Crown Laboratories, Inc.

Job Title:	Computer Systems Validation Engineer
Reporting To:	Quality Assurance Validation Manager
Organizational Unit:	Johnson City Plant Operations
Direct Reports:	None
Budgetary Responsibilities:	N/A

Job Purpose Statement

The Computer Systems Validation Engineer will create and execute Computer System Validation (CSV) protocols for key projects that impact quality systems. They will support the maintenance of the site Master Validation Plan and facilitate critical CSV planning.

Main Accountabilities

- Assist URS creation and support of SRS and FRS testing and review. Ability to create and/or manage VP, CS, IQ, OQ, PQ and applicable support controls to assure on-time completion of CSV projects and meeting all compliance requirements. Provide assistance for developing procedural controls to assure continued system maintenance and compliance.
- Can assess critical, major and minor changes to key quality systems to determine appropriate qualification requirements to support the Change Control System. Can create Risk Assessment reports. Can conduct system audits and as applicable provide gap assessment planning.
- Knowledge of networking principles practices and technologies as well as cloud-based systems architecture are helpful to support IT team members for interfaced software undergoing validation.

Job Related Qualification/Skills

- Bachelor's Degree preferably in computer science, scientific or engineering disciplines. Candidates knowledgeable in advanced LIMS and ERP systems may possess suitable skill sets that can be adapted to support CSV.
- Excels in compiling multiple forms of communications, describing the completed computerized system, simplifying and organizing the given information to create test planning with justifications for how the system will be tested, writing test steps for positively and negativity testing the system utilizing applicable user roles, and then documenting in cGDP format for each tested scenario. Creating a RTM for this testing to assure system control and compliance. Summarizing the collected testing data and including any deviation for required corrective action, review and approval.
- Progressive experience in a related role within a cGMP environment with working knowledge of 210, 211, 820 and 21 CFR Part 11 is preferred. Should be familiar with ISPE, GAMP and all system life cycle deliverables.

- Ability to problem solve and to be able to fully participate in diverse cross functional teams to achieve the business objectives.
- Excellent written and verbal communications skills. A service-centered, team-building, can-do attitude is appreciated.
- Ability to handle multiple tasks simultaneously, having good planning and organizational skills.
- Strong proficiency in Microsoft Office suite of products and having experience with application software and equipment control systems hardware/software/firmware with the ability to navigate and document varied human-machine interfaces.

Working Conditions

This role is primarily an office and plant floor position, where minimal lifting or physical excursion is required. At times a flexible schedule may be required as demanded by project timelines including evening and night shift presence. Some travel will be required, but usually not more than 10%.

Physical Requirements

Minimal lifting is required and this role would not be considered physically demanding.