Registered Quality Assurance Professional in GCP 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. QUALITY MANAGEMENT: SUPPORT	**21.3%**
A. *Planning* provides a mechanism for identifying and tracking the status of clinical quality assurance tasks, functions and responsibilities. In addition, it supports the planning of advanced organizational functions such as managing workload, planning audit/inspections and followup. Workload is managed through risk assessment, tactical planning, and strategic planning.	7.3%
1. Plan audit by type (e.g., investigator site, vendor, process, systems, document)	
2. Plan audit logistics (e.g., face-to-face, virtual, platforms, tools, document access, systems)	
3. Plan directed/for-cause audits in response to sponsor hold or participant/employee/stakeholder complaints or suspected scientific misconduct and noncompliance	
4. Plan support for regulatory inspections	
5. Incorporate risk assessment in the identification and prioritization of QA tasks	
6. Plan quality-related meetings (e.g., timelines, SOPs)	
B. *Generating* and maintaining records includes processes for physically capturing and documenting observations, comments, recommendations, actions and quality assurance activities.	6%
1. Generate and maintain records of audit generated reports (e.g., plans, observations, reports, certificates, correspondence, CAPA)	
2. Generate and maintain records of quality training and staff development activities	
3. Generate and maintain records of regulatory official site visits and inspections	
4. Generate and maintain records of trend analysis records of audit observations and corrective & preventative actions	
5. Generate and maintain records of communications required by the quality system	
C. *Developing* procedures involves preparation of detailed written instruction for quality assurance practice standards to achieve consistency in the performance of a specific function.	8%
1. Prepare procedures for auditing tasks (e.g., plans, schedules, reports, confirmation letters)	
2. Prepare procedures for preparing, managing and reporting of regulatory inspection activities	
3. Prepare procedures for preparing, managing and reporting of sponsor/client audit activities	
4. Prepare procedures for supporting inquiries/investigations into suspected sigificant noncompliance, suspected research misconduct or allegations of fraud or serious breach of GCP	
5. Prepare procedures for the maintenance of quality assurance records	
6. Prepare procedures for CAPA activities	
II. QUALITY MANAGEMENT: ASSESSMENT	**45.3%**
A. *Inspecting* is a critical appraisal by visual, olfactory, and tactile means of the capability, adequacy, and/or current performance of a study facility (e.g., physician's office, hospital, study clinic, equipment) for adherence to established standards and applicable policies and procedures.	7%
1. Inspect areas/facilities where there is interaction with study participants	
2. Inspect areas/facilities where additional study activities are conducted (e.g., contract laboratories, pharmacies, contract research organizations, vendors)	
3. Inspect areas/facilities where specimens are collected, processed and stored to ensure the area is adequate to perform protocol required tests and accommodate study participants	

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4. Inspect storage areas for test article/investigational product, clinical supplies and environment control	
5. Inspect computer facilities including security, environmental controls and the associated uninterruptible power supply	
6. Inspect location and storage of study and source documents (including environment control and security)	
7. Inspect retention samples of test articles/investigational product and specimens	
B. *Auditing* is a systematic and independent examination of activities and documents to evaluate that they are conducted and are recorded, analyzed and accurately reported according to the protocol, regulations and procedural documents, GCPs and applicable requirements.	27%
1. General Audit Activities	
a. Conduct interviews of auditees	
b. Audit procedural documents, procedural document revisions and deviation documentation	
c. Audit personnel qualifications including curricula vitae, job descriptions, certifications, licenses and training records	
d. Audit computer system validation and equipment use and qualification documentation	
e. Audit data storage and security	
f. Audit physical and logical security procedures (e.g., study records, server rooms, facility access)	
g. Audit Business Continuity Plan (BCP) and disaster recovery	
h. Audit contractual obligations and agreements	
i. Audit SOPs/Quality Management System (QMS)	
2. Investigational Site Audit Activities	
a. Audit chain of custody documentation and accountability of test articles/investigational products and specimen records	
b. Audit participant screening, enrollment and randomization documentation	
c. Audit source data and electronic medical records	
d. Audit required clinical trial documents (e.g., Trial Master File, regulatory files, protocols, clinical study reports)	
e. Audit privacy and confidentiality disclosure documents	
f. Audit informed consent process and documents	
g. Audit the IRB/IEC review process and documentation	
h. Audit documentation of protocol violations and deviations, exceptions and waivers	
i. Audit monitoring activities	
j. Audit follow up to monitoring, inspection and/or audit reports	
k. Audit records of storage and retention requirements	
l. Audit adverse event (e.g., SAE, SUSAR, UADE) reporting documentation and compliance with regulatory reporting timelines	
3. Other Audit Activities (e.g., Vendor, Process, Systems)	
a. Audit quality issues/noncompliance management	
b. Audit change control management processes	

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C. *Analyzing and Evaluating*: Analyzing is the methodical examination of information for purposes of explanation and interpretation. Evaluating is the subsequent critical assessment of authenticity, integrity, compliance level, significance, adequacy and quality of a process, system or physical entity.	11.3%
1. Analyze and evaluate compliance of items assessed and inspected with the study protocol, procedural documents, GCPs and applicable regulatory requirements	
2. Analyze and evaluate vendor qualifications and suitability (e.g., fitness for purpose)	
3. Analyze and evaluate adequacy of auditee's resources to complete contractal obligations	
4. Analyze and evaluate adequacy of remediation activities	
5. Analyze and evaluate completeness, accuracy, reliability and validity of study data	
6. Analyze and evaluate the informed consent process, subject privacy and human protection for a study	
7. Analyze and evaluate physical and logical security procedures	
8. Analyze and evaluate trends (e.g., audit observations, deviations, CAPAs, data)	
9. Analyze and evaluate quality and compliance risks	
10. Analyze and evaluate interview responses	
III. QUALITY MANAGEMENT: APPLIED EXPERTISE	**33.3%**
A. *Advising* is a consultative process for providing informed, subject matter expert opinion, advice and/or recommendations on issues pertaining to the interpretation of GCP regulations and requirements.	21.3%
1. Advise regarding applicable regulations and standards	
2. Advise regarding responsibilities of organizational management, investigational staff, sponsors and IRB/IECs	
3. Advise regarding expectations during the conduct of audits/inspections	
4. Advise regarding current industry and regulatory trends and new information	
5. Advise regarding training of staff on GCP	
6. Advise regarding compliance issues arising during inspection and/or pre- and post-inspection	
7. Advise regarding regulatory requirements for electronic record system validation and equipment use and qualification	
8. Advise regarding applicable requirements of the quality assurance program	
9. Advise regarding applicable requirements of documentation practices	
10. Advise regarding content of personnel qualification	
11. Advise regarding protocol and protocol amendment documentation requirements	
12. Advise regarding procedural document content, revision, retention, authorization and distribution requirements	
13. Advise regarding study report content and approval requirements	
14. Advise regarding internal departmental quality control criteria, procedures and documentation	
15. Advise regarding trend analyses of production and interpretation of quality assurance/regulatory inspections, audits and observations	
16. Advise regarding logical and physical security requirements	
17. Advise regarding remediations including adequacy of responses to inspections and/or audits	
18. Advise regarding proactive process improvements	
19. Advise regarding data integrity	

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B. *Communicating, educating, and reporting:* Communicating is the sharing or exchange of quality-related information either formally or informally via oral or written means with stakeholders. Educating is developing the faculty of a person by providing information in a multitude of ways. Reporting is a formal oral or written account of observations and outcomes.	12%
1. Facilitating and contributing to quality-related discussions with various stakeholders (e.g., staff, audit team, site personnel, management)	
2. Facilitating quality-related meetings (e.g., opening meeting, daily debrief, close-out meeting, site audits)	
3. Writing and issuing an audit report	
4. Communicating and reporting sensitive information	
5. Following up on audit report responses/CAPA	
6. Creating and delivering training	
7. Interacting with regulatory inspectors or sponsor/vendor auditors	
8. Providing site education	
9. Reporting trends analysis and evaluation results to management	
10. Communicating and reporting escalation issues	

SAMPLE QUESTIONS

The following are examples of multiple-choice questions as they may appear on the examination. When answering the questions, you are to select the one response that BEST answers the question (or completes the sentence).

1. Documentation of the education, training and experience that qualify an investigator to assume the responsibility for the proper conduct of a clinical trial should be provided in:

   A. a protocol
   B. a curriculum vitae
   C. an investigator's brochure
   D. a study-specific monitoring plan

2. A protocol specifies that a subject should have a physical examination at visit 2. However, the investigator forgot to complete the physical examination at this visit. This should be documented as

   A. an SOP revision.
   B. an SOP deviation.
   C. a protocol deviation.
   D. a protocol amendment.

WANT MORE PRACTICE QUESTIONS?

SQA has created a 30-question RQAP-GCP Practice Examination to help prospective Registrants practice taking the exam. Visit https://www.sqa.org/store/detail.aspx?id=C_GCP_PRACTICE for details.

Answer Key
1. B 2. C