

Quality Manager - Minneapolis, MN

Spectrum Plastics Group has an immediate opening for an experienced Quality Manager. The Minneapolis (St. Louis Park area) facility manufactures components for the medical, aerospace/defense and industrial markets. The facility is certified to ISO 13485, ISO 9001 and AS 9100, as well as being FDA registered. Internal processes include injection and insert molding, various secondary operations (stamping, ultrasonic welding, laser engraving, etc.), assembly, packaging, and machining of plastic components.

Position Summary

The ideal candidate will possess in-depth knowledge of quality assurance and quality control standards and methods associated with the manufacture of medical components. This position is accountable for managing, planning, organizing, directing, and controlling a Quality Assurance Program which includes quality control, quality engineering, regulatory compliance and product safety functions to ensure customer requirements are satisfied.

- Serve as the site advisor on regulatory compliance; ensures regulatory requirements are integrated into the plant's quality system documentation and complies with all applicable FDA QSR's. Manages the sites quality management systems (ISO 13485, ISO 9001, AS 9100).
- Serve as the site quality expert in the areas of quality standards, QA/QC methods, internal auditing, analytical methods associated with fundamental quality systems (SPC, Gage R&R, verification of complaints and CAPAs) and general quality management.
- Facilitate problem-solving efforts utilizing appropriate tools such as error-proofing, 5S, FMEAs, cause-and-effect diagrams, 5-Whys, flowcharting, statistical methods. Provide training to individuals that may lead problem-solving or improvement activities.
- Monitor, analyze and act upon key quality system metrics (product and process) to: inform appropriate functional areas; identify opportunities for improvement; measure the performance of the quality systems; and ensure the attainment of quality and company objectives and goals.
- Represent the company in a professional manner when interacting with suppliers, customers, 3rd party auditors and internal stakeholders.
- Directly manage a team of Quality Engineers including prioritization of activities, mentoring & coaching, and skills development.
- Enhance data-driven decision-making capabilities within the quality function and across the organization.

Position Requirements

- Strong leadership abilities
- A thorough understanding of ISO 13485 and 21 CFR 820 (ISO 9001 and AS 9100 knowledge helpful)
- Practical experience with SPC, capability analyses, MSA, DoE, FMEA, control plans, sampling methods
- Well-versed in quality philosophies and can bridge the gap between theory and practical application
- Bachelor of Science degree in quality, manufacturing, engineering or related discipline
- At least three years of quality engineering experience and at least two years at the quality management level
- Clean room manufacturing experience preferred
- Innovative and creative thinker able to effectively apply process and risk management approaches and methods to continually enhance the effectiveness of the facility's quality management system

- Prefer ASQ certifications (CMQ/OE, CQE, and CBA or CQA)
- Can effectively function independently and collaboratively
- Expertise in facilitating problem-solving and continuous improvement efforts using proven methods and tools

If interested, please email your resume and salary expectations to martin.dale@spectrumplastics.com, placing MNQAM in the subject line.