

Lyophilization Services of New England, Inc.

25 Commerce Drive, NH Facility

JOB DESCRIPTION

JOB TITLE: Director, Quality Systems	LEVEL: Senior Management
DEPARTMENT NAME : Quality	REPORTS DIRECTLY TO: Senior VP of Corporate QA

I. JOB SUMMARY –

Overall responsibility for the cGMP maintenance and improvement of Quality Systems at LSNE facilities to maintain the company's ongoing commitment to quality and continuous quality improvement. Works independently to monitor compliance trends and provide SVP Quality with routine reports on quality, compliance, and validation related issues. Sets priorities and objectives to ensure company compliance with FDA and EU cGMPs as well as other international regulations as required while meeting business objectives. Identifies personnel training needs and ensures training of staff.

II. JOB DUTIES –

1. Review, maintain and update Quality Systems and policies.
2. Oversee LSNE's Quality Systems and programs for compliance with all relevant domestic and international regulatory standards.
3. Provide technical and compliance guidance on quality and validation activities.
4. Provide technical and compliance guidance to company groups executing validation protocols for facilities, equipment, analytical procedures, and processes.
5. Host and co-ordinate client's audits at the Manchester and 25 Commerce facilities.
6. Initiate required programs and system procedures to meet standard quality requirements.
7. Keep management informed and provide corrective measures for Quality-related issues that may affect the company's quality and regulatory compliance status.
8. Assess staff skills against position requirements.
9. Adopts the LSNE philosophy of working together in all that we do to accomplish business.

III. PREPARATION, TRAINING & EXPERIENCE – .

EDUCATION AND PROFESSIONAL EXPERIENCE

- Minimum of four-year degree in directly related sciences
- Minimum of 15 years of management experience in the pharmaceutical or biotechnology industry (last 10 years in quality management)

PERSONAL SKILLS & COMPETENCIES

- Thorough working knowledge of U.S. and international drug, device, and biologics cGMP regulations and guidelines
- Excellent writing and verbal communications skills
- Ability to work independently

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 –

Quality Assurance/Quality Control Manager level

VI. REPORTING RELATIONSHIPS –

Reports directly to the Sr. VP, Corporate QA/QC
