



Quality Support Analyst, QUADRANT BIOSCIENCES

Department: Operations

Reports to: Vice President of Quality

COMPANY

This is a fantastic opportunity to join a rapidly growing company focused on developing novel molecular diagnostics and virtual care solutions to accelerate patient diagnoses and access to life-changing therapeutic treatments. Quadrant Biosciences works with top academic institutions, medical researchers and engineers to translate breakthrough findings into thoughtfully developed, scientifically sound applications. Starting with a simple saliva swab, we leverage next generation sequencing and the power of AI to develop accurate molecular diagnostics for a range of medical conditions including, autism spectrum disorder, concussion and Parkinson's disease. Quadrant Biosciences was recently highlighted on CNN, NPR, Bloomberg, and Huffington Post for its groundbreaking work.

JOB SCOPE

The Quality Support Analyst will be primarily responsible for performing thorough, detailed and timely investigations.

Responsibilities include but not limited to:

- Develop collaborative relationships with the operational leadership, staff in each of the Business Units, and the appropriate Quality representatives.
- Ensure Quality Management Systems for the Quality department are followed and maintained.
- Supports all departments with facilitation of investigations related to complaints, deviations, audit responses, as well as process improvement by performing risk assessments and RCA to determine appropriate corrective action/preventive actions.
- Participate in internal and external audits, as well as regulatory inspections
- Author, review, edit, and revise controlled documents in accordance with GXP standards to ensure compliance with current procedures
- Perform gap analyses to ensure processes and procedures are executed in an efficient, safe, GXP compliant manner
- Act as the lead for assigned technical writing projects.
- Completing the testing, analyzing, reviewing, and reporting of results of commercial products following established laboratory protocols.

KNOWLEDGE, SKILLS AND ABILITIES

- Ability to identify trend and aberrant sample results
- Ability to coordinate tasks across multiple projects, demonstrating prioritization and planning
- Strong communication skills and able to thrive in a fast-paced environment
- Perform various lab techniques to assist with output of samples including pipetting with either a single or multi-channel pipettes, ultracentrifugation, extractions and PCR analysis
- Strong documentation skills in a detailed, accurate and neat manner
- Ability to perform varied and non-routine procedures or tasks
- Must be able to wear provided personal protective equipment (PPE) at all times to keep oneself safe

WORK ENVIRONMENTS AND HAZARDS

Exposure to communicable diseases, toxic substances and other conditions common to a laboratory environment.

PHYSICAL DEMANDS

Requires walking and sitting, bending, stooping and stretching, eye-hand coordination and manual dexterity, ability to distinguish letters, numbers and symbols, use of computerized instruments, computer terminals, and other equipment common to a clinical laboratory. May require prolonged standing or lifting up to 30 pounds or more.

QUALIFICATIONS

- BS or MS in engineering or science field or equivalent experience
- Experience in technical writing
- Strong working knowledge of Google Suite (i.e. Docs, Sheets, etc).
- Experience with basic molecular biology techniques (i.e., PCR and qPCR) as well as nucleic acid extraction and analysis techniques (i.e., bioanalyzer, Qubit, King Fisher fragment analyzer, etc.) is preferred
- Demonstrated ability to work independently while adhering to investigation and CAPA timelines and goals
- Strong general laboratory and organizational skills, effective communication skills, both verbal and written
- Strong interpersonal, written/oral communication and problem solving skills
- Great team player who is collaborative and positive
- Ability to effectively manage multiple tasks utilizing organization and prioritization skills, self-motivated

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This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation and training.