

# Lyophilization Services of New England, Inc.

## 19 Harvey Road Bedford, NH Facility

### JOB DESCRIPTION

<b>JOB TITLE:</b> Quality Associate	<b>LEVEL:</b> II
<b>DEPARTMENT NAME :</b> Quality Assurance	<b>REPORTS DIRECTLY TO:</b> QA/QC Manager

#### **I. JOB SUMMARY –**

Provide support to the Quality Department to include, but not limited to: Records Review and Final Product Release, CAPA Investigations, Documentation and Line Clearance process.

#### **II. JOB DUTIES –**

1. Batch Record Review.
2. Final Product Release.
3. Quality Records Review.
4. Provide support to CAPA program and QA investigations.
5. Creating and Revising documents using MS Office.
6. Maintain Vendor/Subcontractor list.
7. Reviewing calibration certificates.
8. Issuing controlled documents and form.
9. Records retrieval requests.
10. Line Clearance assistance.
11. Data entry of quality records for trending purposes.
12. Other duties as assigned.

**III. PREPARATION, TRAINING & EXPERIENCE – .**

PERSONAL SKILLS & COMPETENCIES

- Excellent organizational skills.
- Detail oriented.
- Ability to multi-task.
- Word Processing.
- Knowledge of MS Office.
- Professional verbal and written communication skills.
- Bachelor of Science Degree and Three to Five years Quality experience in a cGMP environment.

**IV. COMMUNICATIONS & CONTACTS –**

Interacts with all departmental staff.

**V. MANAGERIAL & SUPERVISORY RESPONSIBILITIES –**

Not applicable

**VI. REPORTING RELATIONSHIPS –**

QA/QC Manager

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

*Manager's Signature:*

*Date:*

*Vice President of Quality Signature:*

*Date:*