Job Title:	Quality Assurance Associate	**Date Posted:**	April 20th, 2021
Salary:	Will be determined based on experience	**Position Type:**	Full-time, permanent, salary
Date Posted:	April 22nd, 2021	**Application Deadline:**	May 6th, 2021

Job Description

Overview

AGADA is a contract research organization (CRO) providing specialized services to pharmaceutical and biotech companies. Unlike most CROs, AGADA provides services in niche areas of research that require further standardization. Our mission is to facilitate and accelerate drug development for rare diseases, serving an international clientele. Key to accomplishing this mission is training and retaining a highly skilled workforce in Nova Scotia. We offer both preclinical drug efficacy studies in mouse models and clinical (human) trial drug development and support services. AGADA has performed over 170 drug efficacy studies in mouse models of muscular dystrophy, has supported 8 Phase I clinical studies and is working on 12 Phase II and III clinical efficacy studies (Duchenne, Becker, ALS).

Now that our research team has reached about 30 people and our business has grown substantially, we need to expand our 2-person QA team. This QA position does not require substantial experience in QA, but we are looking for someone who has a keen interest in working alongside the research team to help build and maintain our quality system. AGADA is a non-GLP lab, but our procedures are GLP-like. We are GCP compliant, and, given our work with clinical trials, AGADA is often audited by client companies and is subject to audits from regulatory agencies (FDA, Health Canada, EMA).

Roles and Responsibilities

- Updating and implementation of SOPs, manuals, and forms
- Working to validate excel forms
- Implementing quality control procedures
- Managing the internal audit process
- Managing CAPAs
- Performing supplier assessments
- Managing the temperature monitoring system
- Working on equipment management procedures
- Performing equipment qualifications
- Ensuring SOPs are maintained, updated, and available to all staff
- Researching and interpreting regulatory requirements
- Preparing for regulatory, client, or visitor inspections
- Helping to organize and prepare trial documentation
- Managing archived records
- Managing trial master files
- Collaborating with the Safety Officer for risk management and BSL2 protocols
- Providing QA and training updates to company management
- Participating in new employee orientation and onboarding
- Participating in organization of employee training
- Monitoring and reviewing employee training progress
- Updating training documents

Education and Required Abilities

- Bachelor of Science degree
- Strong administrative skills
- Keen eye for detail
- Excellent client service and communication skills; both verbal and written
- Ability to coordinate with a team

• Ability to effectively present information • Strong time management and prioritization skills • Ability to be proactive and capable of multi-tasking • Ability to act responsibly and ethically when working with sensitive information **Preferred Experience** • Experience working in a laboratory setting • Knowledge of quality assurance principles	
Application Process:	Email resume and cover letter to **LBaker@agadabio.com** Subject Line: Quality Assurance Associate Application