



C-Axis **Job Description**

Job Title: Quality Manager
FLSA Status: Exempt
EEO: Professional

Reports To: President
Department: Quality
Date Revised: December 2015

Summary: Lead and manage the quality system and quality performance for the assigned areas (plants or businesses) of responsibility. Assure compliance to company and regulatory quality requirements. Create and maintain the company quality system in conjunction with other business areas. Provide leadership in technologies used by the company for quality systems (ie: infinity QS) and for the inspection techniques. Manage and lead the inspection group for the assigned businesses. Lead and direct employees to meet our quality policy. Provide training on the quality system to ensure all employees are fully trained on the quality system requirements. Manage the corrective action systems and ensure proper execution and follow up. Participate or lead in quality audits with customers and internal. Employee must comply with company quality standards and guidelines.

Essential Duties and Responsibilities, but are not limited to the following:

Maintain full knowledge of the FDA and other regulatory agencies in our industry.

- Maintain filing systems either electronic or documents
- Belong to associations or groups affiliated with our industry
- Subscribe to Quality information updates as required to ensure compliance

Maintain currency for customer requirements

- Maintain filing systems either electronic or documents
- Ensure customers provide updates to their quality system requirements.

Responsible for Quality System Maintenance and Improvements

- Maintain the revision process for all quality system documents
- Maintain the filing system electronic and any paper copies
- Implement any change to the quality system manual, procedures and forms
- Solicit improvements and implement any improvements to the system
- Communicate changes to the effected employees
- Provide training as required.

Develops the inspection process along with Engineering

- Analyze customer requirements
- Determine customer measurement techniques and measurement tools
- Develop guard bands and inspection techniques
- Define inspection frequencies and plan

Oversee the inspection process to ensure effectiveness

- Manage and support the quality inspectors to ensure that products and processes comply with the relevant requirements of the quality management system.
- Provide technical support to the inspection process techniques
- Ensure that all of the required in process inspections are performed and performed correctly.

Improve manufacturing Quality processes

- Analyze processes to determine more efficient methods or techniques
- Improve processes to improve quality

Develop Statistical Process Control plans for manufacturing

- Implement and maintain Infinity QS
- Define process control plan
- Establish limits
- Ensure implementation
- Review results and determine corrective action

Oversee the management of all Manufacturing/Inspection Gages and Inspection equipment

- Maintenance of a log off all inspection equipment
- Maintenance of all calibration records
- Ensure that all equipment is calibrated or removed from use and segregated.

Measure and Report Quality Metrics for the Plant

- Track all Quality and Delivery data
- Create Monthly reports and post for the plant
- Review with management

Corrective and Preventative Actions

- Manage and maintain our corrective action process
- Ensure that corrective actions are defined and documented per our quality system
- Perform root cause analysis and implement corrective actions as necessary
- Ensure that all corrective actions are relevant and effective
- Ensure that the corrective action process is completed.
- Maintain logs for the corrective actions

Implement Quality Continuous Improvement activities to enhance the quality system

- Maintain knowledge of the various quality improvement processes (5S, Kaizen Lean methods, etc.)
- Provide recommendations to the plant management for improvement projects.

Manage Customer Change requests

- Implement changes requests from customers
- Communicate directly with customer to ensure all changes are understood and documented
- Identify cost and make sure costs are captured and charged back to customer
- Ensure that approvals are received and that changes are properly implemented.

Manage the customer complaint process

- Respond to all customer complaints by creating implementing the customer complaint process
- Prepare the customer complaint forms as required
- Define corrective actions and work with the required other disciplines as required.
- Follow up to make sure all Customer Complaints are completed correctly
- Maintain a log of all customer complaints.

Provide resources or assist in the quotation process as required

- Define process and estimate cycle times
- Define quality requirements
- Identify technical issues and concerns

Provide training to other machinist on specific jobs and on a general basis

- Perform as a technical resource for other employees
- Train the machinist to run specific jobs
- Provide training on inspection criteria and techniques
- Provide generic training to machinist

Maintain the Company Audit process

- Conduct audits along with other employees for the internal audit program
- Prepare nonconformance reports for any issues discovered during the audits.
- Create corrective actions
- Follow through to determine effectiveness

Supplier Management

- Manage suppliers performance
- Conduct supplier audits or surveys
- Track supplier performance and review with management
- Maintain the Approved Supplier List

Special Projects

- Develops and implements projects and programs to standardize efforts; improve processes; and reduce, avoid, or contain costs.

Supervisory Responsibilities:

This position has supervisory responsibilities for the following positions: Quality Engineer, Quality Technician, Quality Inspectors and Documentation Clerk. This position also needs to interact and communicate effectively and on time, with other employees, management and customers to inform matters of importance and to initiate or recommends appropriate action.

Core Competencies:

1. Company Ambassadorship
2. Integrity, Ethics, Confidentiality
3. Quality Oriented
4. Customer Focus
5. Cost Conscious
6. Collaboration/Teamwork
7. Creativity and Innovation

8. Initiative/Adaptability
9. Learning Orientation

Job Competencies:

To perform the job successfully, an individual should demonstrate the following competencies:

1. Problem solving and decision making skills
2. Results Oriented and capable of identifying areas for improvement and new opportunities
3. Time Management Skills to ensure that all projects are completed successfully and on time
4. Excellent communication, interpersonal relations and negotiations skills
5. Able to deliver customer presentation, discuss professionally quotes and proposal with customers.
6. Continually evaluates results from these defined responsibilities and identifies improvement areas and opportunities.
7. Prepares special reports by collecting, analyzing and summarizing information and trends.
8. Keeps management and employees informed of all matters of importance and initiates or recommends appropriate action
9. Maintains objectivity and independence in actions which are in the best interest of the corporation

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.

Education and/or Experience:

- Bachelor degree in Engineering or equivalent related years of experience; or equivalent combination of education and experience
- At least ten (10) years in quality position in manufacturing environment, experience in a metal manufacturing work environment preferred

Other Qualifications:

- Excellent Computer Skills in Word, Excel, Power Point
- Strong attention to detail and numerical accuracy
- Ability to perform data entry of information fast and error free
- Ability to work effectively with all levels of the organization and influence teams to exceed expectations
- Excellent written and verbal communication skills in English
- Knowledge of GMP and medical components and devices
- Skilled in the use and interpretation of SPC

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. Individuals may need to sit or stand as needed. The position may require walking primarily on a level surface for periodic periods throughout the day. The employee may reach above shoulder heights or below the waist or lift as required to file documents or store materials throughout the workday. Proper lifting techniques are required. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception and ability to adjust focus.

Work Environment:

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. The performance of this position may occasionally require exposure to the manufacturing areas that may require the use of personal protective equipment such as safety glasses and hearing protection. For the most part the employee will be exposed to ambient room temperatures, lighting and traditional office equipment as found in a typical office environment.

Employee Name _____

Employee Signature _____

Copy of position job description received on _____