

Position Title: Quality Assurance Manager

Position Description and Responsibilities: As part of the Quality team supporting Bionique Testing Laboratories (BTL), the Quality Assurance Manager identifies and assesses the quality systems to ensure compliance with regulatory requirements and BTL's quality practices. The Quality Assurance Manager reports directly to the Director of Quality Operations.

Duties will include:

- Lead and participate in all quality assurance activities to ensure that the company's operations comply with internal and regulatory requirements (cGMP, safety, corporate/departmental SOPs).
- Provide Quality oversight and guidance relative to adherence to SOPs and requirements; proper change control, corrective action and preventive action plans (CAPA)/Deviation management; impact assessments for changes to equipment and processes; risk management; and ensuring documentation and investigations meet all requirements.
- Determine the logic, adequacy and effectiveness of Quality processes, systems and related requirements.
- Evaluate and perform trend analysis and report results for key quality metrics.
- Lead/support role in client and regulatory audits.
- Lead/support internal audits of the facility.
- Lead/support the development, implementation and execution of the Audit Supplier program to ensure that suppliers meet all applicable internal and regulatory requirements.
- Initiate and review reports and documents that may be submitted to regulatory bodies.
- Work with cross-functional teams to effectively create and support process and quality enhancement initiatives to create and maintain an environment of continuous improvement by proactively challenging practices/procedures and applying industry best practices.
- Write, revise, and approve SOPs as necessary.
- Provide guidance and training to employees on relevant Quality and compliance area(s).
- Develop department goals and contribute to their achievement.
- Supervises and mentors/coached the Quality Assistant(s).
- Assist Quality Assistant with projects as assigned and necessary.
- Act as back up to the Director of Quality Operations as needed.
- Foster the demonstration of Bionique Testing Laboratories' Core Values and leadership behaviors in others.
- Perform other duties as may be required or necessary.

Qualifications:

- Minimum B.S. degree (preferably in Microbiology) with seven (7) years of biopharmaceutical experience in QA/QC operations
- Strong knowledge of GMPs and their application. Knowledge of both international and U.S. regulatory requirements is preferred.

- Prior experience with internal/external audits and regulatory inspections required.
- Knowledge of biopharmaceutical analytical methods and assays, with proven experience in the development and implementation of analytical laboratory systems, SOP's, methods and LIMS.
- Proven ability to strategically design and facilitate Quality programs that improve performance, compliance, and the overall business.
- Highly detailed-oriented, self-motivated and results oriented individual.
- Excellent interpersonal and communication skills required.
- Proven ability to manage projects/teams while meeting all deliverables and timelines.
- Demonstrates strong aptitude for facilitating group or team project endeavors, and building team unity.
- Required proficiency in using Microsoft Office applications. (Word, Excel, PowerPoint)