TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Regulatory Affairs Specialist**

Reporting to: **Regulatory Affairs Team Lead**

Role and Responsibilities

- Execute and complete tasks and deliverables for CE marking activities as required to IVD directive.
- Provide update and maintain status of product registration and notifications.
- Provide documentation and certifications upon request.
- Provide documentation and submit for product registration outside the European Union.
- Maintain a list and original (where necessary) of all current, relevant EU standards and Directives, 21 Code of Federal Regulation (CFR) and FDA Guidance Documents.
- Read and understood the above listed standards.
- Ensure that Technopath is aware of relevant standards and its application.
- Provide, as required, regulatory input and approval for changes and classification of changes to all documents impacting the QMS.
- Assisting in preparing and maintenance of Technical Files for product registration and submissions to EU and International Competent Authorities and / or Regulatory Agencies.
- Provide the required information to EU and International Competent Authorities for product registration and submission as required.
- Input in to Post Market Surveillance and Risk Management processes.
- Responsible for approval and release of customer facing labelling:
    1. Instructions for use
    2. XML files
    3. Rilibäk Guidelines
    4. Lot Confirmation Documentation
    5. Kit & Vial Labelling
- Ensure that provided labelling is meeting relevant standards and regulations.
- Provide support to Technopath Manufacturing QA, R&D Quality and Quality Systems areas from a quality perspective as required.
- Conduct internal quality system audits.
- Other duties as required to support Technopath quality systems.

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

Qualifications:

- Minimum of degree qualification in relevant Science, Engineering or Quality Assurance discipline.
- 3+ years' experience working in a Quality Assurance regulated medical product environment.
- Thorough knowledge of FDA 21CFR820, ISO 13485, IVDD98/79/EC and international regulatory requirements.
- Familiar with ISO 14971.
- Strong interpersonal skills and the ability to communicate well both verbally and in writing.
- Excellent attention to detail and ability to prioritise.