



CLINICAL LAB DIRECTOR, QUADRANT BIOSCIENCES

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 Clinical Lab Director may serve on a full-time or regular part-time basis, and shall not serve as director of more than two clinical laboratories, within or outside New York State. The Lab Director will direct and oversee high complexity clinical tests within a CLIA Laboratory, including responsibility for the following:

- Performance of all tests carried out in the laboratory, adherence to the department's quality assurance standards for such tests, and accurate reporting of test results.
- Spending at least 8 hours weekly on site including meetings to effectively oversee all operation and administration of the laboratory.
- Ensure the employment of qualified laboratory personnel, evaluation of job performance of such personnel and their in service training.
- Ensure qualified personnel are employed by defining the qualifications and responsibilities of all laboratory technical staff and documenting training and/or competency.
- Provide continuing education to laboratory technical staff that is relevant to laboratory medicine.
- Ensure that policies and procedures are established for monitoring staff to assess competency, and whenever necessary, provide remedial training or continuing education to improve skills.
- Provide oversight of all aspects of the laboratory quality management system to ensure conformance to requirements described in the Quality Management System.
- Provide effective and efficient administrative direction of the lab, including budget planning and controls in conjunction with the individual(s) responsible for financial management of the lab.
- Monitor all work performed in the laboratory to ensure that medically reliable data are generated.
- Provide advice to referring physicians regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for specific patient interpretation.

- Ensure that testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the pre-analytic, analytic, and post-analytic phases of testing and are appropriate for the patient population.
- Ensure that physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed.
- Ensure that the environment for employees is safe from physical, chemical, and biological hazards and that the safety and biohazard requirements are followed.
- Ensure that a general supervisor is available to provide day-to-day supervision of all testing personnel and reporting of test results.
- Ensure that the laboratory is enrolled in an approved proficiency testing program for the testing performed and that the proficiency testing samples are tested as required by CLIA.
- Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.
- Maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials and the medical community.
- Effectively implement a plan of correction to deficiencies identified.

QUALIFICATIONS

The Clinical Laboratory Director must meet the qualifications found in the Standards for Laboratory Accreditation, further qualifications include:

- 1) The director must possess training and/or experience, obtained within the previous six years, in generally accepted and currently used methods and techniques in one or more categories listed in section 19.3(d) of Public Health Law, Section 573 (1), and must meet one of the following requirements:
 - a) be a physician who is currently certified by the American Board of Pathology in: (1) clinical pathology; or (2) anatomic pathology; or (3) an area of special competence relevant to the certificate of qualification sought; or
 - b) be a physician or hold an earned doctoral degree from an accredited institution with a relevant chemical, physical or biological science major, and:
 - i) is currently certified by: (i) the American Board of Medical Microbiology; or (ii) the American Board of Clinical Chemistry in clinical chemistry; or (iii) the American Board of Clinical Chemistry in toxicological chemistry; or (iv) the American Board of Forensic Toxicology; or (v) the American Board of Medical Laboratory Immunology; or (vi) the American Board of Internal Medicine in hematology; or
 - ii) subsequent to receiving a doctor of medicine, doctor of osteopathy or earned doctoral degree has had, and has documented to the department, four years of training and/or experience in an acceptable laboratory, including two or more years of training and/or experience in methods and techniques currently in use in the certificate category or categories sought and in general laboratory management, or an equivalent combination of training and/or experience as verified by the commissioner.
- 2) Must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; hold a Certificate of Qualification in Virology; and be certified and continue to be certified by a board approved by HHS.

MGMT-3005 (DOC-161) Ver. 0

Approved By:

[\(CO-9\) CO-9 Implementation of MGMT procedures into GG](#)

Description

Implementation of MGMT procedures into GG

Justification

Transition from paper-based to eQMS

Assigned To:

Stacy Masterson

Initiated By:

Stacy Masterson

Priority:

Medium

Impact:

Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Stacy Masterson	June 9, 2021 6:20 PM GMT	CO-9	0	Published