TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **R&D Scientist**

Reporting to: **VP Science**

Role and Responsibilities

- New product development, control and calibrator product research and development and manufacture.
- Integration of the design and development process within product development, in accordance with ISO13485.
- Integration of the associated risk analysis activities in accordance with ISO14971, where applicable.
- Product improvement/Design Change Projects.
- Creation of verification test protocols and organisation of the evaluation and application studies relevant to new or existing IVD products, on specified clinical systems.
- Protein standardisation and assignment of serum protein values from a reference preparation to the target material.
- Performance of the evaluation studies relevant to new or existing Multichem products, on specified clinical systems. Documentation of test results.
- Analysis of technical data and generation of technical reports and change management documentation ensuring defendable practices and conclusions.
- Generation of outputs for completed projects such as SOPs, specifications (product and quality control), with regard to new designs or improvements to existing ones.
- Ensure that product development projects and changes to existing products are conducted in compliance with applicable Technopath Quality procedures.
- Proficiency and Linearity pool development, production and assignment of values.
- Provide training to R&D Scientists on verification/validation and statistical methods.
- Validation of excel templates for use in R&D or other technical data analysis functions when required.
- Laboratory maintenance.
- Stock control/maintenance in line with department budget plans.
- Adherence to Laboratory health and safety requirements. Adherence to quality standards.
- R&D Equipment calibration/maintenance.
- R&D procedural review and update as required.
- Supporting QA in the internal audit programme.
- Other duties that may become necessary as a result of system/process changes within or impacting R&D.

Please forward your CV to our Human Resources department: **hr@technopathcd.com**

Qualifications

- Minimum of diploma qualification in a relevant Science, Engineering or Quality Assurance discipline.
- 2+ years industry experience working in a Quality role in a regulated environment for medical devices.
- Basic knowledge of FDA 21CFR820, ISO13485, IVDD98/79/EC and international regulatory requirements.
- Excellent communication skills and attention to detail.