

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

JOB TITLE: Development Associate	LEVEL:
DEPARTMENT NAME : Research and Development	REPORTS DIRECTLY TO:

I. JOB SUMMARY – Direct and participate in formulation and lyophilization studies to assess feasibility for both lyophilized and liquid products.

II. JOB DUTIES –

1. Responsible for reviewing of R&D Production Batch records prior to implementation for accuracy and ensuring critical steps are addressed with R&D personnel.
2. Responsible for reviewing executed R&D Batch Records for accuracy and completeness prior to submission to client.
3. Responsible for development of lyophilization cycles, process ranging studies, formulation studies, freeze-drying microscopy analysis, DSC analysis, and other studies associated with the R&D laboratory.
4. Collaborate with Operations to ensure technical transfer from R&D to cGMP.
5. Responsible for performing critical steps in the formulation/filling process including but not limited to, pH adjustment, API dissolution and final QS to ensure batch integrity and prevent errors that could lead to product and or financial loss.
6. Responsible for development of SOPs and Batch Records for R&D use.
7. Set up, change over, operate various manufacturing equipment and processes including, but not limited to: mixers, scales, pH meters, fillers, sterilizers, washers, and labelers
8. Perform routine maintenance and cleaning of complex machine parts and equipment
9. Assist in facility cleaning
10. Assist Operations and Quality departments as needed

III. PREPARATION, TRAINING & EXPERIENCE – .

Education, and Professional Skills / Experience

1. Requires a four-year degree in Chemistry or closely related science.
2. Must have a working knowledge of the effects of pH, order of chemical addition including rate of addition.
3. Requires strong laboratory skills
4. Requires a minimum of 2 years of pharmaceutical experience including previous Formulations experience.

Personal Skills and Competencies

1. Excellent organizational skills
2. Ability to prioritize multiple ongoing projects and activities to meet customer and company timelines
3. Strong oral and written communication skills
4. Experience with MS Office suite is preferable
5. Ability to work individually and collaboratively.
6. Strong work ethic and ability to learn new skills and techniques

Physical Ability to lift up to 50 Lbs may be required

IV. COMMUNICATIONS & CONTACTS – Works directly with R&D personnel. Works closely with Quality Assurance and Operations. May interact with Customers on a regular basis.

V. MANAGERIAL & SUPERVISORY RESPONSIBILITIES –

VI. REPORTING RELATIONSHIPS – .
Operations