit schedules, remote and on-site audits, and document evidence of audit completion.
II G 2	**2. Audit follow-up** Use various methods to evaluate and verify the effectiveness of corrective actions taken. (Evaluate)	
II H	**H. Documents and records management**	
II H 1	**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)	
II H 2	**2. Records** Review various records (e.g., logbooks, tags, and training evidence) to confirm compliance to requirements such as Attributable, Legible, Contemporaneous, Original, Accurate (ALCOA) and PIC/S guidelines for data integrity. (Analyze)	Added Attributable, Legible, Contemporaneous, Original, Accurate (ALCOA) and PIC/S guidelines.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
II H 3	**3. Record retention** Identify regulatory requirements for record retention. (Understand)	
II I	**I. Product complaints and adverse event reports**	
II I 1	**1. Product complaints** Describe and distinguish between product complaints and adverse events. Evaluate complaint-handling processes. (Evaluate)	Minor rewording of subtext.
II I 2	**2. Adverse events** Describe regulatory requirements for the reporting of adverse events (e.g., counterfeit product, fraud). (Analyze)	Added examples of adverse events to subtext.
II I 3	**3. Event response** Evaluate the level of action that needs to be taken in response to adverse events such as corrections and product removal. (Evaluate)	Minor rewording of subtext.
II J	**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)	
II K	**K. Supplier and contractor quality management**	
II K 1	**1. Supplier quality systems** Identify and interpret standards and regulations related to monitoring supplier, vendor, and contractor quality management systems. (Understand)	Added vendor to subtext.
II K 2	**2. Supplier controls** Assess the adequacy of controls over supplier, vendor, and contractor selection and procurement and receipt of raw materials, components, and contract services. Determine the need for formal contracts/quality agreements. (Evaluate)	Added vendor and contractor to subtext.

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
II K 3	**3. Supplier evaluation** Assess the quality systems of suppliers, vendors, and contractors using various methodologies including supplier qualification, certification, evaluation, audit, and supplied product or service performance trending. (Evaluate)	Added vendors to subtext.
New	**4. Quality agreements** Explain the purpose and describe the main elements of a quality agreement. (Understand)	
New	**5. Outsource processes** Use various methods for the management of contract manufacturing, drug development, testing laboratories, and other outsourcing activities including defining the roles and responsibilities of each party. (Apply)	
	III. Laboratory Systems (20 Questions)	Decreased number of questions from 21 to 20
III A	**A. Compendia (United States, Europe, and Japan)**	
III A 1	**1. Required vs. informational compendia** Describe and distinguish between required and informational ("general") compendial chapters. (Apply)	
III A 2	**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)	
III A 3	**3. Compendial methods review** Review compendial methods to ensure they are verified as suitable for use in the testing lab. (Analyze)	Lowered cognitive level from Evaluate to Analyze.
III A 4	**4. Compendial or non-compendial requirements review** Review test methods, qualifications, validation, and verification against required compendial chapters (general and informational, as needed). (Analyze)	
III A 5	**5. Biological, microbiological, chemical, and physical test methods**	

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	Identify and interpret results from compendia identification tests, quantitative analysis, qualitative analysis, and other tests or studies for biological, microbiological, chemical, and physical tests. (Apply)	
III B	**B. Laboratory investigations of atypical results**	
III B 1	**1. Test data** Describe and develop procedures for investigating each type of test data including biological, microbiological, chemical test, and unknowns. (Analyze)	
III B 2	**2. Atypical results** Identify, analyze, and interpret data on processes or products that are out-of-specification or out-of-trend. Determine the outcome of the laboratory portion of the investigation and the criteria for further investigation. (Evaluate)	
III C	**C. Instrument management**	
III C 1	**1. Instrument controls** Apply operating procedures for instrument identification, classification, qualification, calibration, and preventive maintenance. (Apply)	
III C 2	**2. Instrument calibration** Determine that instruments are calibrated within the specified range of operation, and that they are accurate and precise. (Apply)	
III D	**D. Specifications**	
III D 1	**1. Types of specifications** Determine if approved specifications exist for raw materials, intermediates, packaging components, labels, and finished products. (Analyze)	
III D 2	**2. Test data and specifications** Compare test data with specifications to determine if raw materials, intermediates, packaging, labels, and finished products meet requirements. (Analyze)	
III D 3	**3. Specifications revision** Review and update specifications when methods are revised or compendia are changed. (Evaluate)	
III E	**E. Laboratory record-keeping and data requirements**	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
III E 1	**1. Record-keeping requirements** Identify and review record-keeping requirements for data acquisition systems to ensure data integrity. (Apply)	
III E 2	**2. Record review** Ensure data integrity and prevent loss of data by reviewing laboratory records including audit trails of electronic data to detect errors, falsification, and fraud. (Evaluate)	Added auditing electronic data trail, reworded subtext, and increased cognitive level from Apply to Evaluate.
III E 3	**3. Certificates of Analysis (COAs)** Review Certificate of Analysis (COAs) to ensure they are complete, internally reviewed, and appropriately retained. (Apply)	Spelled out COA.
III F	**F. Laboratory handling controls**	
III F 1	**1. Sample handling** Determine whether samples are identified and handled in accordance with requirements including name, sample identification, and chain of custody. (Apply)	
III F 2	**2. Reagents, solutions, and standards identification** Determine if reagents, solutions, and standards are identified and labeled and if quantities are traceable in accordance with requirements including opened-on, expiry, (validated) use-by, and recertify-by dates. (Apply)	Added traceability to subtext.
III F 3	**3. Storage requirements** Describe and use procedures to store samples, reagents, solutions, solvents, and standards in appropriate environmental conditions (e.g., temperature, humidity, light exposure, and absence of oxygen) to maintain the material's characteristics for testing. (Apply)	Added solvents to subtext.
III G	**G. Stability programs**	
III G 1	**1. Release tests vs. stability-indicating tests** Define and distinguish between release and stability-indicating tests. (Analyze)	Reworded subtext and increased cognitive level from Apply to Analyze.
III G 2	**2. Stability test data** Review stability data against specifications and identify trends that can establish, support, or challenge an expiry date. (Evaluate)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
III G 3	**3. Stability-point failure** Identify the stability-point failure of a product or material and evaluate the implications for regulatory compliance. (Evaluate)	
III H	**H. Reserve samples and retains** Describe the various regulatory requirements for retains and reserve samples. (Apply)	
	IV. Infrastructure: Facilities, Utilities, and Equipment (17 Questions)	Minor revision to title.
IV A	**A. Facilities**	
IV A 1	**1. Buildings** Determine and document the requirements for appropriate size and construction of buildings and areas and the location of control systems. Ensure that construction and location facilitate proper operation and minimize the risk of error and cross contamination including meeting requirements that specify separation of antibiotics, hormones, and toxins. (Apply)	Added document and meeting requirements to subtext.
IV A 2	**2. Manufacture and storage environment** Identify requirements for appropriate lighting, ventilation, and drainage to avoid adversely affecting product (either directly or indirectly) during manufacturing and storage. (Apply)	
IV A 3	**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)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
IV B	**B. Utilities**	
IV B 1	**1. Water supply systems** Identify and interpret regulatory requirements for the design of water supply systems including various unit operations (e.g., dichlorination, reverse osmosis, deionization, and distillation), delivery lines, back-flow or back-siphonage prevention, and drainage systems as appropriate for the type of water (potable, purified, and water for injection) needed in various processing steps. (Apply)	
IV B 2	**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)	
IV B 3	**3. Utility design for production** Identify and select utility designs related to production steps (e.g., washing, sterilizing, and depyrogenation) for use with specific materials and processes. (Apply)	
IV B 4	**4. Utilities design specifications** Review operations of utilities to ensure they meet design specifications. (Apply)	
IV B 5	**5. Utilities change control** Verify that change control practices are used to maintain the qualified state of affected utilities. (Apply)	
IV C	**C. Equipment**	
IV C 1	**1. Equipment planning** Review equipment location, design, construction, installation, and maintenance based on the operations to be conducted. (Apply)	
IV C 2	**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)	
IV C 3	**3. Equipment cleaning and maintenance** Review procedures and schedules for equipment cleaning, maintenance, and sanitization (where necessary) to ensure that they meet requirements. (Apply)	Minor rewording of subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
IV C 4	**4. Equipment cleaning validation or verification** Evaluate the need and methodology for product-contact cleaning validation and verification. Evaluate the difference between single-use, multi-use, and dedicated equipment. (Evaluate)	Added single-use, multi-use, and dedicated equipment to subtext.
IV C 5	**5. Equipment change control** Verify that change control has maintained the qualified state of equipment. (Apply)	
IV D	**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) and Design, Installation, Operational, and Performance Qualification (DQ/IQ/OQ/PQ) prior to process validation. (Analyze)	
IV E	**E. Maintenance and metrology systems**	
IV E 1	**1. Maintenance procedures** Verify that procedures are used for routine and non-routine maintenance of Heating, Ventilation, Air Conditioning (HVAC) systems air and water filters and other equipment and utilities. (Analyze)	
IV E 2	**2. Metrology change control** Verify that appropriate calibration and engineering/equipment change control procedures are used and that a metrology program exists for the calibration of instruments that control manufacturing facilities, utilities, and equipment. (Analyze)	
IV F	**F. General cleaning, sanitization, and sterilization systems**	
IV F 1	**1. Cleaning procedures** Review cleaning procedures in accordance with cleaning validation whenever validation is required and performed. (Apply)	
IV F 2	**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)	
IV F 3	**3. Pest control** Review and verify that a pest control program is established and that it uses authorized	Minor rewording to subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	rodenticides, insecticides, fungicides, fumigating agents, and appropriate traps for pest elimination. (Apply)	
IV F 4	**4. Sterilization processes** Verify that appropriate sterilization processes are established and validated. (Apply)	Minor rewording to subtext.
IV G	**G. Automated or computerized systems**	
IV G 1	**1. Validation procedures** Review procedures for implementation and validation of automated or computerized systems. Verify that critical parameters for their operation and maintenance are controlled and monitored. (Evaluate)	Added implementation to subtext.
IV G 2	**2. Open and closed computerized systems** Distinguish between open and closed computerized systems. (Apply)	
IV G 3	**3. Configuration control** Verify that version control and configuration are maintained and monitored. (Evaluate)	
IV G 4	**4. Security requirements** Evaluate on-site, multi-use, and cloud-based 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)	Added on-site, multi-use, and cloud-based to subtext.
IV H	**H. Business continuity and disaster recovery planning**	
IV H 1	**1. Supply chain impact** Review plans and verify procedures for disaster recovery, record recovery, and business continuity that will guard operations from interruption to the supply chain and ensure data integrity. (Evaluate)	Added record recovery and ensuring data integrity to subtext.
IV H 2	**2. Contingency plan** Verify the testing and effectiveness of contingency plans as required or proceduralized. (Apply)	
	V. Materials and Supply Chain Management (17 Questions)	
V A	**A. Receipt of materials**	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
V A 1	**1. Incoming materials** Describe and use processes to receive, label, and store incoming materials (raw materials, bulk chemicals, components, labels, and product labeling) and take appropriate action on deviations (damaged materials, materials from unapproved suppliers, and missing documentation). (Apply)	Added label and product labeling to subtext.
V A 2	**2. Inventory controls** Describe and use procedures for documenting inventory transactions, updating changes in material status, allocation, and "stop shipments" for quality holds. (Apply)	Added updating changes to subtext.
V B	**B. Sampling processes**	
V B 1	**1. Sampling plans** Review sampling plans for representative sampling, appropriate sample size, and test or inspection criteria. (Apply)	
V B 2	**2. Sampling environment** Differentiate and apply the requirements for sampling environment and utensils to the type of the material being sampled. (Apply)	
V B 3	**3. Cleaning** Ensure the sampling environment is appropriately cleaned and monitored and that sampling utensils are appropriately cleaned or are single-use. (Apply)	
V C	**C. Material storage, identification, and rotation**	
V C 1	**1. Storage suitability** Ensure the storage environment is suitable, controlled, and monitored as required for the type of materials. (Apply)	
V C 2	**2. Labelling of stored materials** Confirm that the identification label for stored materials contains the required information. (Apply)	Reworded subtopic title.
V C 3	**3. Stock rotation** Define and use stock rotation requirements such as First in, First Out (FIFO) and First expired, First Out (FEFO). (Apply)	
V C 4	**4. Retest dates vs. expiration dates** Describe the difference between retest dates and expiration dates. (Understand)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
V C 5	**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, and special processes for materials with similar names). (Analyze)	
V D	**D. Shipping and distribution**	
V D 1	**1. Temperature-sensitive requirements** Identify special requirements for temperature-sensitive products including tertiary packaging, design, and monitoring devices. (Analyze)	
V D 2	**2. Special requirements** Determine specific product requirements and apply them to routine shipping processes. (Apply)	
V D 3	**3. Report requirements** Analyze shipping reports and transportation requirements in accordance with good distribution practices. (Analyze)	
V D 4	**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), and serialization. (Apply)	Minor rewording of subtext.
V E	**E. Traceability and sourcing**	
V E 1	**1. Traceability requirements** Define and differentiate the requirements for traceability of incoming materials, intermediates, and finished drugs. (Apply)	
V E 2	**2. Biological agent requirements** Identify and apply the requirements related to biological agents such as Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). (Apply)	Minor revision to wording of subtext.
V E 3	**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, and finished products. Document the supply chain from raw materials through wholesale or retail to end user. (Apply)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
V F	**F. Salvaged/returned goods and destruction**	
V F 1	**1. Disposition** Review salvaged and returned goods and evaluate them for disposition. (Evaluate)	
V F 2	**2. Destruction facilities and processes**. Determine the destruction requirements for materials including suitable facilities and processes. (Apply)	
	VI. Sterile and Nonsterile Manufacturing Systems (2II Questions)	
VI A	**A. Master batch and completed batch records**	
VI A 1	**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)	
VI A 2	**2. Record processing requirements** Confirm that batch records meet requirements for execution, review, and disposition decisions. (Apply)	
VI B	**B. Production operations**	
VI B 1	**1. Application factors** Describe and differentiate the requirements for manufacturing processes according to their application: human drugs, veterinary drugs, or biologics. (Apply)	Added Apply cognitive level
New	**2. Process operations** Understand and differentiate between continuous and batch manufacturing. (Apply)	
VI B 2	**3. 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)	
VI B 3	**4. Sanitization and protection** Identify various production operations that require gowning, sanitization, hygiene, and other product-protective steps. (Apply)	
VI C	**C. In-process controls**	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VI C 1	**1. In-process testing** Identify appropriate tests for each step in the manufacturing process and review results. (Analyze)	
VI C 2	**2. Critical process parameters (CPPs)** Monitor critical process parameters (CPPs). (Analyze)	Minor rewording of subtext.
VI C 3	**3. Process capability** Understand the importance of conducting process capability studies, calculate C_p and C_{pk} and monitor process capability. (Apply)	Reworded subtopic title and added monitoring process capability to subtext.
VI C 4	**4. Specification limits** Assess specification limits in relation to registration or compendial requirements. (Evaluate)	
VI D	**D. Dispensing and weighing controls**	
VI D 1	**1. Staging areas** Review product dispensing and after-dispensing staging areas to determine if they meet requirements. (Apply)	
VI D 2	**2. Dispensing materials** Identify the requirements for using weighing equipment and handling utensils for dispensing raw materials or intermediates, such as proper cleaning, labeling, and environmental controls, based on the type of material and manufacturing process being used. (Analyze)	
VI E	**E. Requirements for critical unit processes**	
VI E 1	**1. Process parameters** Use required critical process parameters (CPPs) for unit processes such as sterilization or sterilizing filtration, aseptic filling, depyrogenation, lyophilization, other drying processes, tablet granulation and compression, terminal sterilization, and cream or ointment emulsification. (Apply)	Minor rewording of subtext.
VI E 2	**2. Validation studies** Explain and evaluate 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)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VI E 3	**3. Unit operations** Assess unit processes and their validations for deviations requiring investigation. (Analyze)	
VI E 4	**4. Operating procedures** Review qualification and validation results and confirm that validated and qualified parameters are reflected in operating procedures or batch records. (Analyze)	Added validated and qualified parameters and batch records to subtext.
VI E 5	**5. Re-evaluation and re-validation** Determine appropriate criteria and frequency for re-evaluation and re-validation of unit processes. (Evaluate)	
VI E 6	**6. Environmental monitoring requirements** Differentiate between environmental monitoring requirements for different manufacturing area classifications. (Apply)	
VI E 7	**7. Environmental monitoring tools** Describe and use various monitoring tools to measure viable and nonviable particulates, pressure differentials, temperature, and humidity. (Apply)	
VI F	**F. Contamination and cross-contamination**	
VI F 1	**1. Sources** Identify potential sources for and implement controls to minimize contamination and cross-contamination. (Analyze)	Added implementing controls to minimize contamination and cross-contamination to subtext. Increased cognitive level from Apply to Analyze
VI F 2	**2. Risk mitigation** Describe and apply various techniques for mitigating the risk of contamination and cross-contamination including cleaning; facility, utility, and equipment design; material and personnel flow; qualified disinfectants; operator training; validation; and monitoring. (Apply)	Clarified subtext
VI G	**G. Reprocessed and reworked materials**	
VI G 1	**1. Disposition process** Distinguish reprocessing from reworking and apply appropriate documentation, approval, and disposition methods for these materials. (Apply**)**	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VI G 2	**2. Storage** Describe and apply requirements for segregation and secure storage of these materials. (Apply)	
	VII. Filling, Packaging, and Labeling (18 Questions)	
VII A	**A. Filling operations and controls**	
VII A 1	**1. Materials control** Develop and review procedures to ensure the identity, strength, and purity of specified materials (e.g., liquids, powders, ointments, tablets, capsules, and suspensions) and to prevent them from being altered. (Evaluate)	Lowered cognitive level from Create to Evaluate.
VII A 2	**2. Filling equipment control** Analyze the controls needed for various types of production equipment and processes and ensure that the appropriate controls are established to verify filling criteria. (Analyze)	
VII A 3	**3. Contamination controls** Identify controls to prevent microbial and other contamination at all stages of filling. (Apply)	
VII A 4	**4. Staged materials** Review staged materials and confirm that they are approved for use. (Apply)	
VII A 5	**5. Status labeling** Identify and apply proper status labeling throughout the process. (Apply)	
VII B	**B. Environmental monitoring** Use various monitoring techniques (e.g., active air sampling, settling plates, swab sampling, nonviable particle counting, and contact plates for surfaces and people) to determine that appropriate environmental conditions are maintained during production operations. (Analyze)	Increased cognitive level from Apply to Analyze
VII C	**C. In-process and finished goods inspections**	
VII C 1	**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)	
VII C 2	**2. Vision and detection systems**	

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
	Ensure that vision and detection systems are qualified, calibrated, and challenged as required for the system. (Apply)	
VII C 3	**3. Defect characterizations** Ensure that defect characterizations are identified for each product and can be detected by inspection or test. (Analyze)	Increased cognitive level from Apply to Analyze.
VII C 4	**4. Equipment failure detection** Confirm by inspection or test that equipment failures can be detected. (Apply)	
VII D	**D. Product inspection**	
VII D 1	**1. Staff evaluation** Ensure that staff who perform manual and semi-automatic inspections are properly trained and that their inspections meet reproducibility requirements. (Analyze)	Increased cognitive level from Apply to Analyze.
VII D 2	**2. Inspector requirements** Establish requirements for inspectors to have periodic eye examinations. Confirm and document that they take frequent breaks from inspection. (Apply)	
VII D 3	**3. Automated inspection processes** Ensure that automated inspection processes are validated. (Apply)	
VII E	**E. Packaging operations and controls**	
VII E 1	**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)	
VII E 2	**2. Qualification and maintenance of equipment** Ensure that equipment used in packaging operations is qualified and maintained. (Apply)	
VII E 3	**3. Line clearance operations** Determine that line clearance is performed and documented. (Analyze)	Increased cognitive level from Apply to Analyze.
VII E 4	**4. Quality check criteria** Identify and apply specified criteria when quality checks are performed. (Analyze)	Increased cognitive level from Apply to Analyze.
VII E 5	**5. Cut-label procedures** Apply appropriate procedures for cut labels and splices. (Apply)	
VII E 6	**6. Hand-applied label procedures** Ensure that hand-applied labels are 100% inspected. (Apply)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VII E 7	**7. Packaging controls** Distinguish between controls needed for different types of packaging processes. (Apply)	Added cognitive level Apply
VII E 8	**8. Contamination controls** Identify controls to prevent microbial and other contamination at all stages of packaging. (Analyze)	Increased cognitive level from Apply to Analyze.
VII E 9	**9. Tamper-evident packaging** Ensure that tamper-evident and child-proof packaging requirements are established for required products. (Apply)	
VII F	**F. Labeling operations and controls**	
VII F 1	**1. Label printing in packaging** Confirm and document that any printing done separately or during packaging is performed correctly. (Analyze)	Increased cognitive level from Apply to Analyze.
VII F 2	**2. Quality of print used** Ensure that any type of print information (engraved and embossed) on packaging materials is clear and resistant to fading, smudging, or erasure. (Apply)	
VII F 3	**3. Label changes** Determine whether regulatory notification and approval is required for proposed label changes. (Evaluate)	Increased cognitive level from Analyze to Evaluate.
VII F 4	**4. Label reconciliation** Confirm that label reconciliation is performed and documented and discrepancies are investigated. (Analyze)	
VII F 5	**5. Unused labels** Confirm that procedures are established and used for controlled, unused, batch-coded labels and labeling materials. (Analyze)	Increased cognitive level from Apply to Analyze.
VII F 6	**6. Label production** Define terms related to offline printing, roll label splicing, gang printing, secure storage, and destruction, (Understand)	
VII F 7	**7. Access control** Ensure that controls are established for the creation, storage, and issuance of labeling such as product labels, package inserts, and printed cartons. (Analyze)	Increased cognitive level from Apply to Analyze and added package inserts and printed cartons to subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VII G	**G. Filling and packaging records**	
VII G 1	**1. Terms** Define terms related to filling and packaging records including evidence of line clearance, printed material reconciliation, and yields. (Understand)	
VII G 2	**2. Setup instructions** Ensure that packaging line setup instructions are appropriate for all components. (Apply)	
	VIII. Product Development and Technology Transfer (13 Questions)	
VIII A	**A. Quality by design concepts**	
VIII A 1	**1. Critical quality attributes (CQAs) and critical process parameters (CPPs)** Identify critical quality attributes (CQAs) for products and critical process parameters (CPPs) for processes. (Evaluate)	Spelled out CQAs and CCPs in subtext.
VIII A 2	**2. Design space** Define the concept of design space as it is used throughout the product lifecycle. (Understand)	
VIII A 3	**3. Process analytical technology (PAT) tools** Identify process analytical technology (PAT) tools including multivariate data analysis, process analyzers, and process and endpoint controls. Describe their use in supporting the manufacture of quality products. (Understand)	Spelled out PAT and increased cognitive level from Remember to Understand.
VIII B	**B. Phase-appropriate Good Manufacturing Practices (GMP) requirements**	Spelled out GMP
VIII B 1	**1. Product life cycle development** Apply phase appropriate Good Manufacturing Practices (GMPs) throughout the product life cycle. (Apply)	Increased cognitive level from Understand to Apply and spelled out GMPs in subtext.
VIII B 2	**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)	
VIII B 3	**3. Combination products** Identify Good Manufacturing Practices (GMP) requirements and various studies required for combination drug-device or drug-delivery products. (Understand)	Spelled out GMPs in subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK	2023 BoK Details	New Elements in 2023 BoK
VIII B 4	**4. Clinical trials material** Describe and apply requirements for production and packaging of clinical trials material and investigational medicinal products (IMPs). (Apply)	
VIII C	**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)	
VIII D	**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)	
VIII E	**E. Scale-up and transfer activities**	
VIII E 1	**1. Development and validation principles** Identify and distinguish between development and validation studies. (Understand)	Minor revision to wording of subtext.
VIII E 2	**2. Technology transfer types** Define different types of technology transfer including manufacturing site change and analytical laboratory site change. Analyze inter-site comparison of results. (Analyze)	Minor revision to wording of subtext.
VIII E 3	**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)	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

Table 3. 2016 CPGP BoK mapped to the 2023 CPGP BoK

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
I	Global Agency Governance	**I**	Global Agency Governance	Increased number of questions from 15 to 17.
I.A	Global regulatory framework	**I.A**	Global regulatory framework	
I.B	Regulations and guidances	**I.B**	Regulations and guidances	Reorganized subtext, removed IPEC and CSA, and added drafts and international standards.
I.C	Mutual recognition agreements	**I.C**	Mutual recognition agreements	
I.D	Regulatory inspections	**I.D**	Regulatory inspections	Reorganized subtext and added preparing for and hosting in-person and remote evaluations and accommodating record requests and digital reporting.
I.E	Enforcement actions	**I.E**	Enforcement actions	
I.F	Regulatory agency reporting	**I.F**	Regulatory agency reporting	
I.F.1	Post-marketing changes	**I.F.1**	Post-marketing changes	
I.F.2	Regulatory reporting requirements	**I.F.2**	Regulatory reporting requirements	
I.F.3	Product surveillance	**I.F.3**	Product surveillance	
I.G	Site Master File (SMF), Validation Master Plan (VMP), Drug Master File (DMF), and Site Reference File (SRF)	**I.G**	Site Master File (SMF), Validation Master Plan (VMP), Drug Master File (DMF), and Site Reference File (SRF)	Expanded subtext to include more context.
II.	Quality Systems	**II.**	Quality Systems	Decreased number of questions from 27 to 26.
II.A	Quality management system (QMS)	**II.A**	Quality management system (QMS)	Added ICH Q7

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
II.B	Quality unit (site) management	**II.B**	Quality unit (site) management	Added Management Representative Expanded subtext to include more context
II.C	Risk management	**II.C**	Risk management and assessment	Revised title of subtopic. Split topic into two subtopics: 2C.1 and 2.C.2
New		**II.C.1**	Risk management	Added ICH Q12
New		**II.C.2**	Risk assessment	
II.D	Training and Personnel qualification	**II.D**	Training and personnel qualification	
II.D.1	Needs analysis	**II.D.1**	Needs analysis	Increased cognitive level to Apply.
II.D.2	Staff development requirements	**II.D.2**	Staff development requirements	
New		**II.D.3**	Training effectiveness and role of supervisor	
II.E	Change control and management	**II.E**	Change control and management	
II.E.1	Pre-change analysis	**II.E.1**	Pre-change analysis	Reworded subtext.
New		**II.E.2**	Change implementation	
II.E.2		**II.E.3**	Post-change analysis	
II.F	Investigations and corrective and preventive action (CAPA)	**II.F**	Investigations and Corrective and Preventive Action (CAPA)	
II.F.1	Trigger events	**II.F.1**	Trigger events	
II.F.2	Response actions	**II.F.2**	Response actions	
II.F.3	CAPA feedback and trending	**II.F.3**	CAPA feedback and trending	
II.G	Audits and self-inspections	**II.G**	Audits and self-inspections	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
II.G.1	Audits processes and results	**II.G.1**	Audits processes and results	Added audit schedules, remote and on-site audits, and document evidence of audit completion
II.G.2	Audit follow-up	**II.G.2**	Audit follow-up	
II.H	Documents and record management	**II.H**	Documents and record management	
II.H.1	GMP document system	**II.H.1**	GMP document system	
II.H.2	Records	**II.H.2**	Records	Added Attributable, Legible, Contemporaneous, Original, Accurate (ALCOA) and PIC/S guidelines.
II.H.3	Record retention	**II.H.3**	Record retention	
II.I	Product complaints and adverse even reports	**II.I**	Product complaints and adverse even reports	
II.I.1	Product complaints	**II.I.1**	Product complaints	Minor rewording of subtext.
II.I.2	Adverse events	**II.I.2**	Adverse events	Added examples of adverse events to subtext.
II.I.3	Event response	**II.I.3**	Event response	Minor rewording of subtext.
II.J	Product trend requirements	**II.J**	Product trend requirements	
II.K	Supplier and contractor quality management	**II.K**	Supplier and contractor quality management	
II.K.1	Supplier quality systems	**II.K.1**	Supplier quality systems	Added vendor to subtext.
II.K.2	Supplier controls	**II.K.2**	Supplier controls	Added vendor and contractor to subtext.
II.K.3	Supplier evaluation	**II.K.3**	Supplier evaluation	Added vendors to subtext.
New		**II.K.4**	Quality agreements	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
New		**II.K.5**	Outsource processes	
III.	Laboratory Systems	**III.**	Laboratory Systems	Decreased number of questions from 21 to 20.
III.A	Compendia (United States, Europe, and Japan)	**III.A**	Compendia (United States, Europe, and Japan)	
III.A.1	Required vs. informational compendia	**III.A.1**	Required vs. informational compendia	
III.A.2	Marketing requirements vs. compendia	**III.A.2**	Marketing requirements vs. compendia	
III.A.3	Compendial methods review	**III.A.3**	Compendial methods review	Reworded subtext and lowered cognitive level from Evaluate to Analyze.
III.A.4	Compendial or non-compendial requirements review	**III.A.4**	Compendial or non-compendial requirements review	
III.A.5	Biological, microbiological, chemical, and physical test methods	**III.A.5**	Biological, microbiological, chemical, and physical test methods	
III.B	Laboratory investigations of atypical results	**III.B**	Laboratory investigations of atypical results	
III.B.1	Test data	**III.B.1**	Test data	
III.B.2	Atypical results	**III.B.2**	Atypical results	
III.C	Instrument management	**III.C**	Instrument management	
III.C.1	Instrument controls	**III.C.1**	Instrument controls	
III.C.2	Instrument calibration	**III.C.2**	Instrument calibration	
III.D	Specifications	**III.D**	Specifications	
III.D.1	Types of specifications	**III.D.1**	Types of specifications	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
III.D.2	Test data and specifications	**III.D.2**	Test data and specifications	
III.D.3	Specifications revision	**III.D.3**	Specifications revision	
III.E	Laboratory record-keeping and data requirements	**III.E**	Laboratory record-keeping and data requirements	
III.E.1	Record-keeping requirements	**III.E.1**	Record-keeping requirements	
III.E.2	Record review	**III.E.2**	Record review	Added auditing electronic data trail, reworded subtext, and increased cognitive level from Apply to Evaluate.
III.E.3	Certificates of analysis (COAs)	**III.E.3**	Certificates of Analysis (COAs)	Spelled out COA.
III.F.	Laboratory handling controls	**III.F.**	Laboratory handling controls	
III.F.1	Sample handling	**III.F.1**	Sample handling	
III.F.2	Reagents, solutions, and standards identification	**III.F.2**	Reagents, solutions, and standards identification	Added traceability to subtext.
III.F.3	Storage requirements	**III.F.3**	Storage requirements	Added solvents to subtext.
III.G	Stability programs	**III.G**	Stability programs	
III.G.1	Release tests vs. stability-indicating tests	**III.G.1**	Release tests vs. stability-indicating tests	Reworded subtext and increased cognitive level from Apply to Analyze.
III.G.2	Stability test data	**III.G.2**	Stability test data	
III.G.3	Stability-point failure	**III.G.3**	Stability-point failure	
III.H	Reserve samples and retains	**III.H**	Reserve samples and retains	
IV.	Infrastructure: Facilities, Utilities, and Equipment	**IV.**	Infrastructure: Facilities, Utilities, and Equipment	Minor revision to title
IV.A	Facilities	**IV.A**	Facilities	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
IV.A.1	Buildings	**IV.A.1**	Buildings	Added document and meeting requirements to subtext.
IV.A.2	Manufacture and storage environment	**IV.A.2**	Manufacture and storage environment	
IV.A.3	Facilities change control	**IV.A.3**	Facilities change control	
IV.B	Utilities	**IV.B**	Utilities	
IV.B.1	Water supply systems	**IV.B.1**	Water supply systems	
IV.B.2	Compressed air and gas systems	**IV.B.2**	Compressed air and gas systems	
IV.B.3	Utility design for production	**IV.B.3**	Utility design for production	
IV.B.4	Utilities design specifications	**IV.B.4**	Utilities design specifications	
IV.B.5	Utilities change control	**IV.B.5**	Utilities change control	
IV.C	Equipment	**IV.C**	Equipment	
IV.C.1	Equipment planning	**IV.C.1**	Equipment planning	
IV.C.2	Equipment layout	**IV.C.2**	Equipment layout	
IV.C.3	Equipment cleaning and maintenance	**IV.C.3**	Equipment cleaning and maintenance	Minor rewording of subtext.
IV.C.4	Equipment cleaning validation or verification	**IV.C.4**	Equipment cleaning validation or verification	Added single-use, multi-use, and dedicated equipment to subtext.
IV.C.5	Equipment change control	**IV.C.5**	Equipment change control	
IV.D	Qualification and validation	**IV.D**	Qualification and validation	
IV.E	Maintenance and metrology	**IV.E**	Maintenance and metrology	
IV.E.1	Maintenance procedures	**IV.E.1**	Maintenance procedures	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
IV.E.2	Metrology change control	**IV.E.2**	Metrology change control	
IV.F	General cleaning, sanitization, and sterilization systems	**IV.F**	General cleaning, sanitization, and sterilization systems	
IV.F.1	Cleaning procedures	**IV.F.1**	Cleaning procedures	
IV.F.2	Sanitization procedures	**IV.F.2**	Sanitization procedures	
IV.F.3	Pest control	**IV.F.3**	Pest control	Minor rewording to subtext.
IV.F.4	Sterilization processes	**IV.F.4**	Sterilization processes	Minor rewording to subtext.
IV.G	Automated or computerized systems	**IV.G**	Automated or computerized systems	
IV.G.1	Validation procedures	**IV.G.1**	Validation procedures	Added implementation to subtext.
IV.G.2	Open and closed computerized systems	**IV.G.2**	Open and closed computerized systems	
IV.G.3	Configuration control	**IV.G.3**	Configuration control	
IV.G.4	Security requirements	**IV.G.4**	Security requirements	Added on-site, multi-use, and cloud-based to subtext.
IV.H	Business continuity and disaster recovery planning	**IV.H**	Business continuity and disaster recovery planning	
IV.H.1	Supply chain impact	**IV.H.1**	Supply chain impact	Added record recovery and ensuring data integrity to subtext.
IV.H.2	Contingency plan	**IV.H.2**	Contingency plan	
V.	Materials and Supply Chain Management	**V.**	Materials and Supply Chain Management	
V.A.	Receipt of materials	**V.A.**	Receipt of materials	
V.A.1	Incoming materials	**V.A.1**	Incoming materials	Added label and product labeling to subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
V.A.2	Inventory controls	**V.A.2**	Inventory controls	Added updating changes to subtext.
V.B	Sampling processes	**V.B**	Sampling processes	
V.B.1	Sampling plans	**V.B.1**	Sampling plans	
V.B.2	Sampling environment	**V.B.2**	Sampling environment	
V.B.3	Cleaning	**V.B.3**	Cleaning	
V.C	Material storage, identification, and rotation	**V.C**	Material storage, identification, and rotation	
V.C.1	Storage suitability	**V.C.1**	Storage suitability	
V.C.2	Labelling of stored materials	**V.C.2**	Labelling of stored materials	Reworded subtopic title.
V.C.3	Stock rotation	**V.C.3**	Stock rotation	
V.C.4	Retest dates vs. expiration dates	**V.C.4**	Retest dates vs. expiration dates	
V.C.5	Mix-up risk	**V.C.5**	Mix-up risk	
V.D	Shipping and distribution	**V.D**	Shipping and distribution	
V.D.1	Temperature-sensitive requirements	**V.D.1**	Temperature-sensitive requirements	
V.D.2	Special requirements	**V.D.2**	Special requirements	
V.D.3	Report requirements	**V.D.3**	Report requirements	
V.D.4	Supply chain security	**V.D.4**	Supply chain security	Minor rewording of subtext.
V.E	Traceability and sourcing	**V.E**	Traceability and sourcing	
V.E.1	Traceability requirements	**V.E.1**	Traceability requirements	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
V.E.2	Biological agent requirements	**V.E.2**	Biological agent requirements	Minor revision to wording of subtext.
V.E.3	Pedigree and sourcing requirements	**V.E.3**	Pedigree and sourcing requirements	
V.F	Salvaged/returned goods and destruction	**V.F**	Salvaged/returned goods and destruction	
V.F.1	Disposition	**V.F.1**	Disposition	
V.F.2	Destruction facilities and processes	**V.F.2**	Destruction facilities and processes	
VI.	Sterile and Nonsterile Manufacturing Systems	**VI.**	Sterile and Nonsterile Manufacturing Systems	
VI.A	Master batch and completed batch records	**VI.A**	Master batch and completed batch records	
VI.A.1	Required elements	**VI.A.1**	Required elements	
VI.A.2	Record processing requirements	**VI.A.2**	Record processing requirements	
VI.B	Production operations	**VI.B**	Production operations	
VI.B.1	Application factors	**VI.B.1**	Application factors	Added Apply cognitive level
New		**VI.B.2**	Process operations	
VI.B.2	Utility requirements	**VI.B.3**	Utility requirements	
VI.B.3	Sanitization and protection	**VI.B.4**	Sanitization and protection	
VI.C	In-process controls	**VI.C**	In-process controls	
VI.C.1	In-process testing	**VI.C.1**	In-process testing	
VI.C.2	Critical process parameters (CPPs)	**VI.C.2**	Critical process parameters (CPPs)	Minor rewording of subtext.
VI.C.3	Process capability	**VI.C.3**	Process capability	Reworded subtopic title and added monitoring process capability to subtext.

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
VI.C.4	Specification limits	**VI.C.4**	Specification limits	
VI.D	Dispensing and weighing controls	**VI.D**	Dispensing and weighing controls	
VI.D.2	Dispensing materials	**VI.D.2**	Dispensing materials	
VI.E	Requirements for critical unit processes	**VI.E**	Requirements for critical unit processes	
VI.E.1	Process parameters	**VI.E.1**	Process parameters	Minor rewording of subtext.
VI.E.2	Validation studies	**VI.E.2**	Validation studies	
VI.E.3	Unit operations	**VI.E.3**	Unit operations	
VI.E.4	Operating procedures	**VI.E.4**	Operating procedures	Added validated and qualified parameters and batch records to subtext.
VI.E.5	Re-evaluation and re-validation	**VI.E.5**	Re-evaluation and re-validation	
VI.E.6	Environmental monitoring requirements	**VI.E.6**	Environmental monitoring requirements	
VI.E.7	Environmental monitoring tools	**VI.E.7**	Environmental monitoring tools	
VI.F	Contamination and cross-contamination	**VI.F**	Contamination and cross-contamination	
VI.F.1	Sources	**VI.F.1**	Sources	Added implementing controls to minimize contamination and cross-contamination to subtext. Increased cognitive level from Apply to Analyze.
VI.F.2	Risk mitigation	**VI.F.2**	Risk mitigation	Clarified subtext
VI.G.	Reprocessed and reworked materials	**VI.G.**	Reprocessed and reworked materials	
VI.G.1	Disposition process	**VI.G.1**	Disposition process	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
VI.G.2	Storage	**VI.G.2**	Storage	
VII	Filling Packaging, and Labeling	**VII**	Filling, Packaging, and Labeling	
VII.A	Filling operations and controls	**VII.A**	Filling operations and controls	
VII.A.1	Materials control	**VII.A.1**	Materials control	Lowered cognitive level from Create to Evaluate.
VII.A.2	Filling equipment control	**VII.A.2**	Filling equipment control	
VII.A.3	Contamination controls	**VII.A.3**	Contamination controls	
VII.A.4	Staged materials	**VII.A.4**	Staged materials	
VII.A.5	Status labeling	**VII.A.5**	Status labeling	
VII.B	Environmental monitoring	**VII.B**	Environmental monitoring	Increased cognitive level from Apply to Analyze
VII.C	In-process and finished goods inspections	**VII.C**	In-process and finished goods inspections	
VII.C.1	Inspections	**VII.C.1**	Inspections	
VII.C.2	Vision and detection systems	**VII.C.2**	Vision and detection systems	
VII.C.3	Defect characterizations	**VII.C.3**	Defect characterizations	Increased cognitive level from Apply to Analyze.
VII.C.4	Equipment failure detection	**VII.C.4**	Equipment failure detection	
VII.D	Product inspection	**VII.D**	Product inspection	
VII.D.1	Staff evaluation	**VII.D.1**	Staff evaluation	Increased cognitive level from Apply to Analyze.
VII.D.2	Inspector requirements	**VII.D.2**	Inspector requirements	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
VII.D.3	Automated inspection processes	**VII.D.3**	Automated inspection processes	
VII.E	Packaging operations and controls	**VII.E**	Packaging operations and controls	
VII.E.1	Content protection	**VII.E.1**	Content protection	
VII.E.2	Qualification and maintenance of equipment	**VII.E.2**	Qualification and maintenance of equipment	
VII.E.3	Line clearance operations	**VII.E.3**	Line clearance operations	Increased cognitive level from Apply to Analyze.
VII.E.4	Quality check criteria	**VII.E.4**	Quality check criteria	Increased cognitive level from Apply to Analyze.
VII.E.5	Cut-label procedures	**VII.E.5**	Cut-label procedures	
VII.E.6	Hand-applied label procedures	**VII.E.6**	Hand-applied label procedures	
VII.E.7	Packaging controls	**VII.E.7**	Packaging controls	Added Apply cognitive level
VII.E.8	Contamination controls	**VII.E.8**	Contamination controls	
VII.E.9	Tamper-evident packaging	**VII.E.9**	Tamper-evident packaging	Increased cognitive level from Apply to Analyze.
VII.F	Labeling operations and controls	**VII.F**	Labeling operations and controls	Increased cognitive level from Apply to Analyze.
VII.F.1	Label printing in packaging	**VII.F.1**	Label printing in packaging	
VII.F.2	Quality of print used	**VII.F.2**	Quality of print used	Increased cognitive level from Analyze to Evaluate.
VII.F.3	Label changes	**VII.F.3**	Label changes	
VII.F.4	Label reconciliation	**VII.F.4**	Label reconciliation	Increased cognitive level from Apply to Analyze.
VII.F.5	Unused labels	**VII.F.5**	Unused labels	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
VII.F.6	Label production	**VII.F.6**	Label production	Increased cognitive level from Apply to Analyze and added package inserts and printed cartons to subtext.
VII.F.7	Access control	**VII.F.7**	Access control	Increased cognitive level from Apply to Analyze.
VII.G	Filling and packaging records	**VII.G**	Filling and packaging records	
VII.G.1	Terms	**VII.G.1**	Terms	
VII.G.2	Setup instructions	**VII.G.2**	Setup instructions	
VIII.	Product Development and Technology Transfer	**VIII.**	Product Development and Technology Transfer	
VIII.A.	Quality by design concepts	**VIII.A.**	Quality by design concepts	
VIII.A.1	Critical quality attributes (CQAs) and critical process parameters (CPPs)	**VIII.A.1**	Critical quality attributes (CQAs) and critical process parameters (CPPs)	Spelled out CQAs and CCPs in subtext.
VIII.A.2	Design space	**VIII.A.2**	Design space	
VIII.A.3	Process analytical technology (PAT) tools	**VIII.A.3**	Process analytical technology (PAT) tools	Spelled out PAT and increased cognitive level from Remember to Understand.
VIII.B	Phase-appropriate Good Manufacturing Practices (GMP) Requirements	**VIII.B**	Phase-appropriate Good Manufacturing Practices (GMP) Requirements	Spelled out GMP
VIII.B.1	Product life cycle development	**VIII.B.1**	Product life cycle development	Increased cognitive level from Understand to Apply and spelled out GMPs in subtext.
VIII.B.2	Development phases	**VIII.B.2**	Development phases	
VIII.B.3	Combination products	**VIII.B.3**	Combination products	Spelled out GMPs in subtext.
VIII.B.4	Clinical trials material	**VIII.B.4**	Clinical trials material	

Certified Pharmaceutical GMP Professional (CPGP)
Body of Knowledge (BoK) Map 2016 – 2023

2016 BoK		2023 BoK		Notes
Code	**Label**	**Code**	**Label**	
VIII.C	Raw materials, packaging, and infrastructure for product development	**VIII.C**	Raw materials, packaging, and infrastructure for product development	
VIII.D	New product development studies and reports	**VIII.D**	New product development studies and reports	
VIII.E	Scale-up and transfer activities	**VIII.E**	Scale-up and transfer activities	
VIII.E.1	Development and validation principles	**VIII.E.1**	Development and validation principles	Minor revision to wording of subtext.
VIII.E.2	Technology transfer types	**VIII.E.2**	Technology transfer types	Minor revision to wording of subtext.
VIII.E.3	Successful technology transfer	**VIII.E.3**	Successful technology transfer	