COMPUTER SYSTEM QUALITY SPECIALIST POSITION DESCRIPTION

- ☑ **Exempt**
- ☐ **Non-exempt**

About Us:

Bionique Testing Laboratories LLC (Bionique) has been a leading global provider of mycoplasma testing services for the biopharmaceutical industry for over 30 years. Bionique offers the full breadth of services from lot and Final Drug Product release testing per regulatory guidelines to a GMP compliant Real-Time PCR assay to support clients' needs from concept to clinical trials and commercialization for biopharmaceutical and cell therapy products. Bionique's experience and expertise extends to development and validation of rapid microbiological methods to support abbreviated release timelines. Additional services such as regulatory and compliance consultancy add to Bionique's unique position in this niche analytical testing space. Located in Saranac Lake, NY, Bionique is an FDA registered and GMP compliant contract testing facility. Bionique aims to offer unsurpassed quality mycoplasma testing services to meet the specific scientific and regulatory needs of each client and partner.

Summary:

This position supports computerized systems and ensures the design, installation, implementation, and data integrity of Bionique customized internal software applications and databases. All systems must meet industry standards and regulatory requirements. This position is responsible for generating, executing and reviewing qualification and validation of computerized systems and digital solutions/applications including, but not limited to, the laboratory information management system (LIMS), the electronic quality management systems and any other automated control system. This position is also responsible for maintaining such systems in a validated state of control at all times and act as administrator, managing changes and updates. They are responsible for writing validation protocols and performing periodic reviews for Bionique computerized control systems including the generation of URS, DQ, IQ, OQ, PW and Trace Matrix documentation. They will analyze the results of testing and determine their acceptability against predetermined criteria. This position will investigate and troubleshoot problems and determine solutions or recommendations for changes and improvements.

Key Accountabilities and Responsibilities:

- Perform administrative functions for computer systems within the Routine Testing and R&D departments. This includes automated controlled systems as well as database integration and database management for laboratory information management systems and electronic quality management systems
- Review & approve specifications, procedures, and other required supporting documents to maintain the qualified/validated state of computerized and electronic systems
- Review the design and implementation of computer/control systems to assure that security and data integrity are maintained.
- Support IT infrastructure qualification activities.
- Analyze data and information to determine whether computer / control systems are within an appropriate state of control during qualification and validation as well as assessing the need for requalification / revalidation on a periodic basis.
- Prepare, document, and/or evaluate change controls for computer/control systems to ensure that they remain in qualified, validated state

- Identify and investigate unusual or unexpected events, data, or sources of variation during the implementation and validation; assess and recommend appropriate corrective/preventive actions
- Ensure that work is performed in accordance with applicable regulations, industry guidelines and practices, approved procedures and CGMP
- Generates and executes summary reports and associated data in accordance to regulations, SOPs, specifications and other applicable acceptance criteria
- Initiate, review, and approve deviation notifications, deviation investigations, corrective actions, change controls, SOPs, reports and other documentation related to assigned tasks
- Identify process improvements before equipment, facilities, systems or processes are placed under change control during qualification/validation
- Prepares, maintains, analyzes, and presents metrics related to Quality systems
- Communicates and coordinates with other departments or outside contractors/vendors to complete qualification/validation tasks
- Ensures compliance to governing regulations, SOPs, qualification/validation plans, and protocols
- Effectively communicates and proactively seeks resolution to compliance matters in accordance with internal and regulatory requirements
- Performs and/or supports periodic review activities for computer systems
- Manages changes and updates to the computerized systems
- Builds collaborative team environment within the department and amongst other company departments
- Supports the achievement of departmental goals
- Completes and reports on special assignments within the agreed upon timeframe
- Additional duties as assigned

Additional Accountabilities and Responsibilities

- Works independently and proactively
- Must have attention to detail. Work requires a high degree of accuracy in complex documentation
- Ability to adhere to a standard timeline and escalate actions appropriately for resolution in a timely manner
- Proactively communicates progress and furthers understanding amongst colleagues and supervisors
- Meets timelines in a reliable and efficient manner
- Ability to independently assess impact and retesting requirements in the event of a deviation
- Problem solving and conflict resolution skills in a cross functional setting
- Ability to drive and meet project timelines individually and by coordinating the work of others
- Subject matter expert in respective field
- Possesses working knowledge of regulatory environment and industry standards

Requirements:

- Bachelor's degree from an accredited college/university in science, IT or engineering; or a two-year degree plus two years of experience in the pharmaceutical or related industry
- 2 years' experience in pharmaceutical or related industry with demonstrated knowledge of computer systems design, database management, qualification, data integrity and validation
- Experience in a CGMP environment and awareness of qualification of control systems and computer system validation preferred
- Ability to handle multiple tasks and projects under deadline pressure
- Thorough understanding of the equipment validation lifecycle, including change control
- Strong organizational and time management skills
- Highly analytical with strong attention to detail
- Excellent verbal and written communication skills, including technical writing and documentation skills
- Able to adapt quickly to change
- A results-oriented team player
- Knowledge of computer system and control system design and validation concepts including GAMP 5
- Working knowledge of CGMP, 21 CFR Part 11 and other applicable guidelines and regulations

Physical Requirements:

- Prolonged periods of sitting on a chair, working at a desk and working on a computer and/or telephone
- Must be able to lift up to 25 pounds

Bionique is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, gender, sexual orientation, gender identity, gender expression, national origin, age, disability, genetic information, marital status, pregnancy status, amnesty, covered veteran, or any other protected status or characteristic protected by applicable federal, state, and local laws.