

### **Cognitive Level Mapping for**

A3Q Certified Filatifiaceutical divir Fibressi						
Торіс	Remember	Understand	Apply	Analyze	Evaluate	Create
I. Regulatory Agency Governance (17 Questions)						
A. Global regulatory framework						
Identify the acts, statutes, and directives that apply to pharmaceuticals. (Understand)		X				
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),		Х				
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)						
C. Mutual recognition agreements						
Interpret requirements that govern product registration, import or export of raw material or		х				
finished product, and the sharing of inspection findings. (Understand)		^				
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		v				
and host in-person and remote evaluations and how to accommodate record requests and		Х				
digital reporting. (Understand)						
E. Enforcement actions						
Define and describe various global enforcement actions and consequences (e.g., warning		x				
letters, consent decree, license withdrawals, product seizure, and import alerts). (Understand)						
F. Regulatory agency reporting						
1. Post-marketing changes						
Describe how post-marketing changes to specifications, processes, and methods are assessed						
for impact to determine the appropriate reporting method [e.g., scale up and post-approval		Х				
changes (SUPAC)]. (Understand)						
2. Regulatory reporting requirements						
Describe global reporting requirements including supplements, field alerts, biological product						
deviation reports, adverse events, product recalls, annual reports, and variations to dossiers		Х				
and applications. (Understand)						
3. Product Surveillance						
Describe monitoring requirements for risk evaluation and mitigation strategy (REMS) and		V				
pharmacovigilance. (Understand)		Х				
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),						
		Х				
Drug Master Files (DMFs), and Site Reference Files (SRFs). (Understand)						
II. Quality Systems (26 Questions)						
A. Quality management system (QMS)						
Describe key elements of the structure of a Quality Management System (QMS). Outline the					Χ	
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)						
B. Quality unit (site) management						
B. Quanty 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		V				
		Х				
release (disposition) requirements for investigational and commercial products, and the need						
for quality units to be independent from operations. (Understand)						
C. Risk management and assessment						
1. Risk management						
Use various methods to apply risk management principles as described in ICH Q9, ICH Q12, and			Х			
other guidance and regulatory documents. (Apply)						
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.			X			
(Apply)						



### **Cognitive Level Mapping for**

ASQ Certified Filatifiaceutical Givir Professi	Oliai Do		wieug	e- 2023		
Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
D. Training and personnel qualification						
1. Needs analysis						
Identify the requirements for determining the type of training, qualification, and experience			Χ			
needed by quality staff members, operations personnel, and related functions. (Apply)						
2. Staff development requirements						
Determine proof of proficiency based on regulations, guidances, and directives including						
documented evidence and periodic reassessment. (Apply)			Х			
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			Х			
assigned functions. (Apply)						
E. Change control and management						
1. Pre-change analysis Assess						
the impact that proposed changes will have on products, processes, facilities, utilities, and				Χ		
systems to minimize risk and ensure regulatory compliance. (Analyze)						
2. Change implementation						
Implement and document the change following a change implementation plan. (Create)						X
3. Post-change analysis						Λ
Analyze data and other inputs to determine the results of a change and evaluate any new risk				V		
				Х		
factors created by the change. (Analyze)						
F. Investigations and corrective and preventive action (CAPA)						
1. Trigger events						
Identify events that require investigation, root cause analysis, and impact assessment both					Χ	
directly and indirectly related to the event. (Evaluate)					X	
2. Response actions						
Define immediate action, corrective action, preventive action, management responsibility, and						
methods of implementing them. (Evaluate)					Χ	
3. CAPA feedback and trending						
Describe how CAPA trending is used to modify appropriate quality system elements. (Create)						X
G. Audits and self-inspections						
1. Audits processes and results						
·						
Develop audit schedules, differentiate between various audit types (systems, product, and		х			Χ	
process) conducted either remotely or on-site, document evidence of audit completion, and		^			^	
analyze audit results to assess conformance to requirements. (Evaluate)						
2. Audit follow-up						
Use various methods to evaluate and verify the effectiveness of corrective actions taken.					Χ	
(Evaluate)						
H. Documents and records management						
1. GMP document system						
Describe the GMP document system to determine compliance to regulatory requirements						
including corporate standards, master plans, procedures, manufacturing, and test instructions.				X		
(Analyze)						
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				Χ		
PIC/S guidelines for data integrity. (Analyze)						
3. Record retention						
Identify regulatory requirements for record retention. (Understand)		Х				
I. Product complaints and adverse event reports						
1. Product complaints						
Describe and distinguish between product complaints and adverse events. Evaluate complaint-					Χ	
handling processes. (Evaluate)						
2. Adverse events						
Describe regulatory requirements for the reporting of adverse events (e.g. counterfeit product				X		
, fraud). (Analyze)						
3. Event response						
Evaluate the level of action that needs to be taken in response to adverse events such as					Χ	
corrections, and product removal. (Evaluate)						



### **Cognitive Level Mapping for**

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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		X				
to data trends and other required elements. (Understand)						
K. Supplier and contractor quality management						
1. Supplier quality systems						
Identify and interpret standards and regulations related to monitoring supplier, vendor, and		Х				
contractor quality management systems. (Understand)						
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					X	
need for formal contracts/quality agreements. (Evaluate)						
3. Supplier evaluation						
Assess the quality systems of suppliers, vendors, and contractors using various methodologies					Χ	
including supplier qualification, certification, evaluation, audit, and supplied product or service						
performance trending. (Evaluate)						
4. Quality agreements						
		v				
Explain the purpose and describe the main elements of a quality agreement. (Understand)		Х				
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			Χ			
responsibilities of each party. (Apply)						
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			Х			
chapters. (Apply)						
2. Marketing requirements vs. compendia						
Distinguish among the U.S. Pharmacopoeia (USP), European Pharmacopoeia (PhEur or EP), and		Х				
Japanese Pharmacopoeia (JP) in terms of requirements for marketing authorization.		^				
(Understand)						
3. Compendial methods review						
Review compendial methods to ensure they are verified as suitable for use in the testing lab.				Χ		
(Analyze)						
4. Compendial or non-compendial requirements review						
Review test methods, qualifications, validation, and verification against required compendial				Χ		
chapters (general and informational, as needed). (Analyze)						
5. Biological, microbiological, chemical, and physical test methods						
Identify and interpret results from compendia identification tests, quantitative analysis,						
qualitative analysis, and other tests or studies for biological, microbiological, chemical, and			Х			
physical tests. (Apply)			^			
B. Laboratory investigations of atypical results						
1. Test data						
Describe and develop procedures for investigating each type of test data including biological,				Х		
microbiological, chemical test, and unknowns. (Analyze)						
2. Atypical results						
Identify, analyze, and interpret data on processes or products that are out-of-specification or					X	
out-of-trend. Determine the outcome of the laboratory portion of the investigation and the					^	
criteria for further investigation. (Evaluate)						
C. Instrument management						
1. Instrument controls						
Apply operating procedures for instrument identification, classification, qualification,			Х			
calibration, and preventive maintenance. (Apply)						
2. Instrument calibration						
Determine that instruments are calibrated within the specified range of operation and that			Х			
they are accurate and precise. (Apply)			^			
they are accurate and precise. (Appriy)						



### **Cognitive Level Mapping for**

Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
D. Specifications			11.7	,		
1. Types of specifications						
Determine whether approved specifications exist for raw materials, intermediates, packaging				Х		
components, labels, and finished products. (Analyze)						
2. Test data and specifications						
Compare test data with specifications to determine whether raw materials, intermediates,				Χ		
packaging, labels, and finished products meet requirements. (Analyze)						
3. Specifications revision						
Review and update specifications when methods are revised, or compendia are changed.					Χ	
(Evaluate)						
E. Laboratory record-keeping and data requirements						
1. Record-keeping requirements						
Identify and review record-keeping requirements for data acquisition systems to ensure data			Х			
integrity. (Apply)						
2. Record review						
Ensure data integrity and prevent loss of data by reviewing laboratory records including audit					Χ	
trails of electronic data to detect errors, falsification, and fraud . (Evaluate)						
3. Certificates of analysis (COAs)						
Review Certificates of Analysis (COAs) to ensure they are complete, internally reviewed, and			X			
appropriately retained. (Apply)						
F. Laboratory handling controls						
1. Sample handling						
Determine whether samples are identified and handled in accordance with requirements			Х			
including name, sample identification, and chain of custody. (Apply)						
2. Reagents, solutions, and standards identification						
Determine whether reagents, solutions, and standards are identified and labeled, and			V			
quantities are traceable in accordance with requirements including opened-on, expiry,			X			
(validated) use-by, or recertify-by dates. (Apply)						
3. Storage requirements						
Describe and use procedures to store samples, reagents, solutions, solvents, and standards in			Χ			
appropriate environmental conditions (e.g., temperature, humidity, light exposure, and						
absence of oxygen) to maintain the material's characteristics for testing. (Apply)						
G. Stability programs						
1. Release tests vs. stability-indicating tests				X		
Define and distinguish between release and stability-indicating tests. (Analyze)				^		
2. Stability test data						
Review stability data against specifications and identify trends that can establish, support, or					Χ	
challenge an expiry date. (Evaluate)						
3. Stability-point failure						
Identify the stability-point failure of a product or material and evaluate the implications for					Χ	
regulatory compliance. (Evaluate)						
H. Reserve samples and retains						
Describe the various regulatory requirements for retains and reserve samples. (Apply)			X			
IV. Infrastructure: Facilities, Utilities, Equipment (17 Questions)						
A. Facilities						
4 Bulldham						
1. Buildings						
Determine and document the requirements for appropriate size and construction of buildings			X			
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)						
3. Manufacture and storage environment						
2. Manufacture and storage environment			Χ			
Identify requirements for appropriate lighting, ventilation, and drainage to avoid adversely						
affecting product (either directly or indirectly) during manufacturing and storage. (Apply)						
3. Facilities change control						
Use various methods to verify that change control practices are in use to maintain the			X			
qualified state of the facilities. (Apply)						



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ASQ Certified Pharmaceutical GiviP Professi			wieug	e- <u>ZUZ3</u>		
Торіс	Remember	Understand	Apply	Analyze	Evaluate	Create
B. Utilities						
1. Water supply systems						
Identify and interpret regulatory requirements for the design of water supply systems						
including various unit operations (e.g., dechlorination, reverse osmosis, deionization, and			Х			
distillation), delivery lines, back-flow or back-siphonage prevention, and drainage systems as			X			
appropriate for the type of water (potable, purified, and water for injection) needed in various						
processing steps. (Apply)						
2. Compressed air and gas systems						
Identify and apply regulatory requirements related to compressed air and gas systems			Χ			
including storage, flow regulation, filtration, venting, and purging. (Apply)						
3. Utility design for production						
Identify and select utility designs related to production steps (e.g., washing, sterilizing, and			Χ			
depyrogenation) for use with specific materials and processes. (Apply)						
4. Utilities design specifications						
Review operations of utilities to ensure they meet design specifications. (Apply)			X			
5. Utilities change control						
Verify that change control practices are used to maintain the qualified state of affected			X			
utilities. (Apply)						
C. Equipment						
1. Equipment planning						
Review equipment location, design, construction, installation, and maintenance based on the			Х			
operations to be conducted. (Apply)			^			
2. Equipment layout						
Determine the layout of equipment to minimize the risk of errors, to facilitate effective			X			
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 sanitization			X			
(where necessary) to ensure that they meet requirements. (Apply)						
4. Equipment cleaning validation or verification						
Evaluate the need and methodology for product-contact cleaning validation and verification.					Χ	
Evaluate the difference between single-use, multi-use, and dedicated equipment. (Evaluate)						
5. Equipment change control			Х			
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				Х		
testing (FAT/SAT), design, installation, operational, and performance qualification				Λ		
(DQ/IQ/OQ/PQ) prior to process validation. (Analyze)						
E. Maintenance and metrology systems						
1. Maintenance procedures						
Verify that procedures are used for routine and non-routine maintenance of heating,				V		
ventilation, air conditioning (HVAC) systems, air and water filters, and other equipment and				Х		
utilities. (Analyze)						
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				Х		
manufacturing facilities, utilities, and equipment. (Analyze)						
F. General cleaning, sanitization, and sterilization systems						
1. Cleaning procedures						
Review cleaning procedures in accordance with cleaning validation whenever validation is						
required and performed. (Apply)			X			
2. Sanitization procedures						
Review sanitization procedures for facilities and equipment and ensure all are in accordance			Х			
with any required validation studies including details on cleaning schedules, methods,						
equipment, materials, sanitizers, disinfectants, sporicides, and sterilants. (Apply)						
equipment, materials, summaters, assumedation, sportedes, and sterialis. (Appril)						



#### **Cognitive Level Mapping for**

Test control Review and verify that a pest control program is established and that it uses authorized recovering the control program is established and that it uses authorized recovering the control program is established and that it uses authorized recovering the control program is established and validated. (Apply)  A settlemation processes  A settlemation processes  A settlemation processes  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)  A comparation of computerized systems. (Apply)  A comparation occurred and closed computerized systems. (Apply)  A comparation control and closed computerized systems (Apply)  A comparation control and closed computerized systems to ensure they meet requisitor, and guidance requirements for key elements such as access control, data protection, electronic signature, change control, data arriving, maintenance, transcription, electronic system monitoring, (Evaluate)  1. Business continuity and disaster recovery planning.  2. Contingency plan  2. Contingency plan  3. Receipt of materials and supply the intention of the supply change in maintenance, transcription, electronic systems are equired or proceduralized. (	ASQ Certified Pharmaceutical GiviP Professi						
Review and verify that a pest control program is established and that it uses subtorized conducticution. (Apply)  A Settilization processes Verify that appropriate sterilization processes are established and validated. (Apply)  A Settilization processes Verify that appropriate sterilization processes are established and validated. (Apply)  B CALformated or computerized systems L 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 momitored. (Evaluate) 2. Open and closed computerized systems. Verify that critical parameters for their operation and maintenance are controlled and momitored. (Evaluate) 3. Configuration control 3. Configuration control 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version signature, change control, data architory, and activities of the version of	·	Remember	Understand	Apply	Analyze	Evaluate	Create
rodenticides, insecticides, fungicides, fungiting agents, and appropriate traps for pest dimination. (Apphy) 4. Sterilization processes Verify that appropriate scritization processes are established and validated. (Apphy)  8. Automated or computerized systems 1. Includiation 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) 2. Open and dosed computerized systems Distinguish between open and closed computerized systems. (Apphy) 3. Configuration control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Security requirements Verify that version control and configuration are maintained and monitored. (Evaluate) 4. Business continuity and disaster recovery planning 6. Lisupph chain impact 6. Review plans and verify procedures for disaster recovery, record recovery, and business continuity that will impact 6. Review plans and verify procedures for disaster recovery, record recovery, and business continuity that will impact 6. Automatical plans and verify procedures for disaster recovery, record recovery, and business continuity that will impact operations from interruption to the supply chain and ensure data integrity. (Evaluate) 7. Accepted on the second system monitoring. (Veryfy the s							
robenticities, finitericities, fungating, fungating agents, and appropriate traps for pest elimination, fugiply)  4. Sterifization processes (which is a processed or a stablished and validated. (Apply)  5. Automated or computerized systems  1. Validation procedures for implementation and validation of automated or computerized systems. (Apply)  2. Toylen and closed computerized systems occurred. (Evaluate)  2. Open and closed computerized systems occurred. (Evaluate)  3. Configuration control and closed computerized systems. (Apply)  3. Configuration control and configuration are maintained and monitored. (Evaluate)  3. Configuration control and configuration are maintained and monitored. (Evaluate)  4. Substitution of the control				Х			
4. Sterifization processes  Writing that appropriate sterifization processes are established and validated. (Apply)  G. Automated or computerized systems  1. Validation procedures for implementation and validation of automated or computerized systems. Verify that critical parameters for their operation and validation of automated or computerized systems. Verify that critical parameters for their operation and maintenance are controlled and monitored. (Evaluate)  2. Open and dosed computerized systems  Dostinguish between open and closed computerized systems. (Apply)  3. Configuration control  3. Verify that version control and configuration are maintained and monitored. (Evaluate)  4. Security requirements  5. Verify that version control and configuration are maintained and monitored. (Evaluate)  4. Security requirements  5. Version on the constant of the version							
Verify that appropriate sterification processes are established and validated. (Apply)  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 mominored. (Evaluate)  2. Open and closed computerized systems  Distinguish between open and closed computerized systems. (Apply)  3. Configuration control  4. Security requirements for their operation and maintenance are controlled and monitored. (Evaluate)  4. Security requirements  5. Verify that version control and configuration are maintained and monitored, (Evaluate)  4. Security requirements  5. Verify that version control and configuration are maintained and monitored, (Evaluate)  4. Security requirements  5. Verify that version cignature, change control, data archiving, maintenance, transcription, audit trail, and periodic system monitoring. (Evaluate)  1. Supply chain impact  8. Verify that version development of disaster recovery, record recovery, and business continuity that will guard operations from interruption to the supply chain and ensure data imagerity. (Evaluate)  2. Contingency plan  2. Contingency plan  3. Receipt of materials  1. Incomping materials  3. Incomping materials  3. Incomping materials  3. Incomping materials  3. Incomping materials  5. Incomping materials  6. A Receipt of materials  7. Incomping materials  7. Incomping materials  8. A Receipt of materials  9. A Receipt of materials, materials from unapproved suppliers, and missing documentation. (Apply)  9. Canaming plans for representative sampling, appropriate sample size, and test or inspection criteria. (Apply)  9. Sampling plans for representative sampling, appropriate sample size, and test or inspection criteria. (Apply)  9. Sampling plans for requirements for sampling environment and utensis to the typ							
Cautionated or computerized systems  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)  2. Open and dosed computerized systems  2. Open and dosed computerized systems  2. Open and dosed computerized systems  3. Configuration control  3. Configuration control  4. Security requirements  4. Security requirements  5. Verify that version control and configuration are maintained and monitored. (Evaluate)  4. Security requirements  5. Verify that version control and configuration are maintained such as access control, data  4. Security requirements  5. Verify that version control and configuration are maintained and monitored. (Evaluate)  4. Security requirements  5. Verify that version signature, change control, data archiving, maintenance, transcription, audit trail, and periodic system monitoring. (Fealuate)  1. Supply chain impact  8. 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. (Pobladate)  2. Contingency plan  2. Contingency plan  3. Receipt of materials  3. Incoming materials  3. A Receipt of materials  3. Incoming materials  4. Receipt of materials  5. Incoming materials  6. Describe and super processes to receive, label, and store incoming materials (raw materials, bulk chemicals, components, and product labeling) and take appropriate estion on deviations  7. A Receipt of materials  8. Continuity of the supplication of the supplications of the supplication of t	·			X			
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) 2. Open and dosed computerized systems Destringshib herwen open and closed computerized systems. (Apply) 3. Configuration control 3. Configuration control 4. Security requirements Civalisate on site, multi-site, 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) 4. Security requirements Civalisate on site, multi-site, 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) 4. Supply chain impact Continuity than till guard operations from interruption to the supply chain and ensure data integrity. (Evaluate) 5. Contingency plan 6. Verify the testing and effectiveness of contingency plans as required or proceduralized. Contrigency plan 7. Verify the testing and effectiveness of contingency plans as required or proceduralized. Capphy 8. Acception of materials 8. Accepti							
Neview procedures for implementation and validation of automated or computerized systems.   X   Y   X   X   X   X   X   X   X   X	·						
Verify that critical parameters for their operation and maintenance are controlled and monitored. (Evoluate)  2. Open and closed computerized systems  Distinguish between open and closed computerized systems. (Apply)  3. Configuration control  4. Security requirements  5. Sequence of the control and configuration are maintained and monitored. (Evoluate)  4. Sequency requirements  5. Sealuate on-site, multi-liste, 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)  1. Supply chain impact  8. Review plans and verify procedures for disaster recovery, record recovery, and business  8. Review plans and verify procedures for disaster recovery, record recovery, and business  8. Contingency plan  9. Verify the testing and effectiveness of contingency plans as required or proceduralized.  1. Apply)  1. Materials and Supply Chain Management (17 Questions)  1. Receipt of materials  1. Incoming materials  1. Incoming materials  1. Incoming materials  1. Incoming materials  1. Describe and use processes to receive, label, and store incoming materials (raw materials, bulk chemicals, components, and product labeling) and take appropriate action on deviations (damaged materials, materials from unapproved suppliers, and missing documentation).  1. (Apply)  2. Sampling processes  1. Sampling processes  1. Sampling processes  1. Sampling processes  2. Sampling processes  3. Sampling processes  4. Sampling processes  5. Sampling processes  6. Sampling processes  7. Sampling processes  8. Sampling processes  9. Sampling processes  1. Sampling proces	·						
verify that critical parameters for their operation and maintenance are controlled and monitored. (Evaluate)  2. Open and closed computerized systems. (Apply)  3. Configuration control  4. Security requirements control  4. Security requirements control  5. Support control and configuration are maintained and monitored. (Evaluate)  4. Security 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)  1. Supply chain impact  8. Business continuity and disaster recovery planning  1. Supply chain impact  8. Business continuity and disaster recovery planning  1. Supply chain impact  8. Periodic system monitoring, (Evaluate)  9. Contingency plan  9. Contingency plan  9. Contingency plan  9. Verify the testing and effectiveness of contingency plans as required or proceduralized. (Apply)  9. Materials and Supply Chain Management (17 Questions)  1. Incoming materials  1. Incoming materials  1. Receipt of materials  1. Incoming materials  1. Receipt of materials  1. Contingency plan  9. Contingency plans  9. Contingency plan  9. Contingency plan  9. Contingency plans  9. Contingency plan  9. Contingency plan  9. Contingency plans  9. Contingency plan  9. Contingency plans						X	
2. Open and closed computerized systems   Distinguish between open and closed computerized systems. (Apply)   X						^	
Distinguish between open and closed computerized systems. (Apply)  X Configuration control  X Sconfiguration control  X Sconfiguration control and configuration are maintained and monitored. (Evaluate)  X Security requirements  Evaluate on-site, multi-site, and cloud-based computerized systems to ensure they meet regulatory and guidance requirements for key elements such as access control, data protection, electron signature, change control, data archiving, maintenance, transcription, audit trail, and periodic system monitoring. (Evaluate)  1. Supply chain impact Review plans and verify procedures for disaster recovery planning  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)  2. Contingency plan  Verify the testing and effectiveness of contingency plans as required or proceduralized. (Apply)  4. Watterlals and Supply Chain Management (17 Questions)  A. Receipt of materials  1. Incoming materials  Describe and use processes to receive, label, and store incoming materials (raw materials, bulk chemicals, components, and product labeling) and take appropriate action on deviations (damaged materials, materials from unapproved suppliers, and missing documentation). (Apply)  2. Inventory controls  Describe and use procedures for documenting inventory transactions, updating changes in material status, allocation, and "stop shipments" for quality holds. (Apply)  8. Sampling processes  1. Sampling plans for representative sampling, appropriate sample size, and test or inspection criteria. (Apply)  2. Labelling of stored materials  3. Cleaning  6. Saurage environment  5. Cleaning  6. Saurage environment to appropriately cleaned and monitored and that sampling  4. Cleaning  6. Saurage environment is appropriately cleaned and monitored as required for the type of  5. The saurage environment is appropriately cleaned and monitored as required for the	,						
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#### **Cognitive Level Mapping for**

A Retest dates vs. expiration dates  Oscario the difference between retest dates and expiration dates. (Understand)  S. Misup nisk  S. Misup	"ASQ Certified Pharmaceutical GiviP Profess						
Describe the difference between retest dates and expiration dates. (Understand)  Ministry price of the difference between retest dates and expiration dates. (Understand)  ShiPuping and Sucress of mix-up and identify methods to minimize their risk (material segregation, beliefuls, pedical storage for process, control of markarial etums, in to control methods, and special processes for materials with similar names). (Analyze)  D. Shipping and distribution  1. Temperature-sensitive requirements  Medicarly special requirements for temperature-sensitive products including tertiary packaging.  design, and monitoring devices, Inalyze)  2. Special requirements  Determine specific product requirements and apply them to routine shipping processes.  Apply 3. Report requirements  Determine specific product requirements and apply them to routine shipping processes.  Apply 3. Report requirements  Determine specific product requirements in accordance with good distribution practices. (Analyze)  3. Report requirements  Determine specific product requirements in accordance with good distribution practices. (Analyze)  4. Supply chain sections  A	•	Remember	Understand	Apply	Analyze	Evaluate	Create
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segregation, labeling, special storage for rejects, control of material returns, lot-control methods, and special processes for materials with similar names). (Analyze)  D. Shipping and distribution  1. Temperature-sensitive requirements for temperature-sensitive products including tertiary packaging, design, and monitoring devices. (Analyze)  2. Special requirements for temperature-sensitive products including tertiary packaging, design, and monitoring devices. (Analyze)  2. Special requirements  Setting product requirements and apply them to routine shipping processes.  (Apply)  2. Special requirements  Analyze shipping reports and transportation requirements in accordance with good distribution practices. (Analyze)  4. Supply chain security  (Authority and apply the various means to secure the supply chain including tamper-evident soals, shipping manifects, verification of documentation, barcoding, radio frequency destinations of the supply chain including tamper-evident soals, shipping manifects, verification of documentation, barcoding, radio frequency destinations of the supply destination of the supply chain including tamper-evident soals, shipping manifects, verification of documentation, barcoding, radio frequency destinations of the supply destination of the supply chain including tamper-evident soals, shipping manifects, verification of documentation, floating and supply destinations of the supply chain including tamper-evident soals, shipping manifects, verification of documentation, (Apply)  2. Traceability requirements for traceability of incoming materials, intermediates, and infinite drugs, (Apply)  2. Biological agent requirements in finite drugs, (Apply)  2. Biological agent requirements for manifestion of the supply of the requirements for manifestion of the supply of the requirements for manifestion of the supply of the requirements of manifestion of the supply of the requirements of manifestion of the supply							
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Identify various production operations that require gowning, sanitization, hygiene, and other  X							
product-protective steps. (Apply)				X			
	product-protective steps. (Apply)						



### **Cognitive Level Mapping for**

		ay or itile			_	
Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
C. In-process controls						
1. In-process testing						
Identify appropriate tests for each step in the manufacturing process and review results.				Х		
(Analyze)						
2. Critical process parameters (CPPs)				X		
Monitor critical process parameters (CPPs). (Analyze)				۸		
3. Process capability						
Understand the importance of conducting process capability studies, calculate Cp and Cpk,			Χ			
and monitor process capability. (Apply)						
4. Specification limits					Χ	
Assess specification limits in relation to registration or compendial requirements. (Evaluate)						
D. Dispensing and weighing controls						
1. Staging areas						
Review product dispensing and after-dispensing staging areas to determine if they meet			Х			
requirements. (Apply)			^			
течиненнях. (Арріу)						
2 Planator metadala						
2. Dispensing materials						
Identify the requirements for using weighing equipment and handling utensils for dispensing				Х		
raw materials or intermediates including proper cleaning, labeling, and environmental						
controls, based on the type of material and manufacturing process being used. (Analyze)						
E. Requirements for critical unit processes						
1. Process parameters						
Use required critical process parameters (CCPs) for unit processes such as sterilization or						
sterilizing filtration, aseptic filling, depyrogenation, lyophilization, other drying processes,			Χ			
tablet granulation and compression, terminal sterilization, and cream or ointment						
emulsification. (Apply)						
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					Χ	
such as requirements for aseptic processes including process simulations ("media fills") and					X	
temperature controls. (Evaluate)						
3. Unit operations						
3. Offic Operations						
Access unit processes and their validations for deviations requiring investigation (Apply20)				Χ		
Assess unit processes and their validations for deviations requiring investigation. (Analyze)						
4. Operating procedures						
Review qualification and validation results and confirm that validated and qualified				Х		
parameters are reflected in operating procedures or batch records. (Analyze)						
5. Re-evaluation and revalidation						
Determine appropriate criteria and frequency for re-evaluation and revalidation of unit					Χ	
processes. (Evaluate)						
6. Environmental monitoring requirements						
Differentiate between environmental monitoring requirements for different manufacturing			X			
area classifications. (Apply)						
7. Environmental monitoring tools						
Describe and use various monitoring tools to measure viable and nonviable particulates,			Χ			
pressure differentials, temperature, and humidity. (Apply)						
F. Contamination and cross-contamination						
1. Sources						
Identify potential sources for, and implement controls to minimize, contamination and cross-				Х		
contamination. (Analyze)						
2. Risk mitigation						
Describe and apply various techniques for mitigating the risk of contamination and cross-			Х			
contamination including cleaning; facility, utility, and equipment design; material and			Α			
personnel flow; qualified disinfectants; operator training; validation; and monitoring. (Apply)						
personner now, quantied distinectants, operator training, valuation, and monitoring. (Appry)						



#### **Cognitive Level Mapping for**

ASQ Certified Pilatifiaceutical Givip Professi						
Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
G. Reprocessed and reworked materials						
1. Disposition process						
Distinguish reprocessing from reworking and apply appropriate documentation, approval, and			Χ			
disposition methods for these materials. (Apply)						
2. Storage						
Describe and apply requirements for segregation and secure storage of these materials.			Χ			
(Apply)						
VII. Filling, Packaging, Labeling (18 Questions)						
A. Filling operations and controls						
1. Materials control						
Develop and review procedures to ensure the identity, strength, and purity of specified						
materials (e.g., liquids, powders, ointments, tablets, capsules, and suspensions) and to prevent					X	
them from being altered. (Evaluate)						
them nom being arecrea. (Livalance)						
3 Filling anninment control						
2. Filling equipment control				Χ		
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)						
3. Contamination controls			X			
Identify controls to prevent microbial and other contamination at all stages of filling. (Apply)						
4. Staged materials			X			
Review staged materials and confirm that they are approved for use. (Apply)			^			
5. Status labeling			V			
Identify and apply proper status labeling throughout the process. (Apply)			X			
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				X		
appropriate environmental conditions are maintained during production operations. (Analyze)						
C. In-process and finished goods inspections						
1. Inspections						
Develop criteria for in-process and finished goods inspections of filled and packaged materials						Х
including seal tests, torque testing, and bottle rejection systems. (Create)						^
2. Vision and detection systems						
Ensure that vision and detection systems are qualified, calibrated, and challenged as required			X			
			X			
for the system. (Apply)						
3. Defect characterizations				.,		
Ensure that defect characterizations are identified for each product and can be detected by				X		
inspection or test. (Analyze)						
4. Equipment failure detection			X			
Confirm by inspection or test that equipment failures can be detected. (Apply)						
D. Product inspection						
1. Staff evaluation						
Ensure that staff who perform manual and semi-automatic inspections are properly trained				X		
and that their inspections meet reproducibility requirements. (Analyze)						
2. Inspector requirements						
Establish requirements for inspectors to have periodic eye examinations. Confirm and			X			
document that they take frequent breaks from inspection. (Apply)						
3. Automated inspection processes			.,			
Ensure that automated inspection processes are validated. (Apply)			Х			
E. Packaging operations and controls						
1. Content protection						
Develop and apply procedures to prevent the environment or events from altering the						Χ
identity, strength, purity, and quality of the package content. (Create)						
2. Qualification and maintenance of equipment						
Ensure that equipment used in packaging operations is qualified and maintained. (Apply)			X			
3. Line clearance operations						
Determine that line clearance is performed and documented. (Analyze)				Х		
Determine that line clearance is performed and documented. (Analyze)						



#### **Cognitive Level Mapping for**

ASQ Certified Pharmaceutical GiviP Professi						
Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
4. Quality check criteria				Χ		
Identify and apply specified criteria when quality checks are performed. (Analyze)						
5. Cut-label procedures			Х			
Apply appropriate procedures for cut labels and splices. (Apply)						
6. Hand-applied label procedures			Х			
Ensure that hand-applied labels are 100% inspected. (Apply)						
7. Packaging controls			Х			
Distinguish between controls needed for different types of packaging processes. (Apply)						
8. Contamination controls						
Identify controls to prevent microbial and other contamination at all stages of packaging.				X		
(Analyze)						
9. Tamper-evident packaging						
Ensure that tamper-evident and child-proof packaging requirements are established for			X			
required products. (Apply)						
F. Labeling operations and controls						
1. Label printing in packaging						
Confirm and document that any printing done separately or during packaging is performed				X		
correctly. (Analyze)						
2. Quality of print used						
Ensure that any type of print information (engraved and embossed) on packaging materials is			Х			
clear and resistant to fading, smudging, or erasure. (Apply)			Λ			
3. Label changes						
Determine whether regulatory notification and approval is required for proposed label					Χ	
changes. (Evaluate)						
4. Label reconciliation						
Confirm that label reconciliation is performed and documented, and discrepancies are				X		
investigated. (Analyze)						
5. Unused labels						
Confirm that procedures are established and used for controlled, unused batch-coded labels				Χ		
and labeling materials. (Analyze)						
6. Label production						
Define terms related to offline printing, roll label splicing, gang printing, secure storage, and		Х				
destruction. (Understand)						
7. Access control						
Ensure that controls are established for the creation, storage, and issuance of labeling such as				V		
product labels, package inserts, and printed cartons. (Analyze)				X		
G. Filling and packaging records						
1. Terms						
Define terms related to these records including evidence of line clearance, printed material		Х				
reconciliation, and yields. (Understand)						
2. Setup instructions			v			
Ensure that packaging line setup instructions are appropriate for all components. (Apply)			Х			
VIII. Product Development and Technology Transfer (13 Questions)						
A. Quality by design concepts						
Critical quality attributes (CQAs) and critical process parameters (CPPs)						
Identify critical quality attributes (CQAs) for products and critical process parameters (CPPs)					Χ	
for processes. (Evaluate)						
2. Design space		Х				
Define the concept of design space as it is used throughout the product lifecycle. (Understand)						
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		Х				
manufacture of quality products. (Understand)						
<u> </u>						



# Cognitive Level Mapping for "ASQ Certified Pharmaceutical GMP Professional Body of Knowledge- 2023"

Topic	Remember	Understand	Apply	Analyze	Evaluate	Create
B. Phase-appropriate Good Manufacturing Practices (GMP) requirements						
1. Product life cycle development						
Apply phase appropriate Good Manufacturing Practices (GMPs) throughout the product life			Х			
cycle. (Apply)						
2. Development phases						
Identify recommendations and requirements in relation to phases of development including		v				
method qualification/validation, comparability protocols, and adoption of critical process		Х				
parameters and specifications. (Understand)						
3. Combination products						
Identify Good Manufacturing Practices (GMP) requirements and various studies required for		Х				
combination drug-device or drug-delivery products. (Understand)						
4. Clinical trials material						
Describe and apply requirements for production and packaging of clinical trials material and			X			
investigational medicinal products (IMPs). (Apply)						
C. Raw materials, packaging, and infrastructure for product development						
Select appropriate development studies for raw material selection and evaluate the results to				.,		
determine their critical quality attributes. (Analyze)				X		
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.					Χ	
(Evaluate)						
E. Scale-up and transfer activities						
1. Development and validation principles		V				
Identify and distinguish between development and validation studies. (Understand)		Х				
2. Technology transfer types						
Define different types of technology transfer including manufacturing site change and				Χ		
analytical laboratory site change. Analyze inter-site comparison of results. (Analyze)						
3. Successful technology transfer						
Define various studies including ranging, capability, in-process control, hold times, and						
shipping to ensure successful transfer between development and commercial processes.					X	
(Evaluate)						

SIX LEVELS OF COGNITION						
BASED ON BLOOM'S TAXONOMY - REVISED (2001)						
In addition to <i>content</i> specifics, the subtext detail also indicates the intended <i>complexity level</i> of the test questions for that topic. These levels are based on the Revised "Levels of Cognition" (from Bloom's Taxonomy, 2001) and are presented below in rank order, from least complex to most complex.						
REMEMBER	Х					
Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.						
UNDERSTAND		Х				
Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.						
APPLY			Х			
Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.						
ANALYZE				X		
Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.						
EVALUATE					Х	
Make judgments about the value of proposed ideas, solutions, by comparing the proposal to specific criteria or standards.						
CREATE						Х
Put parts or elements together in such a way as to show a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.						



#### **Cognitive Level Mapping for**

"ASQ Certified Pharmaceutical GMP Professional Body of Knowledge- 2023"

Topic Remember Understand Apply Analyze Evaluate Create

Торіс	Questions	Weightage %
I. Regulatory Agency Governance (17 Questions)	17	11.33
II. Quality Systems (26 Questions)	26	17.33
III. Laboratory Systems (20 Questions)	20	13.33
IV. Infrastructure: Facilities, Utilities, Equipment (17 Questions)	17	11.33
V. Materials and Supply Chain Management (17 Questions)	17	11.33
VI. Sterile and Nonsterile Manufacturing Systems (22 Questions)	22	14.67
VII. Filling, Packaging, Labeling (18 Questions)	18	12.00
VIII. Product Development and Technology Transfer (13 Questions)	13	8.67
Total	150	100.00

#### References

These books cover various parts of the CPGP Body of Knowledge. The ASQE Certification Council does not endorse any one particular reference source.

ANSI/ISO/ASQ Q9001-2008: Quality Management Systems: Requirements

Bioanalytical Method Validation 2018

Code of Federal Regulations (CFR) Title 21

Code of Federal Regulations 21 CFR

Directive 2001/83/EC on the Community Code Relating to human medicinal products

Durivage, Mark A., The Certified Pharmaceutical GMP Professional Handbook, 2nd ed. Milwaukee, WI: ASQ Quality Press, 2016.

Eudralex Volume 4, Parts I and II and Annexes

**FDA Guidances** 

FDA Guide to Inspections

Food and Drug Administration (FDA) Guidances Quality Systems Approach to Pharmaceutical CGMP Regulations

General chapters related to pharmaceutical analytical methods and practices

Good Manufacturing Practices (A Compendium of Guidelines and Related Materials Volume 2: Good Manufacturing Practices and Inspection)

Griffith, Gary K., The Quality Technician's Handbook, 6th ed., New Jersey: Pearson Education, 2013.

Guidance for Industry: PAT- A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance

Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products

Hazard Analysis and Critical Control Point Principles and Application Guidelines, Adopted, August 14, 1997 National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

Health Canada Guidelines 0069 Guidelines for Temperature Control of Drug Products During Storage and Transportation

Health Canada Guidelines Good Manufacturing Practices Guidelines

ICH Quality Guidelines

IPEC GMP Guide for Pharmaceutical Excipients

Note for Guidance on Quality of Water for Pharmaceutical Use

PDA Technical Report No. 26

PIC/S Aide-Memoires

PIC/S GMP Guide Part 1, Part 2 and Annexes, PE 009-10

PIC/S Guidance Documents

PIC/S Site Master File Documents

Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, 2004 WHO

Report No. 30 Parametric release of Pharmaceutical and Medical device products terminally sterilized by moist heat

Standardized Numerical Identification for Prescription Drug Packages

TGA Amended EU (EMEA/410/01) Guideline Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products

WHO Expert Committee on Specifications for Pharmaceutical Preparations

World Health Organization (WHO) Publications