Job Description – ISO 13485 Quality Engineer

Purpose & Scope

The purpose of this position is to assume primary responsibility for the ISO 13485 registration and maintenance of the Dymotek organization. The Medical Quality Engineer is responsible for ensuring the manufacturing and support activities of medical devices produced meet the requirements of 21 CFR Part 820, ISO 13485, the Medical Device Directive and other applicable regulations and standards. This position supports both Program Management and Operations through all phases of our medical products lifecycle. In addition, involvement with the ISO 9001 Quality Management System / IQMS Quality module and internal audit process is required. This is a salaried exempt position.

Duties and Responsibilities

- Safety is everyone's responsibility
- Minimum 5 years' experience as a Quality Engineer in the medical device industry preferred
- BA/BS degree in science or other technical field
- Medical Device Quality System Knowledge Including 21 CFR Part 820 (QSR) & ISO 13485:2003/2016 preferred
- Experience participating in internal and external audits (e.g., FDA, Notified Body, Supplier) preferred
- Experience with CAPA, complaint investigation, field action processes and risk management
- CQE, CQA preferred
- Regular, on-time attendance at work is an essential function of every job at Dymotek
- Strong organizational and time management skills
- Individual must have a hands-on approach
- Additional duties as assigned

Organizational Relationships

Reports to Director of Quality

Working Conditions

Normal manufacturing conditions requiring safety observation at all times

Education & Training

College Degree in Engineering preferred with 3 – 5 years Quality Engineering experience and/or 10 years of advanced experience as Quality Coordinator/Technician/Inspector

Technical Knowledge Skills & Experience

- ISO knowledge and training (ISO 9001:2008/2015 and ISO 13485:2003/2016)
- Advanced Metrology skills - GD&T
- Blueprint and schematics reading
- Well versed in Quality tools such as Lean manufacturing, TPE, Mistake proofing, Kaizen and 5-S.
- Experience/ skills in statistical analysis (E.G. - DOE, Gauge R&R, FEMA, SPC, PPAP and Six Sigma
- Strong computer skills, Excel, Word, PowerPoint, Minitab
- Organizational skills / Planning skills / Observant-Detail oriented

- Excellent communication / interpersonal skills
- Product knowledge
- Process knowledge-Basics of injection molding

Managerial Skills & Experience
N/A

Special Requirements (Physical, etc)
N/A

Quality Management System Requirements
- 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
- Refer to 'Document/Job Function Matrix' (a cross reference of all ISO documents with job titles) for specific documents related to their job positions

This job description has been approved by all levels of management:

Manager or Supervisor_____

Human Resources_____

Employee signature below constitutes employee's understanding of the requirements, essential functions and duties of the position.

Employee Signature_____ Date_____

Employee Name (please print)_____