Chapter 5. Project Management

Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences

5. Project Management

Bradley J. Collins[1], Suramya Waidyanatha[1] (Editors)

[1]Division of Translational Toxicology, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, USA

Last Updated: May 2026

5.1. General Requirements

The contractor shall provide for timely start-up of contract work after award. It is expected that the contractor shall ensure the following items are in order at the time of award:

- All management documents are in place.
- Adequate staff is on hand.
- Facilities are as proposed and ready.

Assignments will be made to the contractor by the contracting officer's representative (COR) via the Division of Translational Toxicology (DTT) project management system (PMS), currently ORBIT (the organizational resource and business information tool). The COR will provide an assignment description along with a tentative milestone schedule. In response to the assignment, the contractor shall update the milestone schedule with a realistic estimate of the timeframe and provide a budget for the assigned work.

During the performance of an assignment, the contractor shall:

- Update the schedules when milestones are reached and/or priorities change.
- Report upside deviations of costs from estimated costs for any assignment to the COR in a timely manner and document such deviations in the assignment form in the DTT PMS. If an assignment is expected to exceed its estimated costs by more than 30%, the principal investigator (PI) shall contact the COR in a timely manner to obtain permission to exceed the estimated costs or to revise the scope of the task to bring the costs within the estimate.
- Costs expected to exceed or that have exceeded their estimated amounts shall be reported in the monthly status report (Chapter 7. Reporting Requirements) for each assignment.

The contractor shall provide for timely and cost-effective continuity of services in the event of contract termination or transfer, including but not limited to the following:

- Provide for orderly transition in the event of award to a new follow-on contractor.
- Provide for orderly transfer of work, government materials, and data to the government in the event of contract termination.

5.2. Quality Program

The PI and contract management are responsible for the quality of work performed and products delivered. Quality assurance (QA) activities provide information that allows management and the PI to assess the quality of work performed and to rectify deficiencies as needed. Quality control (QC) activities ensure that the records, results, and reports (i.e., all information generated by study conduct staff) are accurate and complete.

5.2.1. General Requirements

All work performed by the contractor or any subcontractor for any assignment that directly supports a Good Laboratory Practices (GLP) DTT study shall comply with Food and Drug Administration (FDA) GLP regulations for nonclinical laboratory studies (FDA GLP Regulations; Federal Register, 12/22/78, Subpart B et seq.) unless specifically authorized by the COR.[1]

The contractor shall establish an effective quality program that addresses the following objectives:

- Establish a quality management plan (QMP).
- Establish an effective and independent quality assurance unit (QAU), headed by a qualified quality assurance officer (QAO).
- Establish policies and procedures that ensure QC at all levels, including development of a contract-wide QC program.
- Develop and maintain standard operating procedures (SOPs) for all contract operations, procedures, assignments, and tasks, which describe how each activity is to be performed.
- Ensure that work performed by subcontractors meets the same quality requirements as work performed by the prime contractor.

Additional information about QMPs suitable for nonclinical laboratory work is available from the following sources:

- U.S. Environmental Protection Agency (EPA) QMP requirements (EPA 2001)
- The FDA GLP regulations are available from the Code of Federal Regulations (CFR), 21 CFR Ch.1 (4/1/1999 Edition)[2]

Additional SOP requirements can be found in Chapter 7. Reporting Requirements.

5.2.2. Quality Management Plan

The contractor shall develop and implement a QMP that governs all work performed.

The QMP shall follow the requirements set forth in the U.S. EPA Requirements for Quality Management Plans (EPA QA/R-2) (EPA2001). Specifically, the QMP must include, but is not limited to, the following:

[1] https://www.govinfo.gov/content/pkg/CFR-2016-title21-vol1/pdf/CFR-2016-title21-vol1-part58.pdf
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

- The QMP shall ensure that all work performed meets all applicable contractual requirements, including the requirement that the work be performed in compliance with federal GLP unless specifically approved by the COR.
- Policies governing the QC review of data generated by the contract.
- Policies for generation, use, and maintenance of SOPs applicable to all contract activities, which describe how all operations, procedures, assignments, and tasks shall be performed (see Section 5.2.5. Standard Operating Procedures for detailed SOP requirements).
- Policies that describe the use of the QAU to inspect and review routine work and work in progress.
- Policies regarding the reporting and resolution of QA findings that have been brought to the attention of management.
- Policies regarding the involvement of the QAU with respect to GLP compliance for all operations, procedures, assignments, and tasks performed under the contract.
- Policies governing the relationships between the QAU and the PI and contract staff.

The QMP shall conform to the requirements found in Chapter 7. Reporting Requirements.

5.2.3. Quality Assurance Unit

The QAU is independent of work managed by the PI and therefore has no direct responsibility for its quality. The primary responsibility of the QAU is to provide information that enables management and the PI to assess the quality of work performed and to rectify deficiencies as needed. Thus, QAU activities enable management and others to assign a proper level of confidence to the work performed and reported by study staff. Requirements for the organization and function of the QAU are specified in the FDA GLP regulations. Requirements of special interest are given below.

- The primary responsibility of the QAU is to provide information that enables management and the PI to assess the quality of work performed.
- The QAO must report to a level of management above the PI.
- The QAU may NOT approve or reject a procedure, datum, result, or report that is generated in the performance of any assignment.
- The QAU may NOT perform any work for which it has responsibility to monitor or which may inhibit its authority to assess any work independently and objectively.

The QAU shall conduct inspections of work in progress and data audits that assess the extent to which work performed complies with protocols, SOPs, contractual requirements, and FDA GLP regulations.

The QAU shall maintain a system for tracking assignments made to the contractor. DTT maintains a computerized PMS (Section 5.3. Information Management) that the QAU may elect to use as the primary schedule.

The QAU shall audit the accuracy, completeness, and consistency of information in final reports compared to original (source) records, prior to submission to the DTT.

The QAU shall prepare assessment reports that enable management and study staff to understand the effectiveness of their overall operations and make decisions that may be needed to ensure or improve product quality.

Records generated by the QAU, and resultant actions taken by management, shall be made available for review by DTT staff during site visits and progress evaluations but are otherwise proprietary documents not available for review by outside parties.

5.2.4. Quality Control

The contractor shall implement policies and procedures that encourage quality performance from the assignment of a task to its conclusion. QC is one of many resources managed by the PI, which along with the study conduct staff are the primary determinants of quality. The purpose of QC is to ensure that the records, results, and reports, i.e., all information generated by study conduct staff, are accurate and complete. Accordingly, QC is an integral part of study conduct; however, it is applied after the primary work has been performed; therefore, its impact on quality is restricted to retrospective measures. Thus, study conduct staff, managed by the PI, determine prospective aspects of product quality such as regular instrument maintenance, good use of laboratory notebooks, and proper sample preparation. Feedback from QC activities is a valuable management tool for use by the PI, but the prospective activities performed by the study conduct staff are the fundamental determinants of study quality.

Internal Quality Control Program

The contractor shall implement an internal QC program that ensures complete and accurate documentation of all operations, procedures, assignments, and tasks performed under the contract. This program should include but is not limited to the following:

- Appropriate calibration samples and system suitability standards shall be utilized.
- Suitable calibration schedules shall be established for each instrument used by the program.
- Procedures that are part of the internal QC program shall be separate from and subject to periodic assessment by the QAU.

External Quality Control Program

The contractor shall participate in an external program to assess the quality of its performance. This program shall include, but is not limited to the following:

- On-site inspection, with prior notification, by the COR and/or their designee, of equipment, facilities, records, and procedures, including those of the QAU
- Periodic evaluation of standard reference materials provided from commercial or noncommercial sources

5.2.5. Standard Operating Procedures

The contractor shall develop SOPs for all contract operations, procedures, and assignments. All laboratory operations, procedures, assignments, and tasks shall have SOPs that describe how each is to be performed.

The contractor shall implement a regular review process for all SOPs in accordance with the policies set forth in the QMP.

The contractor shall ensure compliance with all SOPs by contract staff.

Types of Standard Operating Procedures

Laboratory operations or procedures of a general nature shall be conducted with SOPs that outline the essential parts of the procedure, including documentation. For example, under this requirement, the formulation development (FD) functional activity will have an SOP that describes how an FD is to be performed, the documentation to be used, and the controls to be applied while performing the assignment.

Laboratory operations or procedures of a routine or repetitive nature shall be conducted with explicit SOPs that describe the operation to be performed.

Assignments that are governed by a signed study protocol shall be conducted using explicit SOPs (e.g., Chapter 4. Animal Care and Use Requirements).

- Analyses using validated methods shall be conducted using substance-specific SOPs.
- Assignments that are developmental in nature (e.g., Section 6.4.3. Formulation Development (FD)) shall be conducted using SOPs that describe the procedure(s) that must be followed to meet the requirements of the assignment.

5.2.6. Subcontractors

The contractor shall ensure that all work performed by subcontractors conforms to the requirements of the prime contractor's QMP. In addition, the contractor shall ensure that all work performed by subcontractors shall meet all the requirements set forth in the contract.

The contractor's QAU shall monitor work done by subcontractors and report results to management, so that management may be informed about the quality of work performed by subcontractors.

The contracting officer must be informed of all subcontracting efforts and must approve all subcontracts before they can be issued.

5.3. Information Management

The DTT PMS is used to assign and track the work under the chemistry contracts, to capture all communications related to an assignment, and to provide a multi-user collaboration environment for DTT and its contractors.

5.3.1. General Requirements

The contractor must establish procedures and policies that promote effective communication with the COR related to the status of all ongoing work, including the schedule and costs under this contract. As part of this effort, the contractor shall establish a comprehensive PMS to monitor all ongoing work, establish schedules, and track costs. This system may serve as the contractor's master schedule for work performed under FDA GLP.

The contractor shall have an Internet connection that will provide standard broadband Internet, email, and FTP capabilities.

5.3.2. Assignments

For each new request from the COR, the contractor shall update the DTT PMS by creating or updating a task with a description of the scope of the work requested, estimated cost, and a milestone schedule for each assignment. The milestone schedule shall include dates for some or all of the following at the direction of the COR:

- Commencement of lab work (Estimated Start Date)
- Completion of lab work (Estimated Lab Complete Date)
- Completion of draft final report
- Commencement of QC review
- Commencement of QA review
- Submission of draft final report (Estimated Draft Final Issue Date)

Values in parentheses indicate corresponding fields in the DTT PMS. The contractor shall enter these dates as estimates into the task record in the DTT PMS. The COR will review and approve the entry prior to commencement of work by the contractor.

The first time an assignment is entered, the estimated draft final report date shall be estimated by adding the number of weeks allowed from laboratory work completion to the draft final report due date specified in Chapter 7. Reporting Requirements for each report type.

The contractor shall update the DTT PMS whenever an assignment is modified, a milestone is reached, or the assignment is completed. When the estimated laboratory work completed date changes, the contractor shall update it with the new estimated date and also update the estimated draft final report date. As the work progresses, the contractor shall update the corresponding ORBIT entry with estimated and actual lab start, lab completion, and report dates as necessary.

All communication between the contractor and the COR regarding assignments shall take place in the DTT PMS. This communication includes, but is not limited to, discussions of problems encountered in the course of completing the assignment, interim results, draft final reports, plots, illustrations, and/or articles from the literature related to the assignment.

- The contractor shall update the DTT PMS for each active task as soon as new information is available or weekly, in the absence of new information.
- Interim results reports shall be posted to the DTT PMS as attachments to the relevant task.
- Draft final reports shall be posted to the DTT PMS as review documents attached to the relevant task.

5.3.3. Database Requirements

The contractor shall employ an appropriate Internet browser to access the DTT PMS. Currently Edge, Firefox, Chrome, and Safari are supported.

Licensed seats will be made available to the contractor key personnel or as appropriate to allow access to the DTT PMS. It is the contractor's responsibility to ensure that email settings and security are set to enable its staff to access and fully implement the DTT PMS. Note: ORBIT is based on Microsoft Dynamics 365 Program Operations.

The contractor shall design and implement an internal computerized PMS to provide for task scheduling and shall report the status of all tasks required under this contract as follows:

- The PMS shall be an interactive-type database management program with a user interface to the computer that can be easily accessed and queried and shall display and print reports requested by the COR.
- The PMS shall provide the capability to allow the electronic transfer of the results of analyses to the COR as specified for each task.
- The PMS shall provide the following information for each task: assignment date, work started date, current status of ongoing work, work completion date, draft final report completion date, commencement of QC review date, commencement of QA review date, report submission date (estimated and actual), DTT report-approval date, final report date, and a description of the assigned work. For assignments in Section 6.7. Animal Studies, the information shall include the expected completion dates for each phase of the work (e.g., literature review, in-life, draft final report).
- The PMS may be used to fulfill the functions of a master schedule.

5.3.4. Compound Inventory

The contractor shall maintain electronic inventories of all chemicals received as test articles and analytical standards or reference materials, which are stored at the contractor's facility. The contractor shall maintain a separate inventory for medium to high-throughput screening (MHTS) chemicals stored at its facility. The chemical/test article inventory shall, at minimum:

- Include the amount on hand, updated monthly.
- Contain identifying information, including but not limited to, test article name, Chemical Abstracts Service registry number® (CASRN), distributed structure-searchable toxicity (DTXSID), lot number, source, receipt date, and information on chemical class(es) and use(s) for each test article.
- Be fully searchable by chemical name, CASRN, lot number, source, and/or receipt date.
- Meet all of the requirements in Section 6.10. Medium- to High-Throughput Screening Activities (MHTS).

5.3.5. Record Retention

The contractor shall maintain copies of all paper records related to an assignment, including chemistry reports with all supporting data and instrument output (raw data) in accordance with their corporate records retention policy or a period of 5 years after the end of the contract, whichever is longer.

The contractor shall maintain electronic copies of all data and paper records related to an assignment, including chemistry reports and their supporting raw data in accordance with their corporate records retention policy or a period of 10 years following completion of the contract, whichever is longer. An electronic copy of all records and data shall be submitted as specified by the COR.

At the direction of the COR, paper and/or electronic copies may be sent to a National Institute of Environmental Health Sciences facility (site specified by the COR).

In the event of a change in the contractor's status, the contractor shall arrange to transfer the raw data to a third party designated by the COR.

5.3.6. Information Technology Systems Security

The contractor shall provide a finalized system security plan (SSP) for approval by the COR and DTT contracting officer within 60 days of contract award.

The SSP shall address security procedures, maintenance, and monitoring required for all systems used to store and/or transmit, modify, or otherwise interact with DTT data as well as system-level security procedures, maintenance, and monitoring for the contractor's corporate information technology system.

5.4. References

U.S. Environmental Protection Agency (USEPA). 2001. EPA requirements for quality management plans. Washington, DC: U.S. Environmental Protection Agency, Office of Environmental Information. EPA QA/R-2. EPA/240/B-01/002. https://www.epa.gov/quality/epa-qar-2-epa-requirements-quality-management-plans