
Position Title: Quality Analyst

Job classification: Non-exempt, Full-time Regular

Brief Summary of CGMP Compliance related to Job Description:

As part of the Quality Department supporting Bionique Testing Laboratories, the Quality Analyst will support systems to assure CGMP compliance for all relevant operations carried out, within and for Bionique Testing Laboratories including compliance with relevant parts of the CFR, CGMPs, company policies and procedures and other established standards. The Quality Analyst will report directly to the Quality Assurance Associate.

Description of duties and responsibilities:

Primary Duties:

- Review/audit of daily reports as assigned including, but not limited to: Testing records, Certificates of Analyses, protocols, and non-conforming event reports.
- Support and participate as needed in Quality activities to ensure that Bionique Testing Laboratories' objectives are achieved in compliance with internal and regulatory requirements (CGMP, safety, corporate/departmental SOPs).
- Maintain QA archives as assigned.
- Performs document control functions such as change control procedure for documents and equipment.
- Review Quality Control (QC) data including instrument and equipment records; logbooks; and analytical QC data.
- Review tracking and trending analytical data.
- Assist in document maintenance including paginated DCFs issued to the Diagnostic Laboratory.
- Participate in continuous improvement initiatives.
- Perform other duties as may be required or necessary from time to time.

Qualifications:

- Qualified candidate will possess an A.S. Degree in Quality Assurance or a B.S. Degree with a Life Science concentration.
- A related field or an equivalent combination of education, training and experience may be substituted.
- 1 to 3 years of relevant and recent laboratory experience or experience in a regulated environment is preferred.
- Team oriented individual with excellent communication skills as well as the ability to pay critical attention to detail are required.
- Ability to lift up to 50 pounds and stand for prolonged periods.
- Candidate should be able to critically think and use analytical reasoning.
- Enthusiasm for learning and contributing to improved patient outcomes.