

## Quality Manager

Custom injection molding contract manufacturer producing products for medical, industrial, defense, and other industries, is seeking a Quality Manager for the three-shift operation in Clearwater, FL.

Qualified candidates will have previous plastic injection molding experience with medical products and a proven track record effectively developing staff, implementing quality programs, and interfacing with customers on quality related topics. The qualifying candidate will have a strong quality management system oversight background and will work with all aspects of our business to assure consistent quality of production, customer satisfaction, and continual improvement emphasizing defect prevention and the reduction of variation and waste.

### ESSENTIAL DUTIES AND RESPONSIBILITIES

- Responsible for the maintenance, accuracy, and compliance of the Quality Management System.
- Participate in strategic planning for growth and continual improvement of the organization.
- Establish and perform critical training requirements that are customized to various groups within the organization. Provide evidence of training effectiveness.
- Implementing quality standards; identifying and resolving problems; completing audits; determining system improvements; and implementing change.
- Responsible for ITAR, ISO 9001, ISO13485, & FDA compliance to quality related statutory and regulatory requirements
- Provides immediate and long term preventive and corrective actions to customers.
- Establish quality assurance financial objectives by estimating requirements; preparing an annual budget; scheduling expenditures; analyzing variances; initiating corrective actions.
- Develops quality assurance plans by conducting risk analyses; identifying critical control points and preventive measures; establishing critical limits, monitoring procedures, corrective actions, and verification procedures.
- Coaching members of the organization to effectively meet quality objectives.
- Validates quality processes by establishing product specifications and quality attributes; measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
- Maintains and improves product quality by completing product, company, system, compliance, and surveillance audits; investigating customer complaints; collaborating with other members of management to develop new product and engineering designs, and manufacturing and training methods.
- Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations.
- Continually improves job knowledge by studying trends and developments in quality management; participating in educational opportunities; reading professional publications; maintaining personal networks; participating in professional organizations.
- Works to improve department and organization reputation by accepting ownership for accomplishing new and different requests; exploring opportunities to add value to job accomplishments or product realization.
- Accomplishes quality assurance human resource objectives by training, assigning, scheduling, coaching, counseling, and disciplining employees; communicating job expectations; planning, monitoring, appraising, and reviewing job contributions; enforcing policies and procedures.
- Lead all quality related programs with hands on involvement to assist the production staff.

## **MINIMUM QUALIFICATIONS**

- A minimum academic requirement of a Bachelor's degree in quality, engineering, business discipline, or hold quality science certifications from nationally recognized organizations such as ASQ, RABQSA, etc.
- 5 + years' experience as Quality Manager.
- Must have a strong understanding of GD&T, proficient with measuring instruments, calibration management, GR&R, process validation such as IQ, OQ, PQ, PPAP, etc.
- Strong communication skills to build productive business relationships with customers and staff.
- Some light travel required. (as necessary)

## **PREFERRED KNOWLEDGE, SKILLS AND ABILITIES:**

- Superior organizational and leadership skills with ability to help team grow and thrive
- Experience with Customer interface and meeting customer expectations.
- Demonstrate team building and problem-solving skills
- Ability to effectively prioritize and escalate issues
- Working familiarity with Project Management Tools and Quality Risk Management.
- Working knowledge of ISO requirements (9001; 13485) and Pharmaceutical Industry requirements (cGMP, etc)

## **PHYSICAL & MENTAL REQUIREMENTS:**

- Work in a manufacturing environment
- Work in an office environment. At times must sit for extended periods of time.
- Ability to effectively communicate and comprehend complex ideas and concepts.
- Use written and oral communication skills.
- Read and interpret data, information and documents.
- Must maintain the ability to work well with others in a variety of situations.
- Must be able to multi-task, work under time constraints, problem solve, and prioritize.
- Ability to make independent and sound judgments.
- Observe and interpret situations, analyze and solve problems.
- Able to be aware of all relevant SOPs as per Company policy as they are related to the position covered by this Job Description