Quality Associate, Quadrant Biosciences

Department: Operations **Reports to: Vice President - Quality**

COMPANY

This is a fantastic opportunity to join a rapidly growing biotech company. Quadrant Biosciences works with top academic institutions, medical researchers and engineers to translate breakthrough findings into thoughtfully developed, scientifically sound applications. Our technology includes functional assessments and epigenetic biomarkers for neurological conditions such as concussion, autism spectrum disorder, and Parkinson's disease. Quadrant Biosciences was recently highlighted on CNN, NPR, Bloomberg, and Huffington Post for its groundbreaking work.

JOB SCOPE

The Quality Associate will perform a variety of activities related to the improvement and control of our QMS. The role will work cross-functionally with Operations, Clinical Laboratories, Engineering, R&D and Project Management on Quality Assurance (QA) activities.

Responsibilities include but are not limited to:

- Ensuring compliance with regulatory requirements, FDA and ISO controlled manufacturing practices, and quality standards.
- Participates and/or generates investigations, root cause analysis, Corrective and Preventive Action (CAPA) plans related to process/product deviations, material testing, and Out-of-Specification events.
- Performs batch record review for accuracy, completeness and to identify any potential issues.
- Coordinate with other departments as required to resolve issues and compliance concerns detected during GMP documentation review.
- Review of process, product and/or environmental related data and results associated with batch manufacturing and laboratory testing and make determinations as to whether batches are acceptable for release.
- Perform lot release activities including the generation and review of COA/COC for finished products.
- Performs quality assurance checks on in-process products and finished goods and document results.
- Identify documentation issues and ensure notification is made to the appropriate personnel.
- Generates and reviews Change Control documents and impact assessments to ensure compliance.
- Writes and/or contributes to the creation or revision of Standard Operating Procedures, as applicable.
- Escalates any quality issues immediately to Quality Assurance management.
- Maintains knowledge of current regulatory requirements pertaining to pharmaceutical manufacture.
- Maintain effective communication and partnership with all departments across the organization.
- Provides support for regulatory inspections and client audits, if required.
- Responsible for any other duties and/or tasks that may be assigned.

KNOWLEDGE, SKILLS AND ABILITIES

- Outstanding proficiency in MS Office, particularly Excel and PowerPoint or Google Workspace, particularly Google Sheets and Google Slides.
- Strategic mindset that is highly analytical and detail-oriented and brings a creative mentality to problem-solving.
- Ability to distill massive amounts of complex information into digestible formats that lead to productive insights and discussions.
- Ability to motivate teams and develop buy-in for new initiatives and adherence to overarching corporate goals and our culture of innovation and excellence.

WORK ENVIRONMENTS AND HAZARDS

This position requires sitting for extended amounts of time with a majority of the tasks requiring typing at a computer station.

PHYSICAL DEMANDS

Willing to come into the office, work on the computer for workday. Occasionally may be asked to assist with lifting items up to 30lbs in the office setting.

QUALIFICATIONS

- Bachelor's Degree in a relevant field.
- 1+ years of relevant experience, including Quality and Logistics experience in the Pharmaceutical/Clinical Trial industry.
- Ability to work in a dynamic and fast-paced environment.
- Strong communication and presentation skills with ability to articulate clearly to executives and key business leaders both internally and externally.
- Excellent interpersonal and conflict mediation skills.
- Strong analytical and detail orientation skills.

Quadrant Biosciences Inc. provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

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.

MGMT-3022 (DOC-423) Ver. 0

Approved By:

(CO-71) Implementation of MGMT-3021 and MGMT-3022

Description

Implementation of MGMT-3021 Vice President - Quality Job Description and MGMT-3022 Quality Associate Job Description.

Justification

Job descriptions needed per FDA and Department of Labor requirements.

Assigned To:	Initiated By:	Priority:	Impact:
Allison Iles	Allison Iles	Low	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Allison Iles	September 8, 2021 1:04 PM EDT	CO-71	0	Published