

**Job Title:** Senior Quality Engineer

**Reports to:** Director of Quality

**Direct reports:** N/A

### **Position Overview**

The Senior Quality Engineer will support both Program Management and Operations through all phases of our products lifecycle to ensure the manufacturing and support activities for products are executed to meet the requirements of ISO 13485 and other applicable regulations and standards.

### **Position Responsibilities/Essential Functions**

- Safety is everyone's responsibility
- Work with Project Managers to schedule and complete all new product introduction quality work using available department resources to ensure project timeline commitments are achieved
- Work with Operations Manager & Production Supervisors to produce quality products; lead the practice of problem solving process on production floor and provide technical support
- Develop methods for and conduct product testing, first article and final inspections
- Generate, review, issue and control all documentation on the Production floor with a major priority set on maintaining the IQMS database
- Support assigned customer complaint evaluation and resolution; maintain the corrective and preventive action processes in IQMS
- Act as the primary member/champion of the MRB team
- Support the internal QMS audit process along with the ISO Management Representative
- Sign off on product Certifications; maintain records of the same
- Train employees on procedures and work instructions including ISO requirements
- Meet with operators regarding quality issues and training
- Meet department productivity and quality goals
- Evaluate department processes; recommend process and product changes and improvements
- Work with raw material and component suppliers on quality issues
- Communicate with Customers, Suppliers, External Third Party Audit Bodies and Governmental Agencies in regards to quality and compliance issues
- Regular, on-time attendance at work is an essential function of every job at Dymotek
- Support the organization's needs in various functions

### **Minimum Qualifications/Skills**

- Personal core values that align with Dymotek's core values of living Dymotegrity, taking ownership, respectfully speaking your mind and possessing a passion for winning
- BA/BS degree in science or other technical field or equivalent work experience
- Minimum of 5 years' experience in related position; medical device industry preferred
- Blueprint and schematics reading with hands on inspection experience; GD&T preferred
- Experience/skills in statistical analysis (E.G. - DOE, Gauge R&R, FEMA, SPC, PPAP)
- Experience participating in internal and external audits (e.g., FDA, Notified Body, Supplier)
- Experience with root cause, corrective action, complaint investigation and risk management
- Strong organizational and time management skills with ability to work independently
- Initiative, attention to detail, and the ability to work as a team player
- Individual must have a hands on approach
- Exhibit high ethical standards and act in a trustworthy manner

- Proficient use of Microsoft Office products including Excel, Word, PowerPoint, Outlook, and Minitab software
- Ability to understand and follow oral and written instructions
- Communicate clearly and concisely, both orally and in writing

#### **Highly Desirable**

- ISO 9001/13485 knowledge
- Working knowledge of SmartSheet and IQMS
- CQE, CQA, CMQ/OE preferred
- Advanced knowledge of both silicone and thermoplastic injection molding
- Six Sigma Blackbelt

#### **Additional Requirements**

- Flexibility to work outside regular business hours to accomplish tasks
- Refer to 'Document/Job Function Matrix' (a cross reference of all ISO documents with job titles) for specific documents related to their job positions
- Normal manufacturing conditions requiring safety observation at all times
- All employees are responsible for knowing the Quality Policy Statement, how their job supports the statement and quality objectives
- All employees are responsible for product identification
- All employees are responsible for supporting both facilities

#### **Miscellaneous Employment Information**

- Indirect, Dept. 500
- Salary
- Regular full-time
- Job level - 10
- Cell phone reimbursement

---



---

Signatures below constitute understanding of the requirements, essential functions and duties of the position.

\_\_\_\_\_  
Manager/Supervisor Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Human Resources Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Employee Name (please print)