Sr. Quality Assurance Engineer

Location: Lexington, MA

Reports to: Vice President of QA/RA

Position Summary

To support its growth and expansion, Fractyl is seeking a Senior Quality Assurance Engineer. The Sr. Engineer provides technical guidance and support for product development, sustaining engineering, production, and quality system activities to assure conformance to established specifications, standards, and regulations. S/he will also serve as the liaison between Fractyl and various design and manufacturing partners, and facilitate the optimization and continuous improvement of internal operations to meet department, quality, and company objectives.

Primary Responsibilities

- Provide quality support for new product development activities and change management in accordance with internal design control requirements.
- Compile and analyze quality control and production metrics to ensure key process indicators are trended and assessed. Identify, implement resulting corrective actions
- Manage non-conformance material investigations, dispositions and internal/supplier corrective actions
- Prepare and maintain technical product documentation including design history files, engineering drawings, bills of materials, test protocols and reports by using engineering change order process.
- Collaborate with manufacturing engineer/process engineer to identify opportunities for process improvements using statistical methods such as Six Sigma (including implementation of SPC, use of DOE, etc.).
- Identify opportunities for continuous improvement in Operations and New Process Introduction
- Lead projects related to design transfer to manufacturing and production process improvements
- Facilitate and actively lead the production risk management activities including the development and management of PFMEAs for new and released products and procedures.
- Write, review and/or approve reports for: test method validations, design verification, design validation, and process validations (IQ, OQ, PQ).
- Participate in supplier quality management activities including risk management, qualification, inspection plans, process audits and quality agreements.
- Lead or participate in supplier product, component or assembly qualifications.
- Write, review and / or approved quality plans to support both internal and external product activities.
- Support company initiatives to assure compliance with Quality System requirements
- Bring a “can do” spirit to work and deliver on other responsibilities as assigned.

Education or Certification Requirements

- BS in Engineering or related disciplines required

Professional Work Experience

- 5+ years in Quality Assurance or a similar role
- Experience in Quality Control, supplier interaction, manufacturing, and labeling.
- Experience in biotech, pharmaceutical and/or medical device industries preferred.
- Prior vocational experience in related fields a plus (i.e. Co-Ops, Internships, Fellowships, etc.).

Qualifications and Skills

- Understanding of implementation and maintenance of a quality management system, including familiarity with quality control, sampling, and manufacturing operations
- Knowledge of Lean manufacturing and 6 Sigma a plus
- Strength in data analysis and statistics, with a familiarity with software tools
- Knowledge of FDA and EU regulations and guidance documents
- Proficient ability to read, analyze and interpret documents, professional journals, technical procedures and government regulations
- Strong writing skills with ability to write procedures, protocols and reports
- Strong computer skills including Microsoft Office
- Certified CQE, desirable but not required
- **Other Essentials and Key Success Factors:**
    - Successful track record of working in high-growth and dynamic organizations
    - Demonstrated record of intellectual curiosity, innovation and creative problem solving with an entrepreneurial spirit
    - Ability to lead fast-paced projects with a keen sense of urgency to get the job done well
    - Evidence of "hands-on" experience and expertise
    - Proven and successful track record as a team-player and collaborator in small working environments
    - Highly organized and detail oriented with a passion to deliver quality results
    - Excellent verbal and written communication skills, with experience translating technical concepts into user-friendly documentation
    - Highest levels of professionalism, confidence, personal values and ethical standards

Travel

- May be required to travel up to 10% - 25% (domestically and/or internationally)

The description and requirements outlined above are general; additional requirements may apply.