

Quality Manager Job Description

Position: Quality Manager

Department: Quality Assurance

Reports to: President

FLSA Status: Exempt

Summary of Position

The Quality Manager will ensure products and services meet the organizations ISO9001 Quality Management System (QMS) and will serve as the Quality liaison between operations, purchasing, design engineering and customer service. The ability to develop and maintain strong, productive working relationships across functional disciplines using objective, data driven methodologies will be essential to the success of this role.

Primary Duties and Responsibilities

- Ability to develop, implement and maintain the company's ISO 9001 Quality Management System (QMS)
- Increase plant wide employee engagement in Quality Initiatives.
- Create and be accountable for visual KPI dashboard that includes leading indicators of plant wide Quality levels using both continuous and attribute data sets
- Plans, manages, and controls programs and procedures that maintain an acceptable level of product quality as established by various federal, state, customer, and company requirements, including quality of purchased material, in-process material, and finished goods
- Maintains higher level quality system documents including Quality System Manual (QSM), Work Instructions (WI), Standard Operating Procedures (SOP) related to Quality.
- Provides oversight and ensures compliance of Quality System (QS) supporting elements for QMS, Internal audits, Training, Document Control, Supplier Quality Management, Complaint Management, CAPA, NC Management, and Calibration Systems
- Maintains product/manufacturing process changes and related quality system documentation changes
- Develop testing procedures for products and write/approve inspection instructions
- Perform process validation and verification
- Serves as Management Representative for the Quality System (QS) and represents the Company in all audits: customer-requested, external regulatory, 3rd party registrar and internal audits. This role reports to top management and relays this information and the need for improvement

- Report to top management on the performance of the QMS (e.g., results of quality audits, corrective actions), including the need for improvement
- Oversees Vendor Approval Process and customer part approval process (PPAP if required)
- Implement a cross functional MRB process

Minimum Education & Experience Requirements

- BS/BA degree in related industrial, scientific or business field
- At least 5-8 years of related experience in manufacturing and production with an emphasis on Quality Management Systems
- Analytical, critical-thinking and problem-solving skills to review systems, and pose solutions
- Strong Interpersonal, leadership, management and communication skills
- Thorough understanding of quality control standards and methodology

Preferred Qualifications

- Professional certification, such as Six Sigma, Quality Engineer, or Quality Auditor
- Knowledge and understanding of ISO 13485 and FDA Regulations
- ERP system knowledge and background
- Strong computer skills including Microsoft Office, Excel, Minitab
- Knowledge and understanding of RoHS, REACH, CMRT compliance

Required Values

- Considers multiple factors (Safety, Quality, Delivery, Cost & Inventory) when making recommendations/decisions.
- Demonstrates high levels of positive energy and enthusiasm and a willingness to take on new challenges, responsibilities and assignments - strives to go beyond what is expected.
- Projects a professional image in appearance, communication, and behavior even during times of stress, instills trust and is open, honest and approachable.
- Seeks and takes advantage of opportunities to learn from others and share own knowledge so others may benefit.
- Involves and informs others as appropriate in identifying issues, problems, opportunities and developing solutions.
- Acts and communicates in an ethical and truthful manner, leading by example and earning the respect and trust of co-workers, customers, and other stakeholders.
- Effective problem solving and critical thinking skills.