

Siegfried USA, LLC
Pennsville, NJ
Job Description – Page 1 of 2

Job Title: Computerized Systems Validation Specialist (LabWare LIMS Administrator)
Department: Compliance
Reports to: Quality Systems Manager
FLSA Status: Exempt
Grade: 4E
Approved by: Tracy Renschler
Approved on: February 14, 2019

SUMMARY:

The System Administrator position will provide overall maintenance of QC laboratory computerized systems including LabWare LIMS and Empower CDS. The position will create and maintain necessary procedures, assist in the configuration/customization of the system and provide training to staff members.

ESSENTIAL DUTIES, RESPONSIBILITIES AND ACCOUNTABILITIES:

- Empower/Labware/Laboratory Standalone Systems/Overall Site Manufacturing & Equipment Computer System Validation (e.g., Delta V)
- Support implementation and maintenance activities
- Configures and customizes systems
- Integrate instruments
- Conducts user-training sessions for users
- Performs entry and edit of all relevant static data
- Acts as liaison between internal laboratory users and vendor to address various system issues
Evaluates product enhancements and capabilities, in addition to implementing upgrades as required
- Act as Subject Matter Expert during customer and regulatory audits
- Adheres to personal moral, ethical, legal, and behavioral conduct that is in compliance with the Siegfried Code of Conduct
- Adheres to all applicable SHE and cGMP regulations

SUPERVISION:

N/A

EDUCATION AND EXPERIENCE:

- A BS in chemistry or related science and 2-5 years of work experience is required
- Knowledge of cGMP is desirable as applied to computerized systems, electronic records/signatures, etc.

OTHER REQUIREMENTS:

- CSV GAMP Model
- Two years+ experience supporting laboratory systems in a R&D or QC laboratory in a cGMP regulated industry
- Excellent verbal and written communication skills
- Demonstrated working understanding of laboratory operations and practices strong organizational and/or project management skills
- Strong analytical and problem solving skills

Siegfried USA will explore and provide reasonable accommodations to assist any qualified individual with a disability in performing the essential functions of his/her job. Please speak with HR should you require an accommodation or have any questions.

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By the Incumbent

By the Direct Supervisor

Name of Incumbent

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Date

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