QUALITY ENGINEER

Medical Murray is a leading medical device development and manufacturing company, serving clients throughout the world.

Medical Murray focuses on providing its clients with any or all of the development engineering and/or manufacturing services required to move a new medical device along the development path from concept to production.

Our focus is on three market areas: less invasive vascular, urologic and surgical applications. Our core experience is with custom catheter systems and components, complex disposables and implantables.

We're looking for team players with a can-do attitude to share in our vision and corporate values. Medical Murray offers competitive salaries, a comprehensive benefits package, and an energetic work environment.

Currently, we are searching for a Quality Engineer to join our facility located in Lake Zurich, IL.

Job Description:

The Quality Engineer position performs engineering duties in the quality department in support of the quality department objectives to provide goods and services that meet customer's requirements for quality, quantity and timeliness. Position's responsibilities pertain to addressing technical activities within the quality organization.

Duties and Responsibilities:

- Responsible to follow Medical Murray Quality system, including all applicable SOP's included in the Training Matrix
- Supervise and perform testing and inspection activities, including training of inspectors or technicians
- Maintenance of inspection records
- Provide quality and reliability engineering functions on product development projects (per ISO and FDA requirements)
- Reviews components, products and processes for optimization of inspection method, sampling plan and documentation
- Train employees concerning quality standards
- Develop and document control plans which define verifications during production to ensure all stated requirements are met
- Work with production in support of validation and qualification studies
- Create, modify and implement quality systems and procedures (internal and external)
- Provide general quality support as required by management
- Analyze nonconforming conditions in production to determine root cause
- Communicate with process owners to resolve nonconforming conditions by developing or facilitating corrective and preventative actions
- Summarize and report nonconformance information and evaluate trends and major causes
- Plan and document studies of measurement repeatability and reproducibility; and process capabilities
- Perform internal audits of the quality system and verification activities; and supplier audits as requested

- Use inspection, measuring and test equipment as necessary,
- Support sterilization systems companywide. Set up product specific requirements and maintain Medical Murray standard cycles

Skills/Qualifications:

- BS in engineering discipline or equivalent experience
- Six Sigma Green belt desired
- Quality assessment / audit experience is desirable
- 3-5 years of experience in Quality Engineering for medical devices or 5-8 years of experience
- Experience in the area(s) of ISO and FDA Quality Systems
- Knowledge and understanding of ISO-13485 and FDA 21 CFR Part 820 cGMP standards,
- Technical skills must include disposable medical device testing, protocols, analysis and report writing, knowledge of statistics, for example experiment design and SPC
- Computer skills needed include Microsoft Office or equivalent
- Strong analytical and problem solving skills
- Excellent verbal and written communication skills