TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Manufacturing Quality Assurance Specialist**

Reporting to: **Manufacturing Quality Assurance Manager**

Role and Responsibilities

- Perform batch record review to release components, controls and finished devices.
- Review and approval of protocols, reports, and change management documentation ensuring defendable practices and conclusions.
- Provide technical assistance to carry out problem analysis/complaint investigation as required and define through negotiation effective corrective actions.
- Support technical complaint investigation from a QA perspective.
- Ensure correct use of statistical QA methods into the production/distribution environment.
- Utilise quality tools to track and trend quality performance and identify key opportunities for improvement ensuring all process developments are managed in accordance with the Quality Management System.
- Utilise DFMEA/PFMEA and other QA risk analysis techniques in order to minimise potential risk during development/implementation activity.
- Implement quality systems / systematic approach across Technopath Manufacturing businesses.
- Ensure compliance with all documented Quality system requirements, as per FDA QSR's and ISO 13485/9001 during day to day.
- Conduct internal quality system and supplier quality audits.
- Maintain a good level of housekeeping in designated areas, and observe all Health and Safety at work requirements.
- Other duties as required to support Technopath quality systems.

Qualifications

- B.Sc. in Science/Engineering/QA or related discipline.
- A minimum of 3 years practical experience required in a quality function.
- Strong initiative and troubleshooting skills required

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