Registered Quality Assurance Professional in GCP or GLP Examinations

RQP

Candidate Handbook

Society of Quality Assurance (SQA)
154 Hansen Road Suite 201, Charlottesville, VA 22911 USA
Phone: +1 434.297.4772 • Fax: +1 434.977.1856
www.sqa.org • sqa@sqa.org
# TABLE OF CONTENTS

ABOUT SQA .............................................................. 1  
ABOUT RQAP ............................................................ 1  
STATEMENT OF NONDISCRIMINATION POLICY .... 1  
TESTING AGENCIES ......................................................... 1  
EXAMINATION POLICIES  
  EXAMINATION.......................................................... 1  
  EXAMINATION APPLICATION INFORMATION ... 2  
  REFUNDS ............................................................. 2  
ELIGIBILITY REQUIREMENTS ............................................. 2  
REQUESTS FOR SPECIAL EXAMINATION  
ACCOMMODATIONS ..................................................... 2  
SCHEDULING YOUR EXAMINATION .................... 3  
RESCEDULING OR CANCELING A CBT  
EXAMINATION.............................................................. 3  
ADMISSION TO THE TEST CENTER ................. 3  
INCLEMENT WEATHER OR OTHER  
CIRCUMSTANCES PREVENTING TESTING ......... 3  
TAKING THE EXAMINATION ............................................. 3  
CANDIDATE COMMENTS .................................................. 3  
COPYRIGHT .................................................................. 4  
REPORTING RESULTS .................................................... 4  
CONFIDENTIALITY .......................................................... 4  
RE-EXAMINATION .......................................................... 4  
GENERAL EXAMINATION PREPARATION  
  EXAMINATION CONTENT ............................................. 4  
  STUDY ADVICE ........................................................ 5  

ADDENDUM 1 - RQAP-GLP EXAMINATION OUTLINE  
AND STUDY REFERENCES  
  REGISTERED QUALITY ASSURANCE PROFESSIONAL  
  IN GLP EXAMINATION DETAILED CONTENT  
  OUTLINE .............................................................. 6  
  SAMPLE QUESTIONS ................................................. 10  
  STUDY REFERENCES .................................................... 11  
ADDENDUM 2 - RQAP-GCP EXAMINATION OUTLINE  
AND STUDY REFERENCES  
  RQAP-GCP EXAMINATION DETAILED CONTENT  
  OUTLINE .............................................................. 15  
  SAMPLE QUESTIONS ................................................. 18  
  STUDY REFERENCES .................................................... 19  

A NOTE ABOUT THE OUTREACH COUNTRY  
EXAM DISCOUNT .......................................................... 20  

ADDENDUM 3 - RQAP EXAMINATION APPLICATION  
AND ACCOMMODATION FORMS  
  REGISTERED QUALITY ASSURANCE PROFESSIONAL  
  EXAMINATION APPLICATION ..................................... 21  
  REQUEST FOR SPECIAL EXAMINATION  
  ACCOMMODATIONS .................................................... 23  
  DOCUMENTATION OF DISABILITY-RELATED  
  NEEDS ................................................................. 24  

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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 30 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
Over the past decade, 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.

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.

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
Fax: +1 407.264.2855
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 and during special administrations. During a special administration, the examination will be offered in paper and pencil format.
EXAMINATION APPLICATION INFORMATION

Apply for a Computer-based Examination: To apply for the RQAP examination, complete the application included with this handbook and mail, fax or e-mail 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.

Apply for a Paper and Pencil Examination: If you wish to take the examination by paper and pencil, please fill out the application included in this handbook. Dates and locations for paper and pencil examinations being offered may be found on the GLP and GCP examination web pages of the SQA website, www.sqa.org.

REFUNDS

Refunds will NOT be granted to individuals requesting to withdraw from an examination after submitting an accepted application. If you fail to appear for the examination on the scheduled date you will forfeit the full amount of the examination fee (excepting the extenuating circumstances noted below). Examination fees are NOT transferable to another examination date or individual (note: CBT candidates do have the option to reschedule an examination appointment with advance notice; see subsequent section on Rescheduling a CBT Examination). If you wish to take the examination at a future examination date, a new application and fee must be submitted. If, for any reason, your application does not meet the established eligibility requirements, the examination fee will be refunded minus a $75 processing fee.

Emergency Illness or Death of Registrant or Immediate Family Member: Attendees who are unable to attend the examination based on a serious illness or death may receive a partial refund of the full fee minus a processing charge that Pearson VUE charges SQA if you neglect to cancel your testing appointment 24 hours prior (according to Pearson VUE policy) or a full credit for a future examination if you did cancel your testing appointment 24 hours prior (according to Pearson VUE policy) in the following instances:

- Personal illness or death of the attendee; or
- Illness or death in the immediate family of the attendee.

Requestors shall submit the request in writing to SQA Headquarters along with written documentation from a doctor.

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; OR
2. Have a baccalaureate degree AND the equivalent of two (2) years of full-time quality assurance experience as defined below.

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 11 for GLP and page 19 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 6 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 YOUR EXAMINATION
If you are taking an exam via computer-based testing (CBT), 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 A CBT EXAMINATION
Candidates 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. Appointments must be rescheduled within the authorized exam delivery period. All registrations with special accommodations for language or disabilities must be rescheduled or canceled by phone. Refunds are not available except as described in the previous section on refunds.

ADMISSION TO THE TEST CENTER
Candidates taking the computer-based test are encouraged to report to the test center one-half hour 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, two forms of valid ID are required. Candidates must present a valid government-issued photo ID with their signature and a second form of ID with their signature. (See information below on acceptable forms of ID.) The name on the IDs must match the name on the exam confirmation e-mail.

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)
- Permanent resident visa

Acceptable forms of SIGNATURE identification include the following:
- Any on the above photo ID list
- Social Security card
- Credit/bank ATM card (signature required)

UNACCEPTABLE forms of identification include the following:
- Employee identification or work badge
- University/college identification

Candidates without a valid photo ID or signature ID and those who arrive more than 15 minutes after the scheduled exam time will NOT be permitted to enter the test center, and their examination fees will be forfeited. Seating of candidates, distribution of test materials, and testing instructions will begin at the scheduled exam time.

INCLEMENT WEATHER OR OTHER CIRCUMSTANCES PREVENTING TESTING
If for any reason a testing center is closed or 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. For a 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. For a paper and pencil administration, you may use the examination booklet for scratch paper. You will not be allowed to bring personal items into the testing room.

For a computer administration, you are provided instructions by the proctor and on-screen. 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. For a paper and pencil administration, you will be provided oral and written instructions to guide the testing process.

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. Be sure to answer each examination question before ending the examination. There is no penalty for guessing.
CANDIDATE COMMENTS
For a computer administration, comments may be provided for any question in a comments section in the software. For a paper and pencil administration, comments may be provided on the answer sheet on the day of the examination. Comments will be reviewed, but individual responses will not be provided. Comments must be given during the 3½ hour exam time.

COPYRIGHT
All examination questions are the property of SQA and are protected by copyright. It is forbidden under the copyright laws of the United States and other countries to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may result in severe civil and criminal penalties.

REPORTING RESULTS
Notification of Results: In most cases, you will receive a diagnostic score report from the testing facility 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 at the testing center 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, raw scores (the actual number of questions correctly answered) are reported for each minor category on the content outline. The number of questions answered correctly in each category is compared to the total number of questions possible in that category on the score report (e.g., 10/15). 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.

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. 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.

<table>
<thead>
<tr>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>43%</td>
</tr>
</tbody>
</table>

### I. COMPLIANCE ASSESSMENT

#### A. Monitoring is the direct observation, testing and assessment of in-process activities and personnel for independent evaluation of regulatory compliance and the quality and integrity of the process.

**Monitor:**

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 company policies
7. data collection processes (manual and automated)
8. equipment maintenance and calibration
9. archive including the appropriateness of raw data for archival storage and retrieval
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:**

1. component laboratories such as chemistry, histology, pathology, clinical, pathology, surgery, microbiology, electron microscopy and reproductive toxicology
2. non-laboratory sites such as field sites, test plots, mesocosms and simulation structures
3. storage areas for items such as test, control and reference materials; specimens, samples, media, feed, bedding; chemicals, reagents and unused equipment/supplies to include equipment for low temperature storage
4. computer facilities and associated controlled procedures and/or systems
5. location in each laboratory/site of protocols, SOPs, facility records, operating permits and/or related documentation
6. location in each laboratory/site of data under active collection
7. labeling of 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, 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.

### 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.

<table>
<thead>
<tr>
<th>Audit:</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. protocols, amendments and deviations including the associated documentation</td>
<td></td>
</tr>
<tr>
<td>2. SOPs, revisions and deviations including the associated documentation</td>
<td></td>
</tr>
<tr>
<td>3. reporting structure of the organization and personnel qualifications including curricula vitae, job descriptions and training records</td>
<td></td>
</tr>
<tr>
<td>4. equipment verification and/or validation including the associated documentation</td>
<td></td>
</tr>
<tr>
<td>5. computer system development, verification, validation, release, maintenance, and retirement processes including related documentation</td>
<td></td>
</tr>
<tr>
<td>6. test article, control and reference material characterization, dosing mixture(s), concentrations, stability analyses and/or homogeneity analyses including data and other related documentation</td>
<td></td>
</tr>
<tr>
<td>7. analytical method validation and documentation</td>
<td></td>
</tr>
<tr>
<td>8. chain of custody documentation (e.g., specimens and samples)</td>
<td></td>
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<tr>
<td>9. data traceability (e.g., electronic and paper)</td>
<td></td>
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<tr>
<td>10. certificates of analyses</td>
<td></td>
</tr>
<tr>
<td>11. final reports (including contributing scientists’ reports), amendments and GLP Compliance Statement</td>
<td></td>
</tr>
<tr>
<td>12. accountability records for test, control and/or reference materials including records for preparation, administration and disposal</td>
<td></td>
</tr>
<tr>
<td>13. test system randomization documentation</td>
<td></td>
</tr>
<tr>
<td>14. equipment maintenance, calibration and repair records</td>
<td></td>
</tr>
<tr>
<td>15. temperature, humidity and other environmental control records</td>
<td></td>
</tr>
<tr>
<td>16. study notebooks and raw data (e.g., electronic and paper) and data calculations including transformations, transcriptions and derivations (e.g., statistical analyses and summary tables)</td>
<td></td>
</tr>
<tr>
<td>17. archival and other authorized access/tracking records</td>
<td></td>
</tr>
<tr>
<td>18. animals/test system history, receipt, health, quarantine, maintenance, and disposal records</td>
<td></td>
</tr>
<tr>
<td>19. study director/scientist notes and memoranda related to the study including records documenting unforeseen circumstances and assessment of study impact</td>
<td></td>
</tr>
<tr>
<td>20. findings and responses to quality assurance unit inspections</td>
<td></td>
</tr>
</tbody>
</table>

### II. COMPLIANCE MANAGEMENT

#### 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.

<table>
<thead>
<tr>
<th>Schedule:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. protocol audits</td>
<td></td>
</tr>
<tr>
<td>2. critical phase study inspections</td>
<td></td>
</tr>
<tr>
<td>3. raw data and supporting documentation audits</td>
<td></td>
</tr>
<tr>
<td>4. draft, interim and/or final report audits</td>
<td></td>
</tr>
<tr>
<td>5. release of the Quality Assurance Statement for inclusion in the final report</td>
<td></td>
</tr>
<tr>
<td>6. facility and support area inspections</td>
<td></td>
</tr>
<tr>
<td>7. follow-up for issue resolution</td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Percentage</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. maintain a copy of the Master Schedule and its updates</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>9. GLP training of personnel involved in the GLP process including the quality assurance unit, study personnel, archivist, etc.</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>10. site visits, inspections and audit activities of sponsors and regulatory officials</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td><strong>B. Reporting/Record Keeping</strong> are processes for physically capturing, documenting and/or communicating the observations, comments, findings, recommendations and activities of quality assurance unit.</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Report on and/or keep records of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. GLP compliance status of facilities, systems and processes</td>
<td>1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>2. scheduled and ad hoc inspections/audits and findings</td>
<td>2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>3. quality assurance unit copies of study protocols and protocol amendments</td>
<td>3%</td>
<td>3.6%</td>
</tr>
<tr>
<td>4. protocol and SOP deviations</td>
<td>4%</td>
<td>4.8%</td>
</tr>
<tr>
<td>5. quality assurance unit reports to management, study director and other key individuals such as principal investigator, sponsor/client representative, etc.</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>6. quality assurance unit SOPs</td>
<td>6%</td>
<td>7.2%</td>
</tr>
<tr>
<td>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</td>
<td>7%</td>
<td>8.4%</td>
</tr>
<tr>
<td>8. Master Schedule</td>
<td>8%</td>
<td>9.6%</td>
</tr>
<tr>
<td>9. inventory of quality assurance unit study materials for archival retention and access, removal and replacement of materials from Archives</td>
<td>9%</td>
<td>10.8%</td>
</tr>
<tr>
<td><strong>C. Documenting</strong> is the process of writing the procedures and work of the Quality Assurance Unit.</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Document:</td>
<td></td>
<td>12.2%</td>
</tr>
<tr>
<td>1. inspection and audit results and responses</td>
<td>1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>2. schedules to ensure the timely performance of required activities</td>
<td>2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>3. status of recommended corrective actions based on facility and/or study audits</td>
<td>3%</td>
<td>3.6%</td>
</tr>
<tr>
<td>4. quality assurance unit statements for study reports</td>
<td>4%</td>
<td>4.8%</td>
</tr>
<tr>
<td>5. quality assurance unit SOPs</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>6. training and qualifications of quality assurance unit personnel</td>
<td>6%</td>
<td>7.2%</td>
</tr>
<tr>
<td>7. records of regulatory and sponsor/client inspection activities, findings and quality assurance unit and management responses (including issue escalation)</td>
<td>7%</td>
<td>8.4%</td>
</tr>
<tr>
<td><strong>III. APPLIED EXPERTISE</strong></td>
<td></td>
<td>28%</td>
</tr>
<tr>
<td><strong>A. Evaluating</strong> is the critical assessment of the nature, significance, adequacy, value and/or quality of a person, process, system or physical entity.</td>
<td>13%</td>
<td>13.4%</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. personnel qualification records (e.g., curricula vitae, job descriptions, training records)</td>
<td></td>
</tr>
<tr>
<td>8. training programs designed to support GLP compliance</td>
<td></td>
</tr>
<tr>
<td><strong>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.</strong></td>
<td></td>
</tr>
<tr>
<td>Advise management and staff regarding:</td>
<td>15%</td>
</tr>
<tr>
<td>1. application of GLPs to studies</td>
<td></td>
</tr>
<tr>
<td>2. application of GLPs to your company/situation/relationship (e.g., lab, field site, vendor, sponsor)</td>
<td></td>
</tr>
<tr>
<td>3. study director and management responsibilities</td>
<td></td>
</tr>
<tr>
<td>4. content and meaning of the GLP Compliance Statement</td>
<td></td>
</tr>
<tr>
<td>5. content and meaning of the Quality Assurance Statement in the final report</td>
<td></td>
</tr>
<tr>
<td>6. responsibilities, obligations and rights of management and the company during the conduct of regulatory inspections</td>
<td></td>
</tr>
<tr>
<td>7. behavior and responsibilities of staff when hosting outside inspectors</td>
<td></td>
</tr>
<tr>
<td>8. current regulatory trends and new information appearing in the Federal Register and other official or unofficial regulatory documents</td>
<td></td>
</tr>
<tr>
<td>9. training modules for facility personnel on GLP related subjects</td>
<td></td>
</tr>
<tr>
<td>10. compliance issues arising during inspection related activities</td>
<td></td>
</tr>
<tr>
<td>11. importance and meaning of quality assurance unit inspectional/audit findings</td>
<td></td>
</tr>
<tr>
<td>12. regulatory dimension of systems validation and equipment qualification</td>
<td></td>
</tr>
<tr>
<td>13. scope of the quality assurance unit compliance program</td>
<td></td>
</tr>
<tr>
<td>14. GLP documentation for study events and reports</td>
<td></td>
</tr>
<tr>
<td>15. content of personnel curricula vitae, job descriptions and/or personnel training records</td>
<td></td>
</tr>
<tr>
<td>16. protocol and protocol amendment and deviation documentation requirements</td>
<td></td>
</tr>
<tr>
<td>17. SOP content, revision, authorization and distribution requirements</td>
<td></td>
</tr>
<tr>
<td>18. study report content, revision, and approval requirements</td>
<td></td>
</tr>
<tr>
<td>19. proper documentation procedures</td>
<td></td>
</tr>
<tr>
<td>20. corrective actions following inspections and/or audits including the adequacy of responses (e.g., root cause analysis)</td>
<td></td>
</tr>
<tr>
<td>21. continuous process improvements (e.g., risk analysis) related to GLP compliance</td>
<td></td>
</tr>
</tbody>
</table>
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?
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
   US Environmental Protection Agency (EPA)
   Laboratory Data Integrity Assurance Division
   2805 Jefferson Davis Highway
   Arlington, Virginia 22202

2) Advisory/Policy  1993
   Good Laboratory Practice Standards Inspection Manual
   EPA/OPPTS
   Office of Prevention, Pesticides, and Toxic Substances
   US Environmental Protection Agency
   Washington, DC 20460

   A manual that provides EPA inspectors with guidance in conducting GLP inspections under both FIFRA and TSCA. EPA number 723-B-93-001.

3) Advisory/Policy  1992
   FIFRA Good Laboratory Practice Standards (GLPs) Regulations Questions and Answers Document
   Office of Compliance Monitoring
   Office of Prevention, Pesticides, and Toxic Substances
   US Environmental Protection Agency
   Washington, DC 20460

   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.

4) Advisory/Policy  1991
   Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Good Laboratory Practice (GLP) Regulations
   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.

   This publication describes liabilities, fines and procedures for violations of the FIFRA GLPs; it was effective as of September 30, 1991.

5) Advisory/Policy 1991
   Points to Consider for Internal Reviews and Corrective Action Operating Plans
   US Food and Drug Administration
   National Technical Information Service (NTIS) Publication Number PB91-228106, $17 (paper), $9 (MICROFICHE)
   US Department of Commerce, NTIS
   5285 Port Royal Road
   Springfield, VA 22161

   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).”
6) Advisory/Policy  1991
   Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy.
   US Food and Drug Administration (FDA)
   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) Advisory/Questions  1981
   Good Laboratory Practice Regulations: Questions and Answers. [Part II], Lepore, P.D.
   FDA Freedom of Information Office (FOI)
   Food and Drug Administration, (HFI-35)
   5600 Fishers Lane
   Rockville, Maryland 20857
   Ask for the most recent version. Must order by letter or by fax. Be specific about records required.
   Include your 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 send
   money.

8) Advisory/Questions  1979
   Good Regulatory Practice Regulations: Questions and Answers. Subpart B. [Part I], Lepore, P.D.
   (Good Laboratory Practices Regulations Management Briefings – Post Conference Report)
   FDA Freedom of Information Office
   Food and Drug Administration, (HFI-35)
   5600 Fishers Lane
   Rockville, Maryland 20857
   (Ask for the most recent version.)

9) FDA Bioresearch Compliance Program Guidance Manual   February 21, 2001
   Program 7348.808
   Good Laboratory Practices for Non-Clinical Laboratory Studies
   US Food and Drug Administration

10) Regulations – US/CFR  most current version plus preambles from all versions
    Good Laboratory Practices for Non-Clinical Laboratory Studies; Title 21, Part 58, Code of Federal Regulations.
    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.

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

12) Regulations – US/CFR  most current version plus preambles from all versions
    Good Laboratory Practice Standards (TSCA); Title 40, Part 792, Code of Federal Regulations.
    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.
13) Principles – OECD – most current version
The Organisation for Economic Cooperation and Development Principals of Good Laboratory Practice,
ENV/MC/CHEM (98) 17
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

14) Guidance/Policy
Guidance for GLP Monitoring Authorities Revised Guidance for the Conduct of Laboratory Inspections and Study Audits – Environment Monograph No. 111
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 3 (Revised)
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

15) Guidance/Policy
Quality Assurance and GLP – Consensus Document
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 4 (Revised),
ENV/JM/MONO(99)20
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

16) Guidance/Policy
Compliance of Laboratory Suppliers with GLP Principles – Consensus Document
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 5 (Revised),
ENV/JM/MONO(99)21
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

17) Guidance/Policy
The Application of the GLP Principles to Field Studies – Consensus Document
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 6 (Revised),
ENV/JM/MONO(99)22
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France

18) Guidance/Policy
The Application of the GLP Principles to Short Term Studies – Consensus Document
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 7 (Revised),
ENV/JM/MONO(99)23
OECD Environment Directorate
Environmental Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16, France
19) Guidance/Policy
   The Role and Responsibilities of the Study Director in GLP Studies – Consensus Document
   OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 8 (Revised),
   ENV/JM/MONO(99)24
   OECD Environment Directorate
   Environmental Health and Safety Division
   2 rue André-Pascal
   75775 Paris Cedex 16, France

20) Guidance/Policy
   The Application of the Principles of GLP to Computerised Systems, Environment Monograph No. 116 – GLP
   Consensus Document
   OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 10,
   OCDE/GD(95)115
   OECD Environment Directorate
   Environmental Health and Safety Division
   2 rue André-Pascal
   75775 Paris Cedex 16, France

21) Guidance/Policy
   The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies –
   Consensus Document of the Working group on Good Laboratory Practice
   OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 13,
   ENV/JM/MONO(2002)9
   OECD Environment Directorate
   Environmental Health and Safety Division
   2 rue André-Pascal
   75775 Paris Cedex 16, France

22) Advisory
   The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP – Advisory Document
   of the Panel on Good Laboratory Practice
   OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 11,
   ENV/MC/CHEM(98)16
   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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Percentage</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. QUALITY MANAGEMENT: SUPPORT</strong></td>
<td>25%</td>
<td>Total</td>
</tr>
<tr>
<td><strong>A. Planning</strong></td>
<td>7%</td>
<td>1. Plan audits (e.g., investigator site, vendor, systems, document) 2. Plan directed/for-cause audits in response to sponsor hold or participant/employee complaints or suspected scientific misconduct and noncompliance 3. Plan support for regulatory inspections 4. Incorporate risk assessment in the identification and prioritization of QA tasks</td>
</tr>
<tr>
<td><strong>B. Generating and maintaining records</strong></td>
<td>8%</td>
<td>1. Generate and maintain records of audit generated reports (e.g., plans, observations, reports, certificates) 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 analyses of audit observations and corrective actions 5. Generate and maintain records of communications required by the quality system</td>
</tr>
<tr>
<td><strong>C. Developing procedures</strong></td>
<td>10%</td>
<td>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 research misconduct or allegations of fraud 5. Prepare procedures for the maintenance of quality assurance records 6. Prepare procedures for CAPA activities</td>
</tr>
<tr>
<td><strong>II. QUALITY MANAGEMENT: ASSESSMENT</strong></td>
<td>45%</td>
<td>Total</td>
</tr>
<tr>
<td><strong>A. Inspecting</strong></td>
<td>7%</td>
<td>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 subjects 4. Inspect storage areas for clinical supplies and test article/investigational product 5. Inspect computer facilities including security, environmental controls and the associated uninterruptible power supply 6. Inspect location and storage of study and source documents</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>B. <strong>Auditing</strong> is a systematic and independent examination of regulated activities and documents to evaluate that they are conducted and are recorded, analyzed and accurately reported according to the protocol, sponsor's procedural documents, GCPs and applicable requirements.</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Audit procedural documents, procedural document revisions and deviation documentation</td>
<td></td>
</tr>
<tr>
<td>2. Audit personnel qualifications including curricula vitae, job descriptions, certifications, licenses and training records</td>
<td></td>
</tr>
<tr>
<td>3. Audit computer system validation and equipment use and qualification documentation</td>
<td></td>
</tr>
<tr>
<td>4. Audit chain of custody documentation and accountability of test articles/investigational products and specimen records</td>
<td></td>
</tr>
<tr>
<td>5. Audit participant screening, enrollment and randomization documentation</td>
<td></td>
</tr>
<tr>
<td>6. Audit source data</td>
<td></td>
</tr>
<tr>
<td>7. Audit required clinical trial documents (e.g., Trial Master File, regulatory files, protocols, clinical study reports)</td>
<td></td>
</tr>
<tr>
<td>8. Audit privacy and confidentiality disclosure documents</td>
<td></td>
</tr>
<tr>
<td>9. Audit informed consent process and documents</td>
<td></td>
</tr>
<tr>
<td>10. Audit retention samples of test articles/investigational product and specimens</td>
<td></td>
</tr>
<tr>
<td>11. Audit the IRB/IEC review process and documentation</td>
<td></td>
</tr>
<tr>
<td>12. Audit documentation of protocol deviations, exceptions, violations and waivers</td>
<td></td>
</tr>
<tr>
<td>13. Audit follow ups to monitoring reports, inspections and audits</td>
<td></td>
</tr>
<tr>
<td>14. Audit records of storage and retention requirements</td>
<td></td>
</tr>
<tr>
<td>15. Audit physical and logical security procedures (e.g., study records, server rooms, facility access)</td>
<td></td>
</tr>
<tr>
<td>16. Audit contractual obligations and agreements</td>
<td></td>
</tr>
<tr>
<td>17. Audit adverse event reporting documentation and compliance with regulatory reporting timelines</td>
<td></td>
</tr>
<tr>
<td>18. Conduct interviews of auditees</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. <strong>Analyzing and Evaluating:</strong> 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.</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Analyze and evaluate compliance of items assessed and inspected with the study protocol, procedural documents, GCPs and applicable regulatory requirements</td>
<td></td>
</tr>
<tr>
<td>2. Analyze and evaluate vendor qualifications and suitability</td>
<td></td>
</tr>
<tr>
<td>3. Analyze and evaluate personnel qualification records (e.g., curricula vitae, job descriptions, training records) to assess adequacy</td>
<td></td>
</tr>
<tr>
<td>4. Analyze and evaluate adequacy of auditee’s resources to complete the study</td>
<td></td>
</tr>
<tr>
<td>5. Analyze and evaluate adequacy of remediation activities</td>
<td></td>
</tr>
<tr>
<td>6. Analyze and evaluate completeness, accuracy, reliability and validity of study data</td>
<td></td>
</tr>
<tr>
<td>7. Analyze and evaluate the informed consent process, subject privacy and human protection for a study</td>
<td></td>
</tr>
<tr>
<td>8. Analyze and evaluate physical and logical security procedures</td>
<td></td>
</tr>
<tr>
<td>9. Analyze and evaluate trends (e.g., audit observations, deviations, CAPAs)</td>
<td></td>
</tr>
<tr>
<td>10. Analyze and evaluate quality and compliance risks</td>
<td></td>
</tr>
<tr>
<td>11. Analyze and evaluate interview responses</td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>III. QUALITY MANAGEMENT: APPLIED EXPERTISE</th>
<th>30%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Advising</strong> is a consultative process for providing informed, expert opinion, advice and/or recommendations on issues pertaining to GCP regulations and requirements.</td>
<td>20%</td>
</tr>
<tr>
<td>1. Advise regarding applicable research regulations and standards</td>
<td></td>
</tr>
<tr>
<td>2. Advise regarding responsibilities of organizational management, investigational staff, sponsors and IRB/IECs</td>
<td></td>
</tr>
<tr>
<td>3. Advise regarding expectations during the conduct of audits/inspections</td>
<td></td>
</tr>
<tr>
<td>4. Advise regarding current industry and regulatory trends and new information</td>
<td></td>
</tr>
<tr>
<td>5. Advise regarding training of facility personnel on GCP</td>
<td></td>
</tr>
<tr>
<td>6. Advise regarding compliance issues arising during inspection and/or pre- and post-inspection</td>
<td></td>
</tr>
<tr>
<td>7. Advise regarding regulatory requirements for electronic record system validation and equipment use and qualification</td>
<td></td>
</tr>
<tr>
<td>8. Advise regarding applicable requirements of the quality assurance program</td>
<td></td>
</tr>
<tr>
<td>9. Advise regarding applicable requirements of documentation practices</td>
<td></td>
</tr>
<tr>
<td>10. Advise regarding content of personnel curricula vitae, job descriptions and/or personnel training records</td>
<td></td>
</tr>
<tr>
<td>11. Advise regarding protocol and protocol amendment documentation requirements</td>
<td></td>
</tr>
<tr>
<td>12. Advise regarding procedural document content, revision, retention, authorization and distribution requirements</td>
<td></td>
</tr>
<tr>
<td>13. Advise regarding study report content and approval requirements</td>
<td></td>
</tr>
<tr>
<td>14. Advise regarding internal departmental quality control criteria, procedures and documentation</td>
<td></td>
</tr>
<tr>
<td>15. Advise regarding trend analyses of production and interpretation of quality assurance/regulatory inspections, audits and observations</td>
<td></td>
</tr>
<tr>
<td>16. Advise regarding logical and physical security requirements</td>
<td></td>
</tr>
<tr>
<td>17. Advise regarding remediations including adequacy of responses to inspections and/or audits</td>
<td></td>
</tr>
<tr>
<td>18. Advise regarding proactive process improvements</td>
<td></td>
</tr>
<tr>
<td>19. Advise regarding data integrity</td>
<td></td>
</tr>
<tr>
<td>20. Advise on vendor oversight activities</td>
<td></td>
</tr>
<tr>
<td><strong>B. Communicating, educating, and reporting:</strong> 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.</td>
<td>10%</td>
</tr>
<tr>
<td>1. Facilitating and contributing to quality-related discussions with various stakeholders (e.g., staff, audit team, site personnel, management)</td>
<td></td>
</tr>
<tr>
<td>2. Facilitating quality-related meetings (e.g., opening meeting, daily debrief, close-out meeting, site audits)</td>
<td></td>
</tr>
<tr>
<td>3. Issuing an audit report</td>
<td></td>
</tr>
<tr>
<td>4. Communicating and reporting sensitive information</td>
<td></td>
</tr>
<tr>
<td>5. Following up on audit report responses/CAPA</td>
<td></td>
</tr>
<tr>
<td>6. Creating and delivering training</td>
<td></td>
</tr>
<tr>
<td>7. Interacting with regulatory inspectors or sponsor auditors</td>
<td></td>
</tr>
<tr>
<td>8. Providing site education</td>
<td></td>
</tr>
<tr>
<td>9. Reporting trends analysis and evaluation results to management</td>
<td></td>
</tr>
<tr>
<td>10. Communicating and reporting escalation issues</td>
<td></td>
</tr>
</tbody>
</table>
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?
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:

European Medicines Agency:
http://www.emea.europa.eu

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


US Food and Drug Administration

Compliance Program Guides
Final Guidance Documents

Health Canada

Guidance for Records Related to Clinical Trials – GUI 0043; GUI 0036; GUI 0068; Inspection Strategy for Clinical Trials Regulations Amending the Food and Drug Regulations (Schedule No. 1024 – Clinical Trials, 20 JUN 2001)

International Conference on Harmonization: As of January 2018

GOOD CLINICAL PRACTICE
E6 (R2): Good Clinical Practice: Consolidated Guidelines
International Standards Organization (ISO)
  14155 - GCP for Medical Devices

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)

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 • 154 Hansen Road, Suite 201 • Charlottesville, VA 22911 USA
Fax: +1 434.977.1856 • E-mail: sqa@sqa.org

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): $430
☐ Non-Member (including Chapter members who are not SQA members): $595

Additional Fees:
☐ Late Fee (application submitted after early application deadline on website): $50
☐ English language accommodation needed (in Special Accommodations above): $50
☐ Testing Center outside of U.S./Canada required: $50 (country: _________________)

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. 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, 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 the percentage of time devoted to QA/audit work in each job position. 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 ___________________________

Requested Test Center Location  ___________________________________________________________________________________________

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:

Location: _______________________________________________________ Date: _________________________________

Please provide or allow (check all that apply):

☐ Extended examination time (1 hour extension maximum)
☐ Allow me to bring a new, unmarked, unwritten-in, basic English to native language dictionary
☐ Special seating or other physical accommodation*
☐ Question reader*
☐ 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.

Signed: ________________________________________  Date: _____________________________

Return this form WITH your examination application to:

Society of Quality Assurance, 154 Hansen Road, Suite 201, Charlottesville, VA 22911 USA
Fax: +1 434.977.1856; E-mail: sqa@sqa.org
If you have questions, call SQA at +1 434.297.4772.
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, 154 Hansen Road, Suite 201, Charlottesville, VA 22911 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:
- Registration fee discount for members
- Formal presentations with current developments and information
- Workshops and round table discussions
- Interactions and networking opportunities with international, national, state and regional regulators
- Training sessions
- Networking with peers and consultants
- Career Center onsite
- Poster session on current issues
- Member consultant information
- Exhibition featuring suppliers to the industry

**Formal Training Opportunities** - basic, specialized and professional enhancement
- Registration fee discount for members
- Two full days preceding and one day following the Annual Meeting in the Spring
- Five day Quality College in the Fall
- Online Learning Opportunities

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**SQA Membership Directory** - available on members-only website
- Searchable listing of members includes name, affiliation, address, telephone and e-mail
- Searchable by name, company affiliation and geographical location
- Customizable “My SQA” profile with picture and biography for online networking

**SQA Newsletter** - electronically distributed quarterly
- News and updates pertinent to regulatory and research quality assurance (GCP, GLP, GMP, etc.)
- In-depth discussion of current regulatory issues
- Regional Chapter, Committee and Specialty Section reports
- 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**
- Regulatory news providing information links to current regulatory issues and trends
- eForum and integrated listserv for all SQA Committees and Specialty Sections
- Regulatory Q&A database containing hundreds of regulatory questions that have been answered by key EPA and FDA representatives and SQA leaders
- Searchable bibliography of references with over 1,000 quality assurance references
- Free webinar library
- Current employment opportunities, Career Center and links to consultant advertising
- Specialty Section and Committee areas featuring pertinent industry information
- Links to regulatory agencies, national QA societies, SQA Regional Chapters, liaison organizations and corporate supporters
- SQA organizational charts and Standard Operating Procedures
- SQA calendar of meetings, training and events

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**Contact Us**

Society of Quality Assurance Headquarters
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Charlottesville, VA 22911 USA
Tel: +1.434.297.4772 • Fax: +1.434.977.1856
www.sqa.org • sqa@sqa.org

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**2015 Benefits of Membership**