Associate Director of Operations

Bionique Testing Laboratories, a global leader in **Mycoplasma Testing Services,** seeks an **Associate Director of Operations** within the laboratory contract testing service team at our facility in Upstate New York. The incumbent will be responsible for managing and developing for operational effectiveness within the laboratory supported by a team of subject matters experts.

The position is responsible for strategic design, development, and tactical deployment of workflow improvements. Additionally, institutes technology upgrades ensuring that business objectives are met by enabling continued growth of the business maintaining a high standard for Quality, Safety and Regulatory compliance. The position will also be expected to promote behaviors of continuous improvement and ensure that the Operations team maintains an inclusive and positive culture within the team.

Key Accountabilities

Operational Responsibilities:

- Operational and capacity coordination of all areas of Bionique's laboratory testing and manufacturing processes.
- Liase with the R&D Team to facilitate technology transfer into the laboratories.
- Cross-functionally and autonomously lead Operational Excellence initiatives guiding the operational workflow and deployment of resources.
- Embed a culture of continuous improvement into the Operations team focused on standardizing processes, reducing process variability, and problem solving.
- Successfully lead project teams to develop high-throughput workflow solutions and integration of assay applications inclusive of automation of sample management and LIMS.
- Recommend Capital Projects.
- Contribute to investigation, CAPA development and design CAPA effectiveness for any Operations-related compliance discrepancies noted during day to day activities, internal or external inspections and/or audits.
- Implement, manage, evaluate and enhance operational processes and procedures in accordance with the organization's policies, procedures, and state, federal and local laws.
- Ensure compliance with current Good Manufacturing Procedures (cGMP), FDA, USP and other applicable global regulatory requirements at all times, and have a deep understanding of USP and FDA microbiology testing requirements.
- Provide coaching, development, and performance enhancement to the team.
- Build and sustain employee engagement by creating a culture of execution and an environment within which individuals and teams can excel and continuously improve.
- Perform other duties as assigned.

Qualifications and Experience

- Minimum B.S. degree in Biology or Life Sciences required. 7+ years of experience to encompass managing, developing and growing a team within a CRO Contract testing environment along with strong technical background and hands-on experience in a similar role.
- Applied knowledge in the areas of biopharmaceutical manufacturing, drug development, and analytical testing is required.
- Prior experience in pharmaceutical operations with experience in technical and process development, IT deployment and validation of for laboratory settings.
- Thorough understanding and experience of applicable US and EU GMP regulations as demonstrated from 5+ years working experience in these environments. Possess excellent presentation, written, and oral communication skills to provide high level interactions with clients and industry representatives.
- Communicate effectively with peers, Senior Management and cross-functional peers and Corporate Management.
- Being able to motivate and drive a team.
- Possess high-level analytical problem-solving skills.
- Desire to be part of a fast-paced, rapidly growing company.

The position offers competitive salary and excellent benefit package.