

# Lyophilization Services of New England, Inc.

## 25 Commerce Drive, NH Facility

### JOB DESCRIPTION

<b>JOB TITLE:</b> QA Manager	<b>LEVEL:</b> <i>Middle Management</i>
<b>DEPARTMENT NAME :</b> Quality Assurance	<b>REPORTS DIRECTLY TO:</b> Senior VP of Corporate QA/QC

#### **I. JOB SUMMARY –**

Responsible for oversight of all daily functions of the quality system. Directly supervises Documentation Control, QA Associates and QA Trainer. Serves as backup and support to department activities.

#### **II. JOB DUTIES –**

1. Work directly with the Sr VP of Quality on continuous improvement activities.
2. Responsible for ensuring that client specifications are met during materials receipt, drug / device processing and final product shipment.
3. Responsible for ensuring that procedures are followed and quality standards are met.
4. Works directly with the Sr VP of Quality to evaluate products and materials for compliance to specifications.
5. Oversee established quality systems (Document Control, CAPA, Deviation, Environmental Monitoring, Change Control, Complaint, Calibration, Documentation, Training, Component Control, Batch Record Review, Label Control, Product Release).
6. Review/approval of Validation Protocols (master and final reports).
7. Approval of Deviations and CAPAs.
8. Responsible for Environmental Monitoring and Water-Trend Reports.
9. Provide QA Staff support (and backup) including:
  - Scheduling updates and assignment of duties.
  - Documentation Control prioritization: document processing, batch record issuance, change control issuance.
  - Training: issuing notifications for training needs, maintenance of training files, initiating core training for new employees, present training to personnel as needed.
  - Operations: provide line clearances and documentation as needed.
  - Product and Materials Records Review: batch record review and release, materials review and approval, including - calibration, water testing, environmental monitoring, temperature and humidity review.

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

EDUCATION AND PROFESSIONAL EXPERIENCE

- Four-year degree in a related science discipline
- 7 to 10 years experience in an FDA regulated Pharma or Biotech industry

PERSONAL SKILLS & COMPETENCIES

- Excellent organizational skills required
- Strong oral and written communication skills required
- Detail oriented
- Ability to multi-task, flexibility is required
- Computer skills (Excel, Word, Access, and PowerPoint)

**IV. COMMUNICATIONS & CONTACTS –**

Works closely with the QA management team, QA, Operations, Validation, Shipping and Receiving, Project Management, and Facilities staff. In addition, provides direct support to clients as required.

**V. MANAGERIAL & SUPERVISORY RESPONSIBILITIES –**

Must have prior supervisory experience.

**VI. REPORTING RELATIONSHIPS –**

Senior VP of Corporate QA/QC
