

**Nortech Systems, Inc.**  
**Job Description**

**Job Title:** Quality Manager  
**Department:** Quality  
**Reports To:** Sr. Vice President, Commercial Business  
**FLSA Status:** Exempt  
**Prepared Date:** 7/8/2010  
**Approved By:** Curt Steichen  
**Approved Date:**

**Summary:** Responsible for managing the quality management system, serving as the Quality management representative and assuring regulatory compliance. This person will respond to customer complaints, coordinate and perform internal audits of the quality systems and develop & implement QMS for EMS and Medical Device Build.

**Essential Duties and Responsibilities:** Provides support to location in all or some of the following areas:

- Provide leadership to continuously improve the quality management system.
- Manage on-site FDA inspections and mitigate any findings
- Coordinate and conduct internal assessments of the overall quality management system to ensure its ability to achieve objectives and meet regulatory requirements.
- Management of all aspects of the quality management system and assure adherence to all applicable ISO, FDA and other regulatory requirements.
- Serve as the management representative for facilities quality management system as well as guide for all supplier and agency audits.
- Support customer regulatory submissions such as 510k, PMA, supplements thereto or annual reporting requirements.
- Develop, plan and implement QMS for EMS & Medical Device Build
- Assist in the development of Quality Plans and regulatory compliance strategies for new customers.
- Provide and coordinate ISO and FDA regulation training and other quality training as needed/required.
- Monitor quality indicators, coordinate and conduct corrective and preventative actions as well as provide leadership on addressing issues affecting quality system, regulatory, compliance and product quality.
- Work with all levels and areas of the company on quality system and regulatory document development, issues and improvements.
- Ensure that customer quality and regulatory requirements are communicated throughout the organization.
- Improve Total Cost of Quality
- Other duties as assigned.

**Supervisory Responsibilities**

Will provide work direction to others on a consistent basis.

**Qualifications** To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

**Education and/or Experience**

- Bachelor's degree in a scientific or engineering discipline.
- 5+ years (10 or more preferred), with at least 3 in an FDA regulated environment.
- Prior Quality Leadership experience
- Experience in establishing and maintaining ISO 13485 registration
- An equivalent combination of education and or experience will be considered.

**Language Skills**

Ability to read and interpret documents such as; blueprints, operating instructions procedure manuals and safety rules. Ability to write routine reports and correspondence with high level of accuracy and professionalism. Ability to speak effectively before groups. Ability to negotiate.

**Mathematical Skills**

Basic math skills, such as, addition, subtraction, multiplication, division, unit of measure, and percentages/ratios to calculate pricing, discounts, specifications and units of measure

**Reasoning Ability**

Ability to interpret a variety of instructions furnished in written, oral, diagram or schedule form.

**Computer Skills**

Demonstrated proficiency with Microsoft Office programs such as Word, Excel and PowerPoint, etc.

**Certifications, Licenses and Registrations**

Regulatory Affairs (RAC) Certification preferred.

**Physical Demands** The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to sit and talk or hear. The employee frequently is required to use hands to finger, handle or feel. The employee is frequently required to walk, stand, and reach with hands and arms. The employees must be able to stand for extended periods of time.

Must be able to lift up to 25 lbs.

Specific vision abilities required by this job include close vision, distance vision, color vision, depth perception and peripheral vision.

**Work Environment** The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. The noise level in the work environment is usually moderate.

**Comments:** This job description in no way states or implies these are the only duties to be performed by the employee occupying this position. Employees will be required to follow any other job-related instructions and to perform any other job-related duties requested by their supervisor or manager.

This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.