



Job Description

Quality Project Manager

Job Purpose

The Quality Project Manager oversees the conduct of services provided by FDAQRC Consultants to Clients.

Primary Duties and Responsibilities

This position is home-based. The employee must provide a dedicated workspace. Travel for internal and to visit customers may occur. Employees shall have a flexible working schedule and may be required to work outside of traditional hours to meet deliverable timelines.

The Quality Project Manager ensures quality oversight of various projects with an understanding of applicable regulatory requirements and current industry standards and practices assuring compliance.

Quality Project Managers work to schedule and oversee assurance audits and other projects as assigned. This may include clinical investigator sites, vendors, processes, systems, gap assessments, and validations to assure quality assurance compliance about all internal procedures as well as regulatory guidelines.

Quality Project Managers may work to schedule kick-off calls, communicate with clients and audit resources as well as internal staff following company policies to respond to all communications within one business day.

FDAQRC has two (2) customers, Clients, and Consultants. Customer service is what makes us successful and therefore each employee is expected to understand and demonstrate above average customer service skills. This results in high retention of our customers.

Clients:

- / Ensure client needs are identified and exceeded through effective project oversight
- / Respond to queries and follow-up on pending items through proactive communication



- / Participate in the customer service program (sending and completing surveys)
- / Review feedback and action any quality issues

Consultants:

- / Proactively engage consultants
- / Manage consultant relationships
- / Facilitate communication through various methods (email, phone, etc.)
- / Ensure information is rapidly disseminated
- / Provide materials so the project is set-up for success
- / Provide support through the time and expense review processes
- / Review feedback and action any quality issues

The Quality Project Manager performs a wide range of duties, including some or all the following:

- / Identifying and interviewing new consultants
 - Conducting project management duties such as:
 - Conducting kick-off meetings and project status calls
 - Completing meeting minutes and maintaining the Collaboration Plan
- / Fulfilling both Client and Consultant needs
- / Tracking deliverables/reports and updating project Stakeholders
- / Evaluating the project against success criteria
- / Conducting peer reviews of deliverables/reports
- / Supporting the needs of the FDAQRC Quality Management System (QMS)
- / Conducting services in technical areas of expertise

Qualifications

Experience

1. A bachelor's degree in a scientific discipline.
2. At least five (5) years of technical Quality Assurance (QA) experience, GxP regulated industry experience, Pharmaceutical or Device Project Management experience, or a combination of the above.
3. Proven employee/resource management skills are required over a minimum of two (2) years

4. An in depth understanding of multiple GxP requirements, including Good Clinical Practice, Good Laboratory Practice, Good Manufacturing Practice, and/or Pharmacovigilance, and knowledge of national and international regulations
5. Additional experience in project management is desirable
6. Quality or project management certifications and multi-language skills are desirable

Skills

1. Proficiency in the use of computers for the professional working environment such as: Microsoft Office (e-mail, word processing (including track changes), spreadsheets and graphs).
2. Requires the ability to work well with all levels of internal management and staff, as well as outside clients and vendors.
3. Sensitivity to confidential matters is required.

Knowledge, skills, and abilities in line with duties and responsibilities described above.

Characteristics

The Quality Project Manager should demonstrate competence in all the following:

Behave Ethically: Understand ethical behavior and business practices and ensure that own behavior and the behavior of others is consistent with these standards and aligns with the values of the organization.

Communicate Effectively: Speak, listen and write in a clear, thorough and timely manner using appropriate and effective communication tools and techniques.

Creativity/Innovation: Develop new and unique ways to improve operations of the organization and to create new opportunities.

Foster Teamwork: Work cooperatively and effectively with others to set goals, resolve problem, and make decisions that enhance organizational effectiveness.

Lead: Positively influence others to achieve results that are in the best interest of the organization.

Make Decisions: Assess situations to determine the importance, urgency and risks, and make clear decisions which are timely and in the best interests of the organization.



Organize: Set priorities, develop a work schedule, monitor progress towards goals, and track details/data/information/activities.

Plan: Determine strategies to move the organization forward, set goals, create and implement actions plans, and evaluate the process and results.

Solve Problems: Assess problem situations to identify causes, gather and process relevant information, generate workable solutions, and make recommendations and/or resolve the problem.