

Title: Quality Control Manager, Ireland

Reporting to: V.P Quality & Regulatory Affairs

Role and Responsibilities

- · Management of the QC Laboratory including open vial studies and value assignment.
- Manage the QC team to ensure best in class Lab practice is observed and a robust cross training plan is in place to drive the team's performance
- Drive a continuous improvement culture by identifying and driving initiatives to increase the efficiency in the area
- Analysis of work flows and optimisation of both human and instrumentation resources currently in place in Technopath including the cost analysis of reagent usage
- Validation (PQ Performance Qualification) of new analysers prior to commissioning for routine use. Preparation of documentation including validation report, operating instructions for use and training schedule for all new analysers.
- Analysis of technical data for laboratory data generated (e.g. value assignment, assay investigations)
- Setting up and preparation of the Lot Confirmation testing laboratory including review of resources. Review processes as the project expands to optimise work flow and turnaround times.
- Manage inventory of Multichem products for QC release, value assignment, lot confirmation, shelf life stability testing.
- Supporting R&D department in carrying out its laboratory functions
- · Contribute as a subject matter expert when required to
 - Re-assignment of target and ranges to existing Multichem products when required
 - Assignment of target and ranges to new products
- Performing GAP analysis of current practices versus ISO/regulatory requirements in conjunction with QA Department
- Reviewing results produced during in-process testing for anomalies and/or issues
- Assisting in troubleshooting technical customer complaints
- Performs other related duties as assigned by management.

Qualifications

- · Minimum of degree qualification in Biomedical Science, Biochemistry or equivalent.
- Minimum 3+ years management experience working in a Quality Assurance regulated laboratory environment, experience in a clinical laboratory environment desirable.
- · In-depth working knowledge of chemistry and immunochemistry instrument platforms.

Please forward your CV to to our Human Resources department:

hr@technopathcd.com



THE QUALITY CONTROL COMPANY