

Lyophilization Services of New England, Inc.
25 Commerce Park - Bedford, NH Facility
JOB DESCRIPTION

JOB TITLE: <i>Senior Validation Engineer</i>	LEVEL: Individual Contributor
DEPARTMENT: Validation	REPORTS DIRECTLY TO: Validation Manager

I. JOB SUMMARY –

The position will be responsible for performing validation activities in a cGMP pharmaceutical contract formulation/aseptic filling/packaging facility.

II. JOB DUTIES –

Main Responsibilities:

- Develop protocols, final reports, project execution plans, and execute large scale projects while meeting current regulatory requirements and industry practices
- Conduct statistical analysis of validation test results
- Investigate/ troubleshoot validation problems
- Develop and execute Validation Project Plans and IQ/OQ/PQ PV Protocols
- Conduct component verifications
- Review of equipment operation and sterility testing based on process specific validations
- Conduct periodic validation reviews of equipment, facilities, utilities and sterilization
- Support aseptic filling process validations

III. PREPARATION, TRAINING & EXPERIENCE –

EDUCATION

- Engineering/science bachelor's degree with 3-5 years of experience in validation (desired)
- HS diploma with a minimum of 5 years of experience in validation (considered)
- Minimum of 5 years of experience in pharmaceutical manufacturing or quality required

PROFESSIONAL SKILLS & EXPERIENCE

- Innovative and capable of developing alternative solutions to issues at hand
- Working knowledge of GMPs, 21CFR, and other international regulatory requirements
- Validation using risk-based approach (i.e., FMEA, ASTM E-2500, etc.)
- Ability to read/interpret engineering drawings and design documents
- Skills in development of protocols, final reports, project execution plans and execution of large size projects
- Knowledge of Validation Lifecycle Approach (i.e., ASTM E2500)
- Able to conduct statistical analysis of validation test results
- Experience in the Investigation/troubleshooting of validation problems
- Experience with lyophilization and aseptic filling equipment (preferred but not required)
- Experience with Kaye Validator data acquisition systems

PERSONAL SKILLS & COMPETENCIES

- Excellent technical writing, verbal communication, and presentation skills
- Must be people oriented and a team player
- Proficiency in Microsoft Office including Word, Excel, PowerPoint, Project, and Visio
- General knowledge of PLC/software validation