Chapter 1. Personnel Requirements

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

1. Key Personnel

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This chapter describes the personnel requirements, including those for the principal investigator (PI), deputy PI, leads (e.g., task leader, discipline leader, project manager) for each functional area, laboratory animal veterinarian, quality assurance officer (QAO), and health and safety officer (HSO) as part of the contract team. The PI, deputy PI, and all leads shall be employees of the contractor (i.e., not consultants or subcontractors). The interaction and coordination of efforts needed among these functional areas make it critical that they be physically and organizationally together. Consultants may be used periodically only to advise the contractor on various aspects of assigned projects.

1.1. Principal Investigator

The PI has responsibility for the performance of all contractor-assigned work and is responsible for the daily management of the contract. This individual serves as the contractor's authorized point of contact with the contracting officer's representative (COR), Division of Translational Toxicology (DTT) staff, and other contractors as requested by the COR.

The PI must be knowledgeable and up to date in all aspects of the program and the contract, including the status of all assigned work, record keeping, reporting, and detailed analysis of cost for all functions that make up the total operation.

General qualifications expected of the PI/deputy PI include:

- Demonstrated experience in managing large-scale programs in multiple disciplines; demonstrated capability for effective written and oral communication.
- A doctorate or equivalent relevant training and experience in analytical chemistry or a related field (e.g., biochemistry, ADME and TK)

1.2. Task Leaders/Discipline Leaders/Project Managers

1.2.1. Task Leader – Logistics and Handling

This individual is responsible for managing the contractor's chemical containment facility and performance of functional activities as described in Section 6.2. Logistics and Handling. These activities include, but are not limited to, procurement of test articles,[1] formulation of test articles, homogenization and repackaging of test articles into containers specified by the COR, and shipment of test articles, biological samples, or environmental samples to a DTT-designated laboratory or research facility.

[1]Refer to Glossary of Terms.

General qualifications for the task leader for logistics and handling include:

- A master's or bachelor's degree in chemistry, biology, materials science, or a related field, or any combination of years of experience in chemistry, biology, or materials science and full-time college-level study in the particular field totaling 4 years.
- Two or more years of experience managing a material-handling (e.g., chemical, physical, or biological materials) program or facility, shipment, and tracking, including regulations related to domestic and international shipments.

1.2.2. Task Leader – Characterization

This individual is responsible for methods development and subsequent analysis of a test article for confirmation of identity and determination of purity, including analyses to identify other bioactive substances, metals, and volatile organic compounds that may be present in the material as described in Section 6.3 Characterization.

General qualifications for the task leader for Characterization include:

- A Master's or Bachelor's degree in chemistry, biology, materials science, or a related field, or any combination of years of experience in chemistry, biology, or materials science and full-time college-level study in the particular field totaling 4 years.
- Two or more years of experience in trace/impurity analysis and characterization of complex mixtures (e.g., botanical dietary supplements).

1.2.3. Task Leader – Formulations

This individual is responsible for developing formulation and analysis methods and subsequent analysis of dosed vehicles for a specified test article as described in Section 6.4 Formulation.

General qualifications for the task leader for Formulation include:

- A Master's or Bachelor's degree in chemistry, biology, materials science, or a related field, or any combination of years of experience in chemistry, biology, or materials science and full-time college-level study in the particular field totaling 4 years.
- Two or more years of experience related to formulation analysis and formulating test articles for toxicology studies.

1.2.4. Task Leader – Biosample Analysis

This individual is responsible for analytical method development, validation, and analysis of biological matrices for a specified analyte(s) concentration (e.g., test article and/or its metabolites, endogenous metabolites) as described in Section 6.5 Biosample Analysis

General qualifications for the task leaders in the areas of biosample analysis include:

- A Doctoral or a Master's degree with 5 year's of experience in bioanalytical chemistry.

- Demonstrated experience (e.g., publication record) in trace analysis of biological samples using state-of-the art analytical instrumentation.

1.2.5. Task Leader/Project Manager – Omics

The individual is responsible for technical and administrative oversight for exposomics, metabolomics, and proteomics study design, method development, sample analysis, data analysis, and interpretation as described in Section 6.8. Omics.

General qualifications for the task leader/project manager in the Omics area include:

- A master's or bachelor's degree and any combination of graduate work and equivalent relevant experience in chemistry or a related field totaling 5 years in a key scientific discipline (e.g., chemistry (environmental, analytical, or bioanalytical)).
- A significant experience in managing programs of comparable scope and size.
- Two or more years of experience in conducting and/or managing metabolomics, proteomics, and/or exposomics research.
- Demonstrated ability to provide effective written and oral communication.

1.2.6. Task Leader/Project Manager – In Vitro Assays

The individual is responsible for technical and administrative oversight for In Vitro Assays study design, method development and/or implementation, study conduct, data analysis, and interpretation as described in Section 6.9 In Vitro Assays.

General qualifications for the task leader/project manager in the In Vitro Assays area include:

- A Master's or Bachelor's degree and any combination of graduate work and equivalent relevant experience in chemistry or a related field totaling 4 years.
- Two or more years of experience in conducting in vitro assays to assess the absorption, distribution, metabolism, excretion (ADME) and toxicokinetics (TK) behavior of xenobiotics.
- A significant experience in managing programs of comparable scope and size.
- Demonstrated ability to provide effective written and oral communication.

1.2.7. Task Leader/Discipline Leader – Animal Studies

This individual is responsible for the execution of animal studies similar to those described in Section 6.7. Animal Studies. The individual should be knowledgeable in general animal study conduct, ADME and TK study design and conduct, data analysis and modeling (e.g., compartmental analysis of time-course data), and data interpretation as described in Section 6.7 Animal Studies.

General qualifications for the Task Leader/Discipline Leader include:

- A Doctoral or a Master's degree in chemistry or a related field and any combination of additional years of experience.

- Five or more years of experience conducting TK (or pharmacokinetics) and ADME studies.
- A significant experience in managing programs of comparable scope and size.
- Demonstrated experience (e.g., publication record) in designing, interpreting, and modeling ADME and TK data.

1.3. Laboratory Animal Veterinarian

This individual is responsible for monitoring the health of experimental animals and interacting with the PI and the DTT personnel concerning all phases of the animal experiments.

General qualifications of the veterinarian include:

- Graduate of a Veterinary College recognized by the American Veterinary Medical Association.
- Diplomate of the American College of Laboratory Animal Medicine (preferred) or eligible by experience and education to take the examination.
- Previous experience in managing laboratory animals, in particular rodents of all ages, including dams and their litters in toxicology or TK study conduct.

1.4. Quality Assurance Officer

This individual is responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in 21 Code of Federal Regulations Part 58, "Good Laboratory Practices for Nonclinical Laboratory Studies."[2] The QAO shall have management support and organizational independence from the personnel engaged in the direction and conduct of the study. When the quality assurance unit (QAU) consists of more than one person, the QAO shall have supervisory experience.

General qualifications for the QAO include:

- A bachelor's degree or any combination of years of experience in a related field and full-time college-level study in the particular field totaling 4 years.
- Two or more years of experience managing quality assurance, with specific relevant experience in conducting Good Laboratory Practices work related to the chemistry services described in Chapter 6. Functional Areas.
- Appropriate scientific experience to ensure understanding of the assignments or reports being inspected or audited in chemistry, ADME, and TK.

1.5. Health and Safety Officer

A qualified HSO or chemical hygiene officer (CHO) shall be designated to monitor worker health and safety conditions during all phases of the work. In this role, the HSO shall report to someone other than the PI and the PI's subordinates and shall have the authority to bring unsafe

[2] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58

conditions to the attention of higher management. The HSO may have other responsibilities within the contractor's organization; however, the amount of time devoted explicitly to health and safety must be commensurate with the scale of the contractor's operations. The HSO or CHO shall be a full-time employee of the contractor.

General qualifications for the HSO or CHO include:

- A bachelor's degree in industrial hygiene, chemistry, biology, safety engineering, or a closely related science or engineering field.
- At least 2 years of experience (part-time) in occupational health and safety along with completion of courses in general occupational health and hazard control indicating the acquisition of successively greater levels of knowledge of chemical health and safety. This experience shall have taken place within the last 4 years. Training shall have been completed within the last 18 months and shall be refreshed with additional training at an interval not exceeding 18 months. A master's degree in industrial hygiene or safety engineering or a bachelor's degree in industrial hygiene with 1 year of experience is an acceptable substitute for this experience requirement.
- Documented experience in working with the requirements of federal, state, and local statutes relating to occupational health and safety, the Occupational Safety and Health Administration laboratory standard and hazard communication standard, environmental protection, and chemical and biological monitoring.
- Ability to deal effectively with the scientific and managerial staff in responsibly implementing the health and safety program (including the identification of problem areas and the execution of corrective actions required).

All HSO appointments are subject to review and approval by DTT.

1.6. Support Staff

Technical staff shall have education, training, experience, and competency to conduct chemistry activities under the Functional Areas given in DTT Chemistry specifications.

Animal care staff shall have training and experience in the administration of test articles via the required routes of exposure, in providing appropriate animal care, and in evaluating clinical signs of toxicity.

Quality control staff shall have training and experience to provide review of all information generated under functional activities to ensure that it is accurate. Quality control staff shall be specific, designated personnel, normally outside the QAU, who are familiar with the types of data and reports generated by the contractor.

Data management staff includes a data coordinator who shall have appropriate training in data management activities, including electronic data management and data entry for all systems used to collect and store data generated for DTT. Data management staff shall have appropriate experience in data entry and training in data management.