

PAREXEL International

Location: Deerfield Illinois

Title: Project Quality Lead II

Job Description

Serves as quality consultant to Project Managers and Project Leadership teams throughout the project life cycle. Responsible for standard and risk-based quality checks on study/project implementations of technology used in study development and validation in supporting the clinical trials. Ensure proper software validation procedures are followed during project.

Key Accountabilities:

Standard Quality Checks:

- Implement the standard quality checks for assigned projects, verifying compliance with GxP guidelines/regulations, PAREXEL procedures and requirements, and sponsor requirements.
- Review key project documentation and provide feedback to the project team.
- Actively participate in key internal project team meetings and facilitate quality discussions during these meetings, as appropriate.
- Lead quality-focused meetings and/or discussions, as appropriate.
- Provide quality consultation support to project teams.
- Provide CAPA support to project teams including classification of issues, facilitation of root cause assessment, consultation on appropriateness of corrective and preventive actions and tracking of CAPAs through resolution.
- Provide audit and inspection support for assigned projects, including, where feasible, advising the project team during preparation and conduct of audits and inspections.
- Oversee the collection and reporting of project quality metrics.

Risk-Based Quality Checks:

- Identify and evaluate potential risks, in collaboration with project team management and other relevant groups.

- Implement additional quality checks in areas of risk.

Desired Skills & Experience

- Strong understanding of the clinical trial process and the use of technology for various trial-related functions, including subject randomization, enrollment, study data collection, drug accountability, and reporting

- Experience in software/technology and services used in the clinical trial management, including EDC, IVR/IWR, CTMS, reporting tools

- Experience in project/study implementation and validation and system integration

- Excellent verbal and written communication skills

- Excellent time management skills

- Client focused approach to work

- Ability to work independently, take initiative, and have a flexible approach with respect to work assignments and new learning

- Ability to work effectively in a matrix environment and to demonstrate and foster teamwork within the group as well as across the organization

- IT literate: experienced with Microsoft based applications and general knowledge of personal computer functions

- Ability to travel as needed

Education:

- University degree (preferably in a relevant area such as biological science, pharmacy, other health related discipline or technology), equivalent qualification or relevant experience

Minimum Work Experience:

- 3 to 5 years experience in project/study implementation and computer system validation of clinical research systems

- 3 to 5 years experience in clinical trial systems (EDC, IVR/IWR, CTMS and reporting tool, etc.)

- Experience with conducting risk assessments related to clinical trial systems
- Experience with CAPA processes
- Experience with client audits, including hosting, coordination of teams, and responding to audit reports
- Knowledge of SOPs, ICH-GCP and other applicable local and international regulations and guidelines

Please send resumes to: Daniel.roselanod@parexel.com