QRA: Technical Quality Specialist – Molecular Diagnostics (MLT)

Provide medical laboratory leadership, discipline-specific technical expertise and quality management coordination to LifeLabs Genetics and molecular diagnostic testing at LifeLabs. Ensure processes and procedures remain current and compliant with scientific advancements, technical developments, regulatory requirements and patient safety initiatives in molecular diagnostics and genetics testing areas.

Accountabilities:

- Provide technical, quality assurance and quality systems support for methodologies, equipment and supplies currently in use
- Ensure molecular diagnostics policies, processes, procedures, job aids and forms remain current with applicable regulations, legislation and best practice
- Assist Laboratory Management with the preparation and implementation of instructions, evaluation and validation protocols for new technologies, equipment, software, supplies and procedures
- Lead in-function projects and act as subject matter expert for cross-function projects
- Participate in the development of indicators, performance of audits, control of documents, review of QA/QI activities and the evaluation of non-conformances – including design of reports/action plans
- Administer EQA processes including selection of test challenges, documentation of test activities, correspondence with IQMH, CAP, EMQN as required
- Provide support to Operations, Medical/Scientific, Supply Chain Management, Business Development, Specialty Services, IT and Strategy departments as required

Requirements:

- Medical Laboratory Technologist with the Genetics Technologist graduate diploma, or related background
- Current registration with College of Medical Laboratory Technologists of Ontario (CMLTO) with endorsement in the disciplines of Cytogenetics and Molecular Genetics preferred
- Minimum of five years previous laboratory experience, including knowledge of the techniques, equipment and processes for molecular diagnostics, genomic, genetic and molecular pathology testing
- Strong Quality Systems knowledge and understanding, to provide expert support to all customers, internal and external
- Proven ability to facilitate the processes used to design, develop, validate, implement, monitor, control and continuously improve, a Quality Management System within a regulated environment
- A clear understanding of regulatory enforcement procedures and the business impact of failing to meet external regulatory requirements
- Facilitation skills necessary to lead discipline specific teams, and the confidence to conduct audits, issue non-conformance reports requiring corrective actions and follow-up on continued non-compliance

- The ability to use sound risk management analysis to assess the regulatory and business impact of prioritizing goals
- Excellent verbal communication skills to effectively communicate decisions and seek input
- Excellent technical writing skills to create and maintain documentation
- Strong organizational, change and project management skills to ensure that deliverables are achieved on schedule in a controlled manner.