TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Quality Assurance Administrator**

Reporting to: **Manufacturing Quality Assurance Manager**

Role and Responsibilities

Document Control

- Generating, reviewing, and approving, as appropriate, Document Control Change Notifications.

Quality Assurance

- Perform manufacturing batch record review in the areas of Components, Controls and Fill Finishing.

Incoming Inspection:

- Perform and document check of incoming raw materials as per material specifications.

Engineering Support

- Administration and documentation of calibration and preventative maintenance logs.
- Providing notification of scheduled calibrations, PMs and Services to relevant parties.

Training

- Maintain Training system.
- Maintain Organizational Charts.

General

- Support Technopath Internal Audit program.
- Ensure compliance with all documented Quality system requirements, as per FDA QSR's and ISO 13485 during day to day activities.
- Maintain a good level of housekeeping in designated areas, and observe all Health and Safety at work requirements.
- Performs other related duties as assigned by management.
- Demonstrate an understanding of the application of the Quality Policy through daily activities. Maintain vigilance to ensure adherence to the Quality Policy and system procedures by promptly reporting noncompliance issues to management.

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.

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

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