



Society of Quality Assurance

Promoting Quality in the Regulated Research Community

*Registered Quality Assurance
Professional in GCP or GLP
Examinations*



CANDIDATE HANDBOOK

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SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

for the Registered Quality Assurance Professional in GCP or GLP Examinations

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.
7680 Universal Boulevard, Suite 300
Orlando, FL 32819 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.



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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 working under the GCP or GLP regulations noted in the Study References for the selected examination prior to the examination date; OR
2. Have a baccalaureate degree AND the equivalent of two (2) years of full-time quality assurance experience working under the GCP or or GLP regulations noted in the Study References for the selected examination prior to the examination date.

A COPY OF YOUR CURRICULUM VITAE (CV) MUST BE SUBMITTED WITH YOUR APPLICATION.

Experience: To document experience, you are required to provide your supervisor or manager's signature or the signature of an Active Member of SQA (if you do not have a supervisor or manager) on the application.

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.

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.



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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.

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. Two forms of valid identification (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.



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REPORTING RESULTS

Notification of Results: At the conclusion of the RQAP-GLP examination, you will receive a diagnostic score report. For the RQAP-GCP examination, you will receive a diagnostic score report up to six weeks after the conclusion of the test.

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.

CONFIDENTIALITY

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

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.



Registered Quality Assurance Professional in GLP Examination Detailed Content Outline

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
I. COMPLIANCE ASSESSMENT	15	24	27	66
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:	3	9	3	15
1. receipt, handling, storage, preparation (including mixing), analyses /or administration to the test system of the test, control and reference material			X	
2. test system receipt, quarantine, randomization/allocation, identification, acclimation, observations and disposition			X	
3. specimen and/or sample collection, labeling, storage, shipping, receiving, handling and/or disposition		X	X	
4. specimen and/or sample analyses			X	
5. reagent and supply shipping, receiving, handling, storage and disposition		X	X	
6. adherence of procedures specified in protocol, SOPs and company policies				
7. data collection processes (manual and automated)				
8. archive including the appropriateness of raw data for archival storage and retrieval		X	X	
9. 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:	4	7	1	12
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			X	
4. computer facilities and the associated uninterruptible power supply			X	
5. location in each laboratory/site of protocols, SOPs, equipment logs, facility records, operating permits and/or related documentation		X	X	
6. location in each laboratory/site of data under active collection		X	X	



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 Addendum 1 – RQAP-GLP Examination Outline and Study References

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7. labeling of chemicals, reagents, test, control and reference materials, etc.		X	X	
8. equipment associated with test system maintenance (e.g., animal rooms, test plots, aquaria) and study conduct		X	X	
9. archives including the appropriateness of raw data for archival storage and retrieval			X	
10. laboratory or field site that participates in a study, including vendors, contractors or subcontractors				
11. storage conditions of test, control, reference materials and specimens; data and samples			X	
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:	8	8	23	39
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 validation including the associated documentation				
5. computer system development, verification, validation and release processes including related documentation				
6. test, control and reference material characterization, dosing mixture(s), concentrations, stability analyses and/or homogeneity analyses including data and other related documentation			X	
7. analytical method validation and documentation				
8. chain of custody documentation			X	
9. certificates of analyses			X	
10. final reports (including contributing scientists' reports), amendments and GLP Compliance Statement				
11. accountability records for test, control and/or reference materials, specimens and samples including records for preparation, administration and disposal			X	
12. test system randomization documentation			X	
13. equipment maintenance, calibration and repair records			X	
14. temperature, humidity and other environmental control records			X	
15. study notebooks, computer print-outs, and raw data and data calculations including transformations, transcriptions and derivations (e.g., statistical analyses and summary tables)				



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16. archival and other authorized access/tracking records		X	X	
17. animals/test system history, receipt, quarantine and maintenance records			X	
18. quality control records			X	
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	8	29	7	44
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. In addition to the regulatory requirement for a Master Schedule, organizational functions such as managing workload and planning audits/inspections and follow-up are advanced by the use of this tool.				
Schedule:	1	5	2	8
1. protocol audits		X	X	
2. critical phase study inspections				
3. raw data and supporting documentation audits			X	
4. draft, interim and/or final report audits			X	
5. release of the Quality Assurance Statement for inclusion in the final report			X	
6. facility and support area inspections				
7. verification of corrective actions recommended in audits and inspections			X	
8. production of the Master Schedule and its updates			X	
9. period GLP training of personnel involved in the GLP process including the quality assurance unit, study personnel, archivist, etc.			X	
10. site visits, inspections and audit activities of sponsors and regulatory officials			X	
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:	2	10	5	17
1. GLP compliance status of facilities, systems and processes				
2. scheduled and <i>ad hoc</i> inspections/audits and findings				
3. quality assurance unit copies of study protocols and protocol amendments		X	X	
4. protocol and SOP deviations				



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Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
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			X	
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		X	X	
8. Master Schedule			X	
9. inventory of study materials for archival retention and access, removal and replacement of materials from Archives			X	
10. quality assurance unit documentation for all completed, terminated or canceled studies			X	
C. Documenting is the process of writing the procedures and work of the Quality Assurance Unit.				
Document:	5	14	0	19
1. inspection and audit results, and management and study director responses			X	
2. schedules to ensure the timely performance of required activities			X	
3. status of recommended corrective actions based on facility and/or study audits			X	
4. quality assurance unit statements for study reports		X	X	
5. quality assurance unit SOPs			X	
6. training and qualifications of quality assurance unit, study personnel and other staff involved in GLP activities			X	
7. records of regulatory and sponsor/client inspection activities, findings and quality assurance unit and management responses			X	
III. APPLIED EXPERTISE	6	6	28	40
A. Evaluating is the critical assessment of the nature, significance, adequacy, value and/or quality of a person, process, system or physical entity.				
Evaluate:	3	3	12	18
1. contract laboratories, facilities and field sites; vendors or subcontractors and their associated systems for the capability to perform particular studies and adhere to GLP standards				
2. protocols and SOPs related to established procedures and available resources				
3. systems for auditing, inspecting and/or tracking information related to GLPs				
4. corrective actions engendered by inspecting and monitoring				
5. overall facility/site operations and security, management and personnel qualifications, and the functional performance of compliance systems to assure the integrity, reliability and usefulness of the data				



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Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
6. internal organizational reporting procedures				
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 studies and facilities/sites. GLPs require the quality assurance unit to assess and report on the “adequacy” of a particular situation, corrective action or process, making the quality assurance unit one of the compliance information-resources for management and staff. Advising can include training, occur both formally or informally, orally or in writing, and with facility/site employees and contract and/or regulatory officials.				
Advise management and staff regarding:	3	3	16	22
1. application of GLPs to GLP studies or in GLP environments				
2. application of GLPs to your company/situation/relationship (i.e., 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. content adequacy of GLP training course opportunities				
11. compliance issues arising during inspection related activities				
12. importance and meaning of quality assurance unit inspectional/audit findings				
13. regulatory dimension of systems validation and equipment qualification				
14. GLP requirements for standardization as well as for specific and unique studies				
15. comprehensiveness of the quality assurance unit compliance program				
16. GLP documentation for study events and reports				
17. content of personnel curricula vitae, job descriptions and/or personnel training records				



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18. protocol and protocol amendment documentation requirements				
19. SOP content, revision, authorization and distribution requirements				
20. study report content and approval requirements				
21. quality control criteria, procedures and documentation				
22. proper documentation procedures				
23. corrective actions following inspections and/or audits including the adequacy of responses				
24. requirements of overall GLP compliance (e.g., orientation seminars in GLPs for new employees, periodically advising and responding to questions, etc.)				
25. proactive improvements in processes related to GLP compliance issues				
TOTALS	29	59	62	150

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

Answer Key 1. C 2. B 3. C



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 1 – RQAP-GLP Examination Outline and Study References

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)."



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Addendum 1 – RQAP-GLP Examination Outline and Study References

- 6) Advisory/Policy 1991
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) 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 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 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.



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 1 – RQAP-GLP Examination Outline and Study References

- 13) Regulations – OECD – most current version
The Organization 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 Andréj-Pascal
75775 Paris Cedex 16, France
Website: <http://www.oecd.org/ehs/>
- 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 Andrj-Pascal
75775 Paris Cedex 16, France
Website: <http://www.oecd.org/ehs/>
- 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
Website: <http://www.oecd.org/ehs/>
- 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
Website: <http://www.oecd.org/ehs/>
- 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
Website: <http://www.oecd.org/ehs/>
- 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
Website: <http://www.oecd.org/ehs/>



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 1 – RQAP-GLP Examination Outline and Study References

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

Website: <http://www.oecd.org/ehs/>

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

Website: <http://www.oecd.org/ehs/>

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

Website: <http://www.oecd.org/ehs/>

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

Website: <http://www.oecd.org/ehs/>



Registered Quality Assurance Professional in GCP Examination Detailed Content Outline

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
I. COMPLIANCE MANAGEMENT	9	20	13	42
A. Scheduling provides a mechanism for identifying and tracking the status of tasks, functions, and responsibilities of clinical quality assurance. Effective scheduling advanced organizational functions such as managing workload, and planning audit/inspections and followup. Workload is managed through tactical and strategic planning.				
Schedule:	2	10	0	12
1. routine audits (e.g., preparatory, investigator site, vendor)			X	
2. directed audits in response to sponsor hold or participant/employee complaints or suspected scientific misconduct and noncompliance			X	
3. document audits (e.g., protocol, Case Report Forms, Investigator Brochure)			X	
4. system audits (e.g., data management, medical safety, biostatistics, vendor)			X	
5. regulatory official site visits, inspections and audit activities			X	
6. vendor qualifications			X	
7. draft, interim, and/or final report audits			X	
8. reviews of responses and corrective action plans resulting from audits and inspections			X	
9. to prioritize workload conflicts			X	
10. quality assurance trend analyses and discussions with management			X	
11. SOP and GCP training			X	
12. internal quality assurance staff training and development			X	
13. briefings after audits			X	
14. reporting to oversight bodies			X	
B. Reporting and record keeping are processes for physically capturing, documenting and/or communicating observations, comments, recommendations and quality assurance activities.				
Report on and/or keep records of:	5	5	10	20
1. audit observations (e.g., investigators, IRB/IEC, facility, systems, processes)				
2. observations from external auditing groups and regulatory bodies				
3. training and staff development activities				
4. communications with regulatory bodies and legal entities				



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
Addendum 2 – RQAP-GCP Examination Outline and Study References

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
5. quality assurance copies of current and historical versions of applicable SOPs (e.g., review, approval, deviations and retiring of SOPs)				
6. scheduled and <i>ad hoc</i> inspections/audits and observations				
7. archive, inventory, retention, access, removal and replacement of documents				
8. audit certificates for final clinical study reports				
9. individual, interim and summary audits				
10. trend analyses of audit observations and corrective actions				
C. Preparing and disseminating procedures involves preparation of detailed written instruction for quality assurance practice standards to achieve uniformity in the performance of a specific function.				
Prepare and disseminate procedures for:	10	2	5	17
1. training requirements related to GCPs for quality assurance and organizational personnel				
2. auditing tasks (e.g., plans, schedules, reports, confirmation letters)				
3. trend analyses of audit observations				
4. preparing, managing and reporting of regulatory inspection activities				
5. preparing, managing and reporting of sponsor/client audit activities				
6. supporting inquiries/investigations into suspected research misconduct or allegations of illegal activities				
II. COMPLIANCE ASSESSMENT	21	22	26	69
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.				
Inspect areas/facilities:	6	7	2	15
1. where there is interaction with study participants			X	
2. where additional study activities are conducted (e.g., contract laboratories, pharmacies, contract research organizations)				
3. where specimens are collected, processed and stored to ensure the area is adequate to perform protocol required tests and accommodate subjects			X	
4. storage areas for clinical supplies and test article			X	
5. computer facilities including security, environmental controls and the associated uninterruptible power supply				
6. location and storage of study documents			X	
7. location and storage of source documents			X	



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
 Addendum 2 – RQAP-GCP Examination Outline and Study References

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8. location of equipment logs, facility records related to the study and/or related documentation			X	
B. Auditing is a systematic and independent examination of study-related activities and documents to determine whether evaluated activities were conducted, and data were recorded, analyzed and accurately reported according to the protocol, sponsor’s SOPs, GCPs and applicable requirements.				
Audit:	15	15	24	54
1. protocols and amendments				
2. SOPs, SOP revisions and deviation documentation				
3. personnel qualifications including curricula vitae, job descriptions, certifications, licenses and training records				
4. validation documentation for equipment used for a study				
5. equipment maintenance, calibration and repair records				
6. validation documentation of electronic record systems				
7. chain of custody documentation for records, test articles and specimens				
8. final clinical trial/study reports as defined in ICH GCP 5.22				
9. test article accountability records and appropriate test article labeling				
10. participant recruitment practices ensure the protocol and regulatory requirements				
11. participant randomization documentation				
12. temperature, humidity and other environmental control records				
13. source data as defined in ICH GCP 1.51				
14. data collection forms				
15. regulatory binders				
16. privacy and confidentiality disclosure documents (e.g., HIPAA)				
17. informed consent process and documents				
18. retention samples of test articles and specimens				
19. the IRB/IEC review process and documentation				
20. the study-specific IRB/IEC review process and documentation				
21. documentation of protocol deviations, exceptions, violations and waivers				
22. follow up to monitoring reports, inspections and audits				
23. record storage and retention requirements				
24. physical and logical security procedures				
25. study-specific plans (e.g., monitoring, data safety monitoring, data management, statistical analyses)				
26. contractual obligations and agreements				



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
 Addendum 2 – RQAP-GCP Examination Outline and Study References

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
III. APPLIED EXPERTISE	9	14	16	39
A. Evaluating is the critical assessment of authenticity, integrity, compliance level, significance, adequacy and quality of a process, system or physical entity.				
Evaluate:	2	7	9	18
1. facilities, investigator sites, and vendors for compliance with the study protocol, SOPs, GCPs and applicable regulatory requirements				
2. vendor qualifications				
3. personnel qualification records (e.g., curricula vitae, job descriptions, training records)				
4. adequacy of investigator's, sponsor's and vendor's resources to complete the study				
5. adequacy of a corrective action plan				
6. completeness, accuracy, reliability and validity of study data				
7. study performance and data generation to ensure documentation and reporting complied with GCP and the applicable regulatory requirements				
8. the informed consent process for a study				
9. physical and logical security procedures				
B. Advising is a consultation and education process for providing informed, expert opinion, advice and/or recommendations on issues pertaining to GCP studies and facilities/sites. Advising can include training and can occur formally or informally, orally or in writing.				
Advise regarding:	7	7	7	21
1. applicable research (e.g., pre-clinical, clinical, observational) regulations and standards				
2. responsibilities of organizational management, investigational staff, sponsors and IRB/IECs				
3. responsibilities and rights of the organization during the conduct of regulatory inspections				
4. behavior and responsibilities of staff when hosting outside inspectors				
5. current regulatory trends and new information appearing in either official or unofficial regulatory documents				
6. training modules for facility personnel on GCP-related subjects				
7. compliance issues arising during inspection and/or pre- and postinspection				
8. importance and meaning of quality assurance inspection/audit observations for investigators, management and study personnel				
9. regulatory dimension of systems validation and equipment qualification				
10. adequacy of the quality assurance program				



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
Addendum 2 – RQAP-GCP Examination Outline and Study References

Open cells show an examination could include items from indicated cognitive levels. Shaded cells prevent appearance of items on examinations.	Recall	Application	Analysis	Total
11. adequacy of documentation practices				
12. content of personnel curricula vitae, job descriptions and/or personnel training records				
13. protocol and protocol amendment documentation requirements				
14. SOP content, revision, authorization and distribution requirements				
15. study report content and approval requirements				
16. internal departmental quality control criteria, procedures and documentation				
17. trend analyses of production and interpretation of quality assurance/regulatory inspections, audits and observations				
18. GCP security and authorized access requirements				
19. a corrective action plan including adequacy of responses to date following inspections and/or audits				
20. requirements of overall GCP compliance (e.g., orientation seminars in GCPs for new hires, periodically advising and responding to questions from management and study personnel)				
21. proactive improvements in processes related to GCP compliance issues				
TOTALS	39	56	55	150

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.

Answer Key 1. B 2. C



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 2 – RQAP-GCP Examination Outline and Study References

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-mpps/compli-conform/legislation/acts-lois/index_e.html

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/hipaa/>

US Office for Human Research Protections:

<http://www.hhs.gov/ohrp/>

References

International Conference on Harmonization: As of November 2005

CLINICAL SAFETY

E1: The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life Threatening Conditions

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

E2B (R3): Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

E2C (R1): Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
Addendum to E2C: Periodic Safety Update Reports for Marketed Drugs (in E2C (R1))

E2D: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting

E2E: Pharmacovigilance Planning

CLINICAL STUDY REPORTS

E3: Structure and Content of Clinical Study Reports

DOSE-RESPONSE STUDIES

E4: Dose-Response Information to Support Drug Registration

ETHNIC FACTORS

E5 (R1): Ethnic Factors in the Acceptability of Foreign Clinical Data

GOOD CLINICAL PRACTICE

E6 (R1): Good Clinical Practice: Consolidated Guidelines

CLINICAL TRIALS

E8: General Consideration of Clinical Trials

E9: Statistical Principles for Clinical Trials

E10: Choice of Control Group and Related Issues in Clinical Trials

CLINICAL EVALUATION

E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

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Health Canada

The Food and Drug Regulations (C.R.C., c. 870) – Part C, and Part J
Regulations Amending the Food and Drug Regulations (Schedule No. 1024 – Clinical Trials, 20 JUN 2001)
Medical Devices Regulations (SOR/98-282), Part 3
Guidance for Records Related to Clinical Trials – Guide 0068
Health Canada Compliance and Enforcement Policy (POL-0001), Version 2
Inspection Strategy for Post-Market Surveillance (POL-0041)

European Medicines Agency

Commission Directive 2005/28/EC of 8 April 2005
Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004
Commission Directive 2003/63/EC of 25 Jun 2003 Annex 1 “Analytical, Pharmacotoxicological and Clinical Standards and Protocols in Respect of the Testing of Medicinal Products”
Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001

US Code of Federal Regulations: Title 21 Food and Drugs

21 CFR Part 11 – Electronic Records; Electronic Signatures
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 312 – Investigational New Drug Application
21 CFR Part 314 – Applications for FDA Approval to Market a New Drug
21 CFR Part 320 – Bioavailability and Bioequivalence Requirements
21 CFR Part 601 – Biologics Licensing
21 CFR Part 812 – Investigational Device Exemptions
21 CFR Part 814 – Premarket Approval of Medical Devices

Preambles to FDA GCP Regulations: Preambles to the FDA regulations can be found through the FDA website.

Guidance Documents and Information Sheets on Good Clinical Practice in FDA-Regulated Clinical Trials

FDA Information Sheets for Institutional Review Boards, Clinical Investigators and Sponsors
The Belmont Report 18 Apr 1979
The Declaration of Helsinki; World Medical Association; 1983 and 1989 versions
Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection
Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees
Guidance for Industry: Acceptance of Foreign Clinical Studies
Guidance for Industry: Available Therapy
Guidance for Industry: Computerized Systems Used in Clinical Trials
Guidance for Industry: Development and Use of Risk Minimization Action Plans
Guidance for Industry Exploratory IND Studies
Guidance for Industry: Financial Disclosure by Clinical Investigators
Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies
Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
Guidance for Industry: Guideline for the Monitoring of Clinical Investigators
Guidance for Industry: Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs
Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples;
Guidance for Industry: IRB Review of Stand-Alone HIPAA Authorizations under FDA Regulations
Guidance for Industry on Part 11: Electronic Records; Electronic Signatures – Scope and Application
Guidance for Industry and FDA Staff: General Principles of Software Validation
Guidance for Industry: Pharmacogenomic Data Submissions
Guidance for Industry: Premarketing Risk Assessment
Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 2 – RQAP-GCP Examination Outline and Study References

Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct

Guidance for Industry on Using a Centralized IRB Process in Multicenter Clinical Trial

Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable

Bioresearch Monitoring Program (Compliance Program Guidance Manuals – CPGM)

CPGM 7348.811 Clinical Investigators

CPGM 7348.810 Sponsors, Monitors, and Contract Research Organizations

CPGM 7348.001 In-Vivo Bioequivalence Compliance Program

CPGM 7348.809 Institutional Review Boards

Office for Human Research Protections (OHRP)

45 CFR Part 46 Protection of Human Subjects (Common Rule)

Office of Human Research Protections



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
Addendum 3 – RQAP Examination Application and Accommodation Forms

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 _____ Date of Birth _____
 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): _____

Method of Payment

- Base Application Fees:** SQA Member (choose this if you apply for membership prior to or simultaneously with this application): **\$350**
 Non-Member (including Chapter members who are not SQA members): **\$500**

- Additional Fees** (please select all that apply): Late Fee (application submitted after early application deadline on website): **\$50**
 Accommodation needed (under Special Accommodations below): **\$50**
 Testing Center outside of U.S./Canada required: **\$50** (country: _____)

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

Form of Payment

- 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
 MasterCard VISA American Express
 Account Number: _____ Expiration Date: _____
 Statement Billing Address: _____
 Name as it appears on card: _____
 Signature: _____

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.

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.
 Check this box if 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.

Eligibility Status (check one):

A copy of your curriculum vitae (CV) must be submitted with your application.

- I have the equivalent of four years of full-time experience working as a quality assurance professional under the regulations and/or standards listed in the list of Exam Study References for the exam I plan to take prior to the examination date.

OR

- I have a baccalaureate degree AND the equivalent of two years of full-time experience working as a quality assurance professional under the regulations and/or standards listed in the list of Exam Study References for the exam I plan to take prior to the examination date.

(application continued on next page)



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK

Addendum 3 – RQAP Examination Application and Accommodation Forms

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)_____.

Quality Assurance Employment History

Provide the quality assurance employment history information as requested below.

Present Quality Assurance Employment

Employment Date (month/day/year) _____
 Name of Organization _____
 Address _____
 City/State or Province/Postal Code/Country _____
 Your Title or Position _____
 Your Supervisor/Manager's Name _____

Previous Quality Assurance Employment

List previous employer below. DO NOT LIST PRESENT EMPLOYER.

Employment Dates: From (month/day/year) _____ To (month/day/year) _____
 Name of Organization _____
 Address _____
 City/State or Province/Postal Code/Country _____
 Your Title or Position _____
 Your Supervisor/Manager's Name _____

Verification of Experience

Have your supervisor or manager, or an Active Member of SQA (for individuals **without a supervisor or manager**) complete the section below to document your quality assurance experience.

- I certify that I have personal knowledge that this candidate has/will have fulfilled the quality assurance eligibility requirement as indicated on page 1 of this application by the examination date.

Check one: I am the Supervisor/Manager of this candidate
 I am an Active SQA Member vouching for this candidate

Full Name (Please Print) _____
 Signature _____
 Title/Position _____
 Organization _____

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)



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
Addendum 3 – RQAP Examination Application and Accommodation Forms

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*):

- Special seating or other physical accommodation
- Large print examination (available for paper and pencil administrations only)
- Circle answers in examination booklet (available for paper and pencil administrations only)
- Question reader
- Reduced distraction environment
- Extended examination time (1 hour extension maximum)
- Allow me to bring a new, unmarked, unwritten-in, basic English to native language dictionary
- Other special accommodations (please specify)

Comments: _____

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.



SOCIETY OF QUALITY ASSURANCE CANDIDATE HANDBOOK
Addendum 3 – RQAP Examination Application and Accommodation Forms

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, 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.

