Registered Quality Assurance Professional in GLP Examination Detailed Content Outline

The scored items on the exam are comprised of the following sections, with the number of exam items on the topic of each section corresponding to the percentage indicated in this table.	Total
I. COMPLIANCE ASSESSMENT	43%
A. *Monitoring* is the direct observation, testing and assessment of in-process activities and personnel for independent evaluation of compliance and the quality and integrity of the process.	
Monitor:	11%
1. receipt, handling, storage, preparation (including mixing), analyses /or administration to the test system of the test, control and reference material	
2. test system receipt, quarantine, randomization/allocation, identification, acclimation, observations and disposition	
3. specimen and/or sample collection, labeling, storage, shipping, receiving, handling and/or disposition	
4. specimen and/or sample analyses	
5. reagent and supply shipping, receiving, handling, storage and disposition	
6. adherence of procedures specified in protocol, SOPs and applicable company policies	
7. data collection processes and data integrity (manual and automated)	
8. equipment maintenance, calibration and validation	
9. archive of test article, facility and study materials, including disaster recovery and the appropriateness of raw data for archival storage, retrieval and disposition	
10. laboratory, facility and/or site activities that support GLP studies	
B. *Inspecting* is the critical appraisal, by visual, olfactory and tactile means, of the capability, adequacy and/or current performance of a physical entity (e.g., laboratory, testing facility, field site, equipment) for adherence to established regulatory standards.	
Inspect:	11%
1. component laboratories (e.g., chemistry, histology, pathology, clinical pathology, surgery, microbiology, electron microscopy and reproductive toxicology)	
2. non-laboratory sites (e.g., field sites, test plots, mesocosms and simulation structures)	
3. storage areas (e.g., for test, control and reference materials; specimens, samples, media, feed and bedding; chemicals, reagents and unused equipment/supplies to include equipment for low temperature storage)	
4. computer facilities and associated controlled procedures and/or systems (including disaster recovery)	
5. protocols, SOPs, facility records, operating permits and/or related information in each laboratory/site location	
6. data under active collection in each laboratory/site location	
7. labeling (e.g., samples/specimens; chemicals; reagents; test, control and reference materials; etc.)	
8. equipment associated with test system maintenance (e.g., animal rooms, test plots, aquaria) and study conduct	
9. equipment maintenance, calibration, and validation	
10. archives including the appropriateness of raw data (including electronic data) for archival storage, retrieval, and environmental control	
11. laboratory or field site that participates in a study, including vendors, contractors or subcontractors	
12. storage conditions of test, control and reference materials and specimens; data and samples	

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C. *Auditing* is the process of methodical examination, with intent to verify, of raw and derived or transformed data, protocols, reports, standard operating procedures, memoranda, personnel records, notes, electronic records and related documentation for accuracy, integrity and adequacy for GLP compliance.	
Audit:	21%
1. protocols, amendments and deviations including the associated documentation	
2. SOPs, revisions and deviations including the associated documentation	
3. reporting structure of the organization and personnel qualifications including curricula vitae, job descriptions and training records	
4. equipment verification and/or validation including the associated documentation	
5. computer system development, verification, validation, release, maintenance, and retirement processes including associated documentation	
6. test article, control and reference material characterization, dosing mixture(s), concentrations, stability analyses and/or homogeneity analyses including data, reagents and associated documentation	
7. analytical method validation and documentation	
8. chain of custody documentation (e.g., shipping and receipt records for specimens and samples)	
9. data traceability (e.g., electronic and paper)	
10. certificates of analyses and associated documentation	
11. final reports (including contributing scientists' reports, phase reports, amendments and compliance exceptions) and/or GLP Compliance Statement	
12. accountability records for test, control and/or reference materials, including records for preparation, administration, transfer and disposal	
13. test system randomization documentation	
14. equipment maintenance, calibration and repair records	
15. temperature, humidity and other environmental control records	
16. study documentation, raw data (e.g., electronic and paper) and data calculations including transformations, transcriptions and derivations (e.g., statistical analyses and summary tables)	
17. archival process and other authorized access/tracking records	
18. animals/test system history, receipt, health, quarantine, maintenance, and disposal records	
19. study director/scientist notes and memoranda related to the study including records documenting unforeseen circumstances and assessment of study impact	
20. findings and responses to quality assurance unit inspections	
II. COMPLIANCE MANAGEMENT	29%
A. *Scheduling* is a management tool for controlling the flow of work in the Quality Assurance Unit. Scheduling provides a mechanism for identifying and tracking the status of tasks, functions and responsibilities.	
Schedule:	10%
1. protocol audits	
2. critical phase study inspections	
3. raw data and supporting documentation audits	
4. draft, interim and/or final report audits	
5. release of the Quality Assurance Statement for inclusion in the final report	
6. facility and support area inspections	
7. follow-up for issue resolution	

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8. maintain a copy of the Master Schedule and its updates	
9. GLP training of personnel involved in the GLP process (e.g., the quality assurance unit, study personnel, archivist, study director, test facility management)	
10. manage/facilitate site visits, inspections and audit activities of sponsors and regulatory officials	
B. *Reporting/Record Keeping* are processes for physically capturing, documenting and/or communicating the observations, comments, findings, recommendations and activities of Quality Assurance Unit.	
Report on and/or keep records of:	10%
1. GLP compliance status of studies, facilities, systems and processes	
2. scheduled and ad hoc inspections/audits and findings	
3. quality assurance unit copies of study protocols and protocol amendments	
4. protocol and SOP deviations	
5. quality assurance unit reports to management, study director and other key individuals such as principal investigator, sponsor/client representative, etc.	
6. quality assurance unit SOPs	
7. copies of current and previous (historical) versions of facility and quality assurance unit SOPs and records of review of facility and quality assurance unit SOPs	
8. Master Schedule	
9. inventory of quality assurance unit study materials for archival retention and access, removal, and replacement disposition of materials from Archives	
10. report any findings impacting study integrity immediately to the study director and management and keep records of the notification	
C. *Documenting* is the process of writing the procedures and work of the Quality Assurance Unit.	
Document:	9%
1. inspection and audit results and response review	
2. schedules to ensure the timely performance of required activities	
3. status of recommended corrective actions based on facility and/or study audits	
4. quality assurance unit statements for study reports	
5. quality assurance unit SOPs	
6. training and qualifications of quality assurance unit personnel	
7. records of regulatory and sponsor/client inspection activities, findings, and quality assurance unit and management responses (including issue escalation)	
8. records of other activities performed by the quality assurance unit	
III. APPLIED EXPERTISE	28%
A. *Evaluating* is the critical assessment of the nature, significance, adequacy, value and/or quality of a person, process, system or physical entity.	
Evaluate:	10%
1. overall facility/site operations, security, management, and the functional performance of quality systems to assure the integrity, reliability and usefulness of the data	
2. contract laboratories, facilities and field sites, as well as vendors or subcontractors, and their associated systems for the capability to perform particular studies and adhere to GLP standards	
3. protocols and SOPs related to established procedures and available resources	
4. systems for auditing, inspecting and/or tracking information related to GLPs	
5. corrective actions resulting from inspecting and monitoring	

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6. internal organizational structure and lines of communication	
7. personnel qualification records (e.g., curricula vitae, job descriptions, training records)	
8. training programs designed to support GLP compliance	
B. *Advising* is a process for providing management and staff with informed, expert opinion, advice and/or recommendations on issues pertaining to GLP regulations, studies and facilities/sites.	
Advise management and staff regarding:	18%
1. application of GLPs to studies	
2. application of GLPs to your company/situation/relationship (e.g., lab, field site, vendor, sponsor)	
3. study director and management responsibilities	
4. content and meaning of the GLP Compliance Statement	
5. content and meaning of the Quality Assurance Statement in the final report	
6. responsibilities, obligations and rights of management and the company during the conduct of regulatory inspections	
7. behavior and responsibilities of staff when hosting outside inspectors	
8. current regulatory trends and new information appearing in the Federal Register and other official or unofficial regulatory documents	
9. training modules for facility personnel on GLP related subjects	
10. compliance issues arising during inspection related activities	
11. importance and meaning of quality assurance unit inspectional/audit findings	
12. regulatory dimension of systems validation and equipment qualification	
13. scope of the quality assurance unit compliance program	
14. GLP documentation for study events and reports	
15. content of personnel curricula vitae, job descriptions and/or personnel training records	
16. protocol and protocol amendment and deviation documentation requirements	
17. SOP content, revision, authorization and distribution requirements	
18. study report content, revision, and approval requirements	
19. proper documentation procedures	
20. corrective actions following inspections and/or audits including the adequacy of responses (e.g., root cause analysis)	
21. continuous process improvements (e.g., risk analysis) related to GLP compliance	
22. archiving requirements	