Sr. Manager, Quality Engineer

Purpose and Scope

This role is responsible for directing and management of quality engineering staff, ensuring all engineering personnel comply with the company's quality management system.

Primary Organization Responsibilities

- Adheres to Monteris' Core Values and all quality requirements including, but not limited to: Quality Management Systems (QMS), U.S. Food and Drug Administration (FDA) and Health Canada regulations. Drives continuous improvement and best practices to ensure a perpetual state of inspection/audit readiness.
- Supports the Monteris team by directing all aspects of Quality engineering to prepare market introduction of new Monteris projects and execute post market quality activities.
- Oversees design assurance engineering personnel ensuring all Monteris new product development and remediation efforts comply with Monteris quality system requirements while also driving Design for Reliability/Manufacturing principles into new product development projects.
- Oversees post market quality engineering personnel including returned goods analysis, post-market surveillance activities, receiving inspection and manufacturing support. Maintains a common set of quality engineering analytics to proactively monitor product quality levels.
- Oversees supplier quality engineering personnel including identification, selection and qualification of new suppliers. Supports supplier audits, determination and issuance of supplier corrective action request (SCAR), supplier monitoring and management of supplier related non-conforming materials (NCR).
- Establishes and maintains relationships with Executives and Senior Leadership peers to assist in establishing a culture of quality performance for both pipeline and commercialized products.
- Demonstrates consistent leadership within the broader organization and among the Quality team. Interviews, hires, and establishes training plans for direct reports. Provides leadership to the direct staff regarding development of individuals' goals and mentoring of the group.

Personal Qualifications and Experience

Education/Experience

- Bachelor's degree in Engineering or technical discipline strongly preferred
- Medical device background required
- Previous direct supervision of pre-market (design assurance), post-market and supplier quality engineering personnel required.

Skills/Abilities

- Experience with regulatory and voluntary requirements such as 21 CFR parts 801, 802, 803, 820, 806, ISO 13485 and ISO 14971
- Knowledge of FMEA, health hazard evaluation, reliability analysis, process validations, software validations, DOE, SPC, process capability techniques, and CAPA.
- Must understand total business operations, quality systems, business process improvement tools, manufacturing and processing principles.
- Critical thinking, risk assessment, root cause analysis and problem solving skills.
- Proven ability to lead and develop people. Ability to delegate and motivate subordinate staff, as well as executing through others.
- Ability to achieve results through influence and leadership.
- Excellent written and verbal communication skills. Ability to communicate effectively at all levels within the organization and with global business partners
- Excellent organization, resource allocation and prioritization skills. Ability to organize multiple projects, and collaborate effectively within and across departments.
- Proven ability to influence, negotiate and lead without direct line authority across multiple site and functions.
- Must be skilled at taking strategic initiatives and translating them into tactical solutions and negotiate with senior managements to gain approval.
- Strong communication and negotiate skills when interacting with representatives from regulatory bodies.