Society of Quality Assurance™
HOME TO THE WORLD'S BEST QA PROFESSIONALS

RQAP™

Registered Quality Assurance Professional in GCP or GLP Examinations

Candidate Handbook

Society of Quality Assurance (SQA)
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ABOUT SQA

The Society of Quality Assurance (SQA) is a nonprofit, international quality assurance professional membership society based in the United States that has over 2,300 members in over 50 countries. SQA represents professionals in pharmaceutical, agricultural, industrial, chemical and contract testing and research organizations, as well as regulatory agencies and academic institutions. SQA provides leadership to these professionals through its regional chapters and specialty sections and extensive professional development programs of meetings, lectures and information exchanges. SQA fosters interaction, communication and high professional standards and supports extensive interaction with regulatory agencies. SQA recognizes and supports high professional standards, knowledge and experience through registration examinations, currently offered in the Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) disciplines. See www.sqa.org for further information about SQA.

ABOUT RQAP

Surveys suggest that various benefits may accrue to the individual credentialed as a RQAP. In order to make these benefits available to the widest range of professionals, this voluntary program is not restricted solely to SQA members, but is open to any person who meets the examination requirements and maintains registration.

RQAP-GLP

Since 1997, volunteers serving on the SQA Council on Professional Registration, as well as many other participants from SQA, have invested thousands of hours and funds from personal and employer resources to investigate the utility and feasibility of professional certification in GLP (Good Laboratory Practice) quality assurance. Coupled with Professional Registration Task Force and Examination Committee activities and SQA's investment in working with a professional testing services provider to analyze the profession and develop the registry examination, this represents a significant effort by SQA to promote high professional standards throughout the GLP quality assurance profession, as envisioned in SQA's Bylaws. The content outline of this exam is reviewed and revalidated by survey and committee analysis every five years.

RQAP-GCP

In 2004, the Clinical Specialty Section (CSS) of SQA decided to explore the need for a registration examination in Quality Assurance for professionals focused on GCP. Many SQA members working in the GCP area contributed to the development of the examination by participating in surveys and serving on various committees. A team of volunteer content experts (SQA ad hoc RQAP-GCP Examination Committee), and the SQA Council on Professional Registration (CPR) partnered with a professional testing services provider to analyze the tasks that the GCP QA professional performs. The content experts referred to the FDA GCP regulations (21 CFR 11, 50, 54, 56, 312, 314, 812 and 814), the ICH Standards, Health Canada standards and other standards listed in Addendum 2 of this handbook for the task analysis and preparation of the exam. The analysis was reviewed by a broad cross-section of GCP quality assurance professionals for accuracy and relevance. From this analysis, a registration examination was developed. This effort represents a significant step by SQA to promote high professional standards throughout the GCP quality assurance profession, as envisioned in SQA's Bylaws. The content outline of this exam is reviewed and revalidated by survey and committee analysis every five years.

STATEMENT OF NONDISCRIMINATION POLICY

SQA does not discriminate among applicants on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

TESTING AGENCIES

SQA has contracted Professional Testing, Inc., to provide services related to the development, administration, and analysis of the registry examinations. The exams are delivered, in cooperation with Professional Testing, through Pearson VUE's extensive network of testing centers.

Professional Testing, Inc.
301 E. Pine Street, Suite 505
Orlando, FL 32801 USA
Phone: +1 407.264.2993
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E-mail: info@proftesting.com
Web: www.proftesting.com

EXAMINATION POLICIES

EXAMINATION

Both RQAP examinations consist of 165 questions. Fifteen of the questions will not be scored; they are being evaluated to determine if they should be included as scored questions in future examinations. Individuals with expertise in quality assurance write the questions and review them for relevancy, consistency, accuracy and appropriateness. SQA, with the advice and assistance of Professional Testing, Inc., then prepares the examinations. You will be allowed three and a half (3½) hours to complete the examination. Individuals passing the examination will be credentialed as Registered Quality Assurance Professionals in GCP or GLP (RQAP-GCP or RQAP-GLP). The examinations are administered on computer at Pearson VUE Assessment Centers, remotely in your home or office (new in 2022, and with some restrictions), and, very rarely, during special administrations. During a special administration, the examination will be offered in paper and pencil format.

EXAMINATION APPLICATION INFORMATION

Apply for an in-person computer-based (CBT) or at-home remote-proctored examination: To apply for the RQAP examination, complete the application included with this handbook and send it to SQA by the application postmark deadline. SQA processes the application and within approximately two weeks after the application deadline sends a confirmation notice by e-mail including a website address and toll-free telephone number to contact Pearson VUE to schedule an examination appointment. Be prepared to confirm a location and a preferred date and time for testing. APPLICATIONS POSTMARKED AFTER THE DEADLINE MAY BE RETURNED UNPROCESSED.

REFUNDS

If, for any reason, your application does not meet the established eligibility requirements, the examination fee will be refunded minus a $75 processing fee. Outreach candidates will be charged a lower processing fee commensurate with costs.

Refunds will NOT be granted to individuals requesting to withdraw from an examination after submitting an accepted application (excepting the extenuating circumstances noted below). All approved candidates have the opportunity to either reschedule their appointment or defer their examination entirely; see subsequent sections on Rescheduling or Canceling an In-Person CBT or At-Home Remote-Proctored Examination and Deferring an Examination Registration. If you fail to appear for the examination on the scheduled date without having canceled or rescheduled the appointment, you will forfeit the full amount of the examination fee (excepting the extenuating circumstances noted below).

Emergency Illness, Death, or Other Extenuating Circumstance: Attendees who are unable to attend the examination under the following circumstances may receive special consideration:

- Personal illness or death of the Candidate; or
- Illness or death of the Candidate's loved one(s); or
- Significant extenuating circumstances beyond the Candidate's control. (The validity of the extenuating circumstances described for application of this policy shall be at the discretion of the Council on Professional Registration.)

Candidates who neglect to cancel their exam within the allowed cancellation period (see subsequent section on Rescheduling or Canceling an In-Person CBT or At-Home Remote-Proctored Examination) may receive a partial refund of the full fee minus a processing charge that Pearson VUE charges SQA. Candidates who cancel their exam but will be unable to take the exam in future may receive a full refund of the exam fee minus a $75 processing fee. Requestors shall submit the request in writing to SQA Headquarters along with written documentation where possible.

The Council on Professional Registration Chair shall review the request to ensure it is in accordance with written policy.

ELIGIBILITY REQUIREMENTS

To be eligible for the Professional Registry Examination, you must fulfill one of the following requirements:

1. Have the equivalent of four (4) years of full-time quality assurance experience (as defined below) in the specified exam discipline; OR
2. Have a baccalaureate degree AND the equivalent of two (2) years of full-time quality assurance experience (as defined below) in the specified exam discipline.

A full-time QA Professional is one who conducts audits of, evaluates, and inspects activities as described in the GCP or GLP regulations noted in the Study References (on page 12 for GLP and page 20 for GCP). The QA Professional's work experience must encompass auditing, evaluating and inspecting. Any candidate specializing in a subset of these activities must demonstrate experience in all activities as outlined in the applicable Detailed Content Outline (on page 7 for GLP and page 15 for GCP).

- A ***QA Professional*** is one who, through qualification experience and training, performs audits, evaluates, and inspects against compliance requirements.
- An ***audit*** is a systematic and independent examination of activities and documents to determine compliance with applicable requirements.
- ***Independent*** means one who is not involved in the investigation's design, development, execution or reporting.

A COPY OF YOUR CURRICULUM VITAE (CV) MUST BE SUBMITTED WITH YOUR APPLICATION. Your CV must include the years and months worked in each job position, a specific list of your job responsibilities/duties for each job position, and the percentage of time devoted to QA/audit work in each job position.

Experience: To document experience, you are required to provide a professional reference on the application who can verify your experience and eligibility to take this examination.

REQUESTS FOR SPECIAL EXAMINATION ACCOMMODATIONS

SQA and Professional Testing, Inc./Pearson VUE comply with the Americans with Disabilities Act (ADA) and are committed to ensuring that individuals with disabilities are not deprived of the opportunity to take the examination solely by reason of disability. Special examination arrangements may be made for these individuals, provided that an appropriate request for accommodation is submitted with the examination application. Testing facilities in non-US locations must comply with local related requirements. Special accommodations are also available for candidates for whom English is not their first or primary language. A form for requesting special accommodations is provided in the Handbook Addendum. Testing accommodations made for ADA-compliant reasons are not subject to an additional fee. English language testing accommodations are subject to an additional fee.

SCHEDULING AND TAKING THE EXAM

SCHEDULING YOUR EXAMINATION

If you are taking an exam in-person via computer-based testing (CBT) in a testing center or remotely via OnVUE, Pearson VUE's remote-proctored exam environment from your home or office, you will have options to schedule your appointment with Pearson VUE by web or by telephone. Further details about scheduling your appointment will be provided to you via e-mail after your exam application has been reviewed for eligibility and approved.

RESCHEDULING OR CANCELING AN IN-PERSON CBT OR AT-HOME REMOTE-PROCTORED EXAMINATION

Candidates taking an exam in-person via computer-based testing (CBT) in a testing center must cancel or reschedule exam appointments at least one full business day (24 hours) before the original appointment through the Pearson VUE website or the call center. Candidates taking an exam at home via OnVUE, Pearson VUE's remote-proctored exam environment, must reschedule their exam at least 1 hour before the original appointment.

Refunds are not available except as described in the previous section on refunds.

DEFERRING AN EXAMINATION REGISTRATION

Candidates may defer their examination registration to a future examination period up to three times.

Candidates wishing to defer their examination registration **must first cancel any existing examination appointments**. If a candidate does not have an existing examination appointment, or if their previous appointment has been successfully canceled, they may contact rqap@sqa.org to defer their examination registration. This message must include identifying candidate details sufficient to identify the candidate's SQA account and must include the future examination period to which the candidate wishes to defer their registration.

SQA will confirm receipt of the deferral message and provide guidance on next steps. Candidates are responsible for contacting SQA on the timeline provided to reactivate their examination registration.

ADMISSION TO THE TEST CENTER *(CBT Candidates)*

Candidates taking the computer-based test are encouraged to report to the test center 30 minutes before their scheduled exam time. Candidates will have their photo taken (to compare to the candidate's photo identification [ID] and as evidence of who sat for the exam), they will be required to submit a digital signature (to compare to the candidate's ID and as evidence of the candidate's agreement with the testing rules), and they may be asked for a biometric palm scan (to facilitate re-entry into the testing room during breaks). Candidates can request to be opted out of the palm scan **if** they request to opt out at least one week in advance of their exam appointment.

In addition, one primary ID is required. Candidates must present a valid government-issued photo ID with their signature. (See the following list of acceptable forms of ID.) The name on the ID must match the first/personal and last/family name on the candidate's exam registration.

ID must:

- Bear the candidate's name exactly as provided during the exam registration process (as it appears on the exam appointment confirmation letter/e-mail);
- Have a permanently affixed photo of the candidate's face;
- Be current — expired IDs will not be accepted; and
- Be an original document — no photocopies will be accepted.

Acceptable forms of PHOTO identification include the following:

- Government-issued driver's license
- Passport (or U.S. passport card)
- Military ID (except those with chips)
- Identification card (national/state/province ID card)
- Alien registration card (green card/permanent resident/visa)

UNACCEPTABLE forms of identification include the following:

- Employee identification or work badge
- University/college identification

Candidates without an acceptable primary ID and those who arrive more than 15 minutes after the scheduled exam time will NOT be permitted to proceed, and their examination fees will be forfeited. Examination check-in, instructions, and seating of candidates will begin at the scheduled exam time.

TAKING A REMOTE-PROCTORED EXAM FROM YOUR HOME OR OFFICE WITH OnVUE

OnVUE is Pearson VUE's system allowing candidates to take their exam online from their own home or office. Candidates who select this option will be monitored while they take the exam by a live proctor watching them via web camera.

There are many requirements a candidate must meet in order to take the exam using OnVUE, including meeting all of the technical requirements and passing the system test, having an appropriate area for testing, and providing the same personal identification that CBT candidates must provide. In addition, candidates must comply with testing behavior guidelines; among other requirements, candidates may not speak aloud and must remain in view of the web camera at all times. Please review all of the details thoroughly at **home.pearsonvue.com/pti/onvue** before choosing this test format. **If you fail to meet the OnVUE requirements for testing, your exam may be ended and/or you may be required to reschedule your exam to a testing center.**

Please Note: Due to the strict testing requirements imposed to maintain security for OnVUE testing, SQA encourages candidates to schedule an in-person CBT exam appointment if possible. Candidates testing via OnVUE have experienced higher rates of exam non-completion due to technical issues or behavioral violations.

Candidates testing via OnVUE will not be permitted to use a language dictionary as an English-as-a-second-language accommodation. In addition, some countries do not support or permit the testing technology required for OnVUE testing; please see the Country Restrictions at the bottom of the OnVUE information page for more details.

INCLEMENT WEATHER OR OTHER CIRCUMSTANCES PREVENTING TESTING

If for any reason a testing center is closed or Pearson VUE is otherwise unable to administer an exam because of inclement weather, terrorist acts, a natural disaster or other unforeseen emergencies, the candidate will receive an extended testing window (to be determined on an individual basis) and will be allowed to reschedule the examination without being charged a re-examination fee. Candidates will be responsible for their own associated expenses for future testing.

TAKING THE EXAMINATION

After your identity has been verified, you are directed to a testing seat (or, if using OnVUE, you will be seated in your own testing space). For an in-person computer administration, you will be provided a small erasable white board for calculations that must be returned to the examination proctor at the completion of testing. You will not be allowed to bring personal items into the testing room. For OnVUE administration, you will not be permitted to use any scratch paper or devices, and you will not be permitted to leave the testing environment for any reason while you are testing.

For an in-person computer administration, you are provided instructions by the proctor and on-screen. During an at home OnVUE remote test, you are provided instructions on-screen and may reach a proctor via proctor chat if needed. Prior to attempting the examination, you are provided a short tutorial on using the software to take the examination. Tutorial time is NOT counted as part of the 3½ hours allowed for the examination. Only after you are comfortable with the software does the examination begin.

When you reach the end of the exam, if time remains, you may return to the examination and answer any questions you may have skipped. The in-person computer-based and at-home OnVUE remote exam systems provide a method to review both unanswered and flagged questions at the end of the exam. Be sure to answer each examination question before ending the examination. There is no penalty for guessing.

CANDIDATE COMMENTS

Comments may be provided for any question in a comments section in the software. Comments will be reviewed, but individual responses will not be provided. Comments must be given during the 3½ hour exam time.

Candidates will also be sent a survey after the exam has concluded and may offer general feedback there.

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REPORTING RESULTS

Notification of Results: In most cases, you will receive a diagnostic score report from the testing facility on your computer screen at the conclusion of the examination. However, if a new examination form is being used for the first time, it is possible that you will not receive your score report until up to six weeks after the end date of the examination window in which you took your exam. This is to allow time for a statistically valid scoring model to be developed for the new examination form (see Equating Process below), and you will be notified both in advance and during testing if your score report will be delayed in this way.

A diagnostic score report includes raw scores for each section of the exam, the overall raw score and a scaled score. A raw score is the number of correctly answered questions; a scaled score is statistically derived from the raw score. Your total or overall score determines whether you pass or fail; it is reported as a scaled score ranging between 0 and 99.

Minimum Score Needed to Pass: The minimum scaled score needed to pass each examination has been set at 75 scaled score units. The reason for reporting scaled scores is that different forms (or versions) of the examination may vary in difficulty. As new forms of the examination are introduced, questions are replaced. These changes may cause one form of the examination to be slightly easier or harder than another form. To adjust for these differences in difficulty, a procedure called "equating" is used. The goal of equating is to ensure fairness to all candidates.

Equating Process: In the equating process, the minimum raw score (number of correctly answered questions) required to equal the scaled passing score of 75 is statistically adjusted (or equated). For example, if the examination is more difficult than the previously used examination form, then the minimum raw score required to pass will be slightly lower. If the examination is easier, then the minimum raw score will be higher. Equating helps to assure that the scaled passing score of 75 represents the same level of competence no matter which form of the examination you take. In addition to your total scaled score and scaled score required to pass, the percentage correct is reported for each subcategory on the content outline. Content category information is provided to assist you in identifying areas of relative strength and weakness; however, passing or failing the examination is based on your total score.

You will not be provided with information about which specific questions you answered incorrectly as providing this information would threaten the security and statistical validity of the examination.

CONFIDENTIALITY

Individual examination scores are released ONLY to the individual candidate. Questions concerning examination results should be referred to SQA in writing.

RE-EXAMINATION

There is no limit to the number of times unsuccessful candidates may attempt the examination, provided they pay the fee and meet all eligibility requirements in effect at the time of applying for re-examination. To apply for re-examination, candidates must complete and submit the current application and pay the current examination fee, although a new CV is not required.

GENERAL EXAMINATION PREPARATION

The study and test-taking advice described here may be helpful as you prepare for the examination. Try to be objective about yourself and your individual learning needs when you are deciding how best to proceed with your study.

EXAMINATION CONTENT

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. Information regarding the content of the examination is presented in this handbook. The content outline will give you a general impression of the examination and, with closer inspection, can give you specific study direction by revealing the relative question weight given to each category on the examination.

The content for the examination is directly linked to a job analysis and is described in the detailed content outline. The outline indicates the content categories relevant to each of the performance areas and the number of questions for each category.

Complexity levels for questions are also indicated as Recall, Application and Analysis. These levels are defined as follows:

- Recall: The ability to recall or recognize specific information is required.
- Application: The ability to comprehend, relate, or apply knowledge to new or changing situations is required.
- Analysis: The ability to analyze and synthesize information, determine solutions, and/or to evaluate the usefulness of a solution is required.

STUDY ADVICE

Determine how you study best. Some individuals seem to learn faster by listening, while others need to see material written or illustrated, and still others prefer to discuss material with colleagues. A combination of these alternatives can often produce an effective study pattern.

If you had success in lecture courses with little outside review, it may be that you need to hear information for best retention. If you find that you prefer to read material, then you might consider jotting down important facts on 3x5 cards. You can refresh your memory by periodically reviewing these cards. This technique is especially effective if you write the material thoughtfully and concisely, allowing you to digest the material through both reading and writing. You may wish to organize a study group or find a study partner (SQA has online discussion groups in SQA Connect for GCP and GLP Exam Candidates; these are free to join and may aid you in finding study partners). Once you decide on the most effective and comfortable method for you, focus on that preference and use the other techniques to

supplement study activities.

Plan your study schedule well in advance. Use learning techniques, such as reading or audiovisual aids. Be sure you find a quiet place to study where you will not be interrupted. We suggest you concentrate your study efforts on the Study References provided.

PRACTICE EXAMINATIONS

SQA has prepared one 30-question practice examination for for the RQAP-GCP exam and another for the RQAP-GLP exam. These practice examinations are modeled on the same content outline as the actual exams, with the same percentage of questions per section of the content outline as the actual exams, and they have time limits proportional to the time limits imposed on the actual exams as well. The practice exams are available for purchase in the store on the SQA website.

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	

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
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	

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
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	

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
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	

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. Study inspections should be scheduled

   A. before the test initiation date.
   B. before the test subjects are euthanized.
   C. at intervals adequate to ensure integrity of the study.
   D. at intervals adequate to ensure the study director is meeting responsibilities.

2. An SOP specifies that approximately 150 mL of a reagent will be added to another reagent. However, a technician mistakenly adds 90 mL instead. This should be documented as

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

3. A field residue study is being conducted on peaches. The principal investigator is located at the test site (Company A). The study director, a chemist, is located at a project management company (Company B). The sponsor is located at Company C. The protocol requires five test material applications. The last application should be made seven days prior to harvesting the crop. Due to abnormally warm weather, however, the crop matures unusually fast. If the schedule is maintained, the fruit will be 4 to 6 days past market maturity when harvested. The principal investigator at Company A decides to reduce the number of applications to four so that the harvest requirements can be met. Considering the protocol requirements, which of the following are most appropriate for the protocol amendment?

   1. principal investigator's signature (at Company A)
   2. study director's signature (at Company B)
   3. sponsor's approval (at Company C)
   4. QAU approval (at Company B)

   A. 1 and 3 only
   B. 1 and 4 only
   C. 2 and 3 only
   D. 2 and 4 only

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

Answer Key
1. C 2. B 3. C

STUDY REFERENCES

Following is a listing of suggested quality assurance references. This list is not all-inclusive and you should not limit your study to only those references listed below. You are also encouraged to study all historic and current preambles in addition to the current regulations, where applicable.

1) Advisory/Policy: GLP Regulations Advisories, issued by the EPA Policy and Grants Division.
   Compliance Monitoring
   Quality Assurance
   Retention
   Storage
   Study Archive
   Study Director

   US Environmental Protection Agency (EPA)
   Laboratory Data Integrity Assurance Division
   2805 Jefferson Davis Highway
   Arlington, VA 22202

2) Advisory/Policy 1993: http://www.sqa.org/uploadedFiles/SQA_Home/professional-registration/GLP.StudyRef2.EPA-GLP-StandardsInspManual.pdf
   Good Laboratory Practice Standards Inspection Manual. A manual that provides EPA inspectors with guidance in conducting GLP inspections under both FIFRA and TSCA. EPA number 723-B-93-001.

   EPA/OPPTS
   Office of Prevention, Pesticides, and Toxic Substances
   US Environmental Protection Agency
   Washington, DC 20460

3) Advisory/Policy 1992: https://nepis.epa.gov/Exe/ZyPDF.cgi/9100M94N.PDF?Dockey=9100M94N.PDF
   FIFRA Good Laboratory Practice Standards (GLPs) Regulations Questions and Answers Document. This 14-page document consists of responses made by the Office of Compliance Monitoring in past correspondence to members of the regulated community. It was prepared by the Policy and Grants Division of the Office of Compliance and was released on May 12, 1992.

   Office of Compliance Monitoring
   Office of Prevention, Pesticides, and Toxic Substances
   US Environmental Protection Agency
   Washington, DC 20460

4) Advisory/Policy 1991: https://www.epa.gov/sites/default/files/documents/fifraglperp-093091.pdf
   Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Good Laboratory Practice (GLP) Regulations. This publication describes liabilities, fines and procedures for violations of the FIFRA GLPs; it was effective as of September 30, 1991.

   Pesticide Enforcement Policy Branch
   Office of Compliance Monitoring
   Office of Prevention, Pesticides, and Toxic Substances
   US Environmental Protection Agency
   401 M Street, SW, EN-342W
   Washington, DC 20460.

5) Advisory/Policy 1991: http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134744.htm
Points to Consider for Internal Reviews and Corrective Action Operating Plans, US Food and Drug Administration. This publication describes actions that applicants may take to affirm the validity of data that have been called into question by the FDA. Relates to FDA's Compliance Policy Guide 7150.09 on "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities (final policy)." $17 (paper), $9 (MICROFICHE)

National Technical Information Service (NTIS) Publication Number PB91-228106

Department of Commerce, NTIS
5285 Port Royal Road
Springfield, VA 22161

6) Advisory/Policy 1991: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/fr-fda-091091-notice-56-fr-46191-fraud-untrue-statements-material-facts-bribery-and-illegal
Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy.
US Food and Drug Administration (FDA)
Federal Register 56:46191-46200, September 10, 1991.

This publication sets forth the FDA's general approach regarding applicants who seek to subvert the FDA's review and approval process for premarket applications.

7) Good Laboratory Practice (GLP), Amendment, Final Rule, 9/4/1987: https://www.fda.gov/media/75860/download

8) Good Laboratory Practice (GLP), Proposed Rule, 10/29/1984: https://www.fda.gov/media/75849/download

9) 1981 Question and Answer: https://www.fda.gov/media/75866/download

10) Advisory/Questions 1981: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070282.pdf
Good Laboratory Practice Regulations: Questions and Answers. [Part II], Lepore, P.D. Ask for the most recent version. Must order by letter or by fax. Be specific about records required. Include you name, address and phone number. Specify the maximum dollar amount you are willing to be billed, and request a letter if the total will exceed that amount. FOI will send a bill. Do not sent money.

FDA Freedom of Information Office (FOI)
Food and Drug Administration, (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

11) Good Laboratory Practice Regulations Management Briefings, Post Conference Report, Aug 1979: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-laboratory-practice-regulations-management-briefings-post-conference-report-aug-1979

12) Preamble 1978: https://archives.federalregister.gov/issue_slice/1978/12/22/59967-60019.pdf

13) FDA Bioresearch Compliance Program Guidance Manual, May 1, 2018: https://www.fda.gov/media/75891/download
Program 7348.808
Good Laboratory Practices for Non-Clinical Laboratory Studies
US Food and Drug Administration

14) Regulations - US/CFR most current version - Good Laboratory Practices for Non-Clinical Laboratory Studies; Title 21, Part 58, Code of Federal: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&showFR=1

US Food and Drug Administration
US Government Printing Office
Superintendent of Documents
Mail Stop: SSOP
Washington, DC 20402-9328

The most recent edition of the FDA GLPs as they appear in the CFR.

15) US/CFR most current version plus preambles from all versions Good Laboratory Practice Standards (FIFRA); Title 40, Part 160, Code of Federal Regulations.

Regulations: https://research.uga.edu/quality-assurance/glps/epa/ OR https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160

FIFRA Q&A: https://research.uga.edu/quality-assurance/glps/fifra/

US Environmental Protection Agency
US Government Printing Office
Superintendent of Documents
Mail Stop: SSOP
Washington, DC 20402-9328

The most recent edition of the EPA FIFRA GLPs as they appear in the CFR.

16) US/CFR most current version plus preambles from all versions Good Laboratory Practice Standards (TSCA); Title 40, Part 792, Code of Federal Regulations.

Regulations: https://research.uga.edu/quality-assurance/glps/tsca/

US Environmental Protection Agency
US Government Printing Office
Superintendent of Documents
Mail Stop: SSOP
Washington, DC 20402-9328

The most recent edition of the EPA TSCA GLPs as they appear in the CFR.

17) Principles – OECD – most current version. The Organisation for Economic Cooperation and Development Principles of Good Laboratory Practice, ENV/MC/CHEM (98) 17.

All OECD GLP principles, including guidance/policy, advisories, and position papers, can be accessed from the following site: https://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

Or via mail at:

OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

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	

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**
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	

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**
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	

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**
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

STUDY REFERENCES

Following is a listing of suggested quality assurance references. This list is not all-inclusive and you should not limit your study to only those references listed below. You are also encouraged to study all historic and current preambles in addition to the current regulations, where applicable.

Websites

Each of the regulations and guidance documents listed in the references below can be found through the following websites. It may be necessary to search the title of the referenced document at the website.

International Conference on Harmonization:
http://www.ich.org

Health Canada – Drugs & Health Products:
http://www.hc-sc.gc.ca/dhp-mps/index-eng.php

European Medicines Agency:
https://www.ema.europa.eu/en/general-regulatory-procedural-guidance

US Food and Drug Administration:
http://www.fda.gov

US Office for Civil Rights – HIPAA:
http://www.hhs.gov/ocr/privacy/

US Office for Human Research Protections:
http://www.hhs.gov/ohrp/

References

US Code of Federal Regulations

21 CFR Part 11 – Electronic Records; Electronic Signatures
21 CFR Part 312 – Investigational New Drug Application
21 CFR Part 50 – Protection of Human Subjects
21 CFR Part 54 – Financial Disclosure by Clinical Investigators
21 CFR Part 56 – Institutional Review Boards
21 CFR Part 812 – Investigational Device Exemptions
45 CFR Part 46 – Protection of Human Subjects (Common Rule)

European Medicines Agency

Clinical Trials Registry Reg EU536/2014
Commission Directive 2005/28/EC

US Food and Drug Administration

Compliance Program Guides
Final Guidance Documents

Health Canada

Regulations amending the food and drug regulations (1024 -clinical trials)
“Drugs for Clinical Trials Involving Human Subjects” (GUI-0100)
Risk classification guide for observations related to inspections of clinical trials of human drugs (GUI-0043)
POL-0030: Compliance and enforcement approach and inspection strategy for clinical trials of drugs involving human subjects

International Conference on Harmonization: As of January 2018

GOOD CLINICAL PRACTICE
E6 (R3): Good Clinical Practice: Consolidated Guidelines

International Standards Organization (ISO)

ISO14155:2020

Other EU and UK Documents

The Rules Governing Medicinal Products in the European Union: Volume 10 Clinical Trials
UK Statutory Instrument (SI) 2004/1031 - The Medicines for Human Use (Clinical Trials) Regulations
UK Statutory Instrument (SI) 2006/1928 - The Medicines for Human Use (Clinical Trials) Amendment Regulations
REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
European Medical Device Regulation 2017/745 (MDR)

A NOTE ABOUT THE OUTREACH COUNTRY EXAM DISCOUNT

SQA allows examination candidates from Outreach countries to take the exam for a reduced cost. Outreach countries are countries that are identified as low or middle income by the World Bank. You can check to see if your country qualifies as low, lower-middle or upper-middle income on the World Bank's website at https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups. Contact SQA Headquarters to request the Outreach candidate exam application.

Registered Quality Assurance Professional Examination Application

To apply for a Registered Quality Assurance Professional Examination, complete this application and send it with your curriculum vitae (CV) and the appropriate application fee (payable to SQA) to:

Mail: Society of Quality Assurance • 820 East High Street, Suite A • Charlottesville, VA 22902 USA
Fax: +1 434.977.1856 • E-mail: sqa@sqa.org (please do not email your credit card information)

Applicant Information *Please type or print clearly.*

Full Name (as it appears on photo identification) _____

Company/Organization _____

Street Address _____

City/State or Province/Postal Code/Country _____

Daytime Telephone _____

Fax _____

E-mail Address _____

Please choose the exam you would like to take:

☐ **RQAP-GCP** ☐ **RQAP-GLP** ***Preferred exam date** (month/year from those stated on website): _____

Special Accommodations

☐ Check this box if you require examination accommodations because of a disability. If this box is checked, the Request for Special Examination Accommodations form and the Documentation of Disability-Related Needs must also be completed and submitted with this application. You need not pay an additional accommodation fee below.

☐ Check this box if you require examination accommodations because English is not your native language. You may use the Request for Special Examination Accommodations form to request additional time for the examination and/or the use of an approved language translation dictionary. You must pay an additional accommodation fee below.

Method of Payment

Base Application Fees*: ☐ SQA Member (choose this if you apply for membership prior to or simultaneously with this application): **$450**
☐ Non-Member (including Chapter members who are not SQA members): **$625**

Additional Fees: ☐ Late Fee (application submitted after early application deadline on website): **$50**
(please select all that apply) ☐ English language accommodation needed (in Special Accommodations above): **$50**

TOTAL FEES (total of all fees selected above): $_____

Form of Payment

The examination fee must be submitted prior to or with the examination application. The fee may be paid by credit card (MasterCard, VISA or American Express) or by personal check, cashier's check or money order made payable to **SQA**. DO NOT SEND CASH.

☐ Payment submitted online by SQA website: GCP Exam GLP Exam Date submitted: _____

☐ Personal check, cashier's check or money order in U.S. dollars (***made payable to SQA***) Check #: _____

☐ Credit Card (do not complete this section if you paid on the SQA website)

☐ MasterCard ☐ VISA ☐ American Express

Account Number:_____ Expiration Date: _____

Statement Billing Address: _____

Name as it appears on card: _____

Signature: _____

**If you qualify for discounted Outreach country exam fees or if you qualify for a discounted Non-Member application fee because you belong to an MOU organization, contact SQA Headquarters for a different application form.*

(application continued on next page)

Applicant Status (check one):

☐ I am a NEW APPLICANT for the Registered Quality Assurance Professional Examination for which I am applying.

☐ I am a RE-APPLICANT for the Registered Quality Assurance Professional Examination for which I am applying. The last time I attempted this examination was (month/year)_____.

Eligibility Status

A copy of your curriculum vitae (CV) must be submitted with your application. Your CV must include the years and months worked in each job position, a specific list of your job responsibilities/duties for each job position and, for each job position, the percentage of time devoted to QA/audit work in the specified exam discipline. ***If you have not specifically worked in QA auditing in GLP or GCP for the equivalent of 2 years full-time (with a baccalaureate degree) or 4 years full-time (without a baccalaureate degree), you do not meet the eligibility requirements to take this exam.***

☐ Prior to the examination date, I will have met the eligibility requirements for the exam I plan to take as defined on page 2 of this Candidate Handbook and in the statement above.

Verification of Experience

Please provide a professional reference who can verify your experience and eligibility to take this examination:

☐ I certify that the individual below has personal knowledge that I will have fulfilled the quality assurance eligibility requirement as defined on page 2 of this Candidate Handbook by the examination date.

Full Name (Please Print)_____

Email Address_____

Alternate Email Address _____

Phone Number _____

Alternate Phone Number _____

Applicant's Signature

Please mark each box as acknowledgment and sign below.

☐ I certify that I have read all portions of the Registered Quality Assurance Professional Examination Candidate Handbook and application and believe that I comply with all the admission policies for the Registered Quality Assurance Professional Examination.

☐ I certify that the information I have submitted in this application and the documents I have enclosed are complete and correct to the best of my knowledge and belief.

☐ I understand that if the information I have submitted is found to be incomplete or inaccurate, my application may be rejected or my examination results may be delayed, not released or invalidated by SQA.

☐ I understand that Registrants and Candidates are expected to adhere to the highest professional and ethical standards of behavior and judgment. Misrepresentation of any material facts associated with initial registration or maintaining registration status will be considered a violation of this ethics agreement.

***Full Name** *(Please Print)*_____

***Signature** _____ ***Date** _____

(*All items required)

THIS SPACE INTENTIONALLY LEFT BLANK.

REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS

If you have a disability covered by the Americans with Disabilities Act, or English is not your native language, and you require special accommodations, please complete this form. Those with disabilities must also complete the Documentation of Disability-related Needs on the reverse side so that your accommodations for testing can be processed efficiently. The information you provide and any documentation regarding your disability and your need for examination accommodations will be treated with strict confidentiality.

Please type or print clearly.

Applicant Information

Full Name _____ Date of Birth_____

Company/Organization _____

Street Address _____

City/State or Province/Postal Code/Country _____

Daytime Telephone _____

Special Accommodations

I request special accommodations for the administration of the RQAP examination at/on:

- ☐ In-Person Testing Location: _____
- ☐ At-Home OnVue Remote Proctored Test

Please provide or allow (check all that apply):

In-Person Language Accommodations **OR** **OnVUE Remote Proctor Language Accommodations**

- ☐ One hour extended examination time
- ☐ Allow me to bring a new, unmarked, unwritten-in, basic English to native language dictionary

- ☐ Two hours extended examination time†

Disability Accommodations

- ☐ Extended examination time†
- ☐ Special seating or other physical accommodation*
- ☐ Question reader* (you will NOT be able to use a question reader if you test with OnVUE, the remote proctored test option from your own home or office)
- ☐ Reduced distraction environment*
- ☐ Other special accommodations (please specify)*

_____

Comments:_____

_____

**Availability for starred accommodations may be limited in certain testing centers. Additional accommodation fees (beyond those paid on this application form) may be required for starred accommodations if the reason for the accommodation is English language related.*

† *When testing with OnVUE, you will NOT be able to leave your computer for any reason (including bathroom breaks) until your exam is submitted.*

Signed: _____ **Date:** _____

Return this form WITH your examination application to:

Society of Quality Assurance • 820 East High Street, Suite A • Charlottesville, VA 22902 USA

Fax: +1 434.977.1856 • E-mail: sqa@sqa.org

If you have questions, call SQA at +1 434.297.4772.

DOCUMENTATION OF DISABILITY-RELATED NEEDS

If you have a disability covered by the Americans with Disabilities Act and you require special accommodations, please have this form completed by an appropriate professional (education professional, physician, psychologist, psychiatrist) so that SQA may provide the required examination accommodations. The information you provide and any documentation regarding your disability will be treated with strict confidentiality.

Please type or print clearly.

Applicant Name _____

Professional Documentation

I have known _____ since ____/____/_____
(insert applicant's name) (mm/dd/yyyy)

in my capacity as a _____.
(insert complete professional title)

The applicant discussed with me the nature of the examination administered. It is my opinion that, because of this applicant's disability described below, s/he should be accommodated by SQA providing the special arrangements listed on the previous page (Request for Special Examination Accommodations).

Comments: _____

_____

_____

_____

_____

_____

_____

Professional's Full Name: (Please print) _____

Signature: _____

Date: _____ **License # (if applicable):** _____

Return this form WITH your examination application to:

Society of Quality Assurance • 820 East High Street, Suite A • Charlottesville, VA 22902 USA

Fax: +1 434.977.1856 • E-mail: sqa@sqa.org

If you have questions, call SQA at +1 434.297.4772.

Benefits of Membership

SQA Annual Meeting and Formal Training Opportunities

Annual Meeting - held for three days each year in different locations throughout North America or via virtual platform:

- Reduced registration rates for SQA members
- Formal presentations with current developments and information
- Round table discussions
- Interactions and networking opportunities with international, national, state and regional regulators
- Networking with peers and consultants
- Poster session on current issues
- Member consultant information
- Exhibition featuring suppliers to the industry

Formal Training Opportunities - basic, specialized, and professional

- Reduced registration rates for SQA members
- Quality College - Two full days preceding and one-and-a-half days following the Annual Meeting in March/April
- Virtual Quality College in September
- Online Self-paced Courses
- Webinars throughout the year - many included with membership

SQA Webinars — available free to members

- SQA webinars presented on a variety of regulatory quality assurance topics
- Access to webinar recordings library
- SQA Connect Lounge panels on hot topics

SQA eNewsletter — distributed bimonthly

- News and updates pertinent to regulatory and research quality assurance (GCP, GLP, GMP, etc.)
- Discussion of current regulatory issues
- Committee, Specialty Section, and Regional Chapter news
- Relevant articles and book reviews
- SQA training and meetings calendar
- Advertisements for job openings, professional services, and much more
- Technical article supplements

Members-Only Website and SQA Connect Forum

- Online community and integrated mobile app for all SQA Committees and Specialty Sections, including discussion forum, calendar, and document library
- Regulatory news providing information links to current regulatory issues and trends
- Access to a searchable database with information on 483s
- Searchable listing of members includes name, affiliation, address, telephone and e-mail
- Searchable by name, company affiliation, geographical location, area of expertise, and consultant status
- Customizable profile with picture, biography, web address, and social media links for online networking
- Current employment opportunities and links to consultant advertising
- Resume database in SQA Connect
- Links to regulatory agencies, national QA societies, SQA Regional Chapters, liaison organizations and corporate supporters

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