Title: Director of Quality Assurance - Software Engineering

Location: Charlotte, NC (must be based in the greater Charlotte area)

Website: https://monarchmedtech.com/

The Director of Quality Assurance - Software Engineering will be responsible for managing software testing and quality assurance programs and processes to ensure the organization's software systems meet operational, quality and FDA standards as established by our corporate objectives. This person will serve as a leader in the areas of testing, development of automated testing programs and continuous improvement to ensure the company's software applications meet all design elements and safety requirements. The role will also serve as a directly contributor in test execution activities to support the delivery of both new product releases and upgrades.

Position Responsibilities

- Develop, implement and maintain testing procedures and quality assurance policies to ensure the company's standards and measurements are detailed, robust and consistent
- Partner with Product Management, Development and Regulatory departments to develop and implement quality assurance programs and processes that meet with industry and regulatory quality requirements for medical device software
- Perform testing with other QA members; track, monitor and resolve discrepancies with development team
- Prioritize the testing of all software application releases
- Establish/Maintain Manual and Automation test strategies for the QA team
- Estimate, prioritize, plan and coordinate quality assurance testing activities
- Develop standard QA and system performance metrics for the team
- Keep management up to date of significant issues or developments identified during QA activities and report test metrics
- Maintain required software testing documentation and provide timely feedback to team
- Stay informed of trends and developments in quality standards, testing tools, test strategies and regulatory requirements
- Ensure compliance with FDA and ISO's quality system procedures and records requirements, including the preparation of records to be maintained in design history file and/or included in pre-market submissions
- Contribute to regulatory filing strategy for new and modified systems

Education Minimum: BS or equivalent experience in Computer Science or other technical fields

Required Skills and Experience:

- 8+ years of software testing experience
- Experience as a software testing Lead/Manager, preferably with at least 2 years of experience in a FDA-regulated industry
- Experience with software QA automation tools
- Thorough understanding of quality assurance standards and methodologies
- Experience with Manual and Automation Test Methodologies
- Strong analytical and problem-solving skills
- Ability to coordinate release testing and planning
- Excellent organizational skills and attention to detail
- Excellent verbal and written communication skills with the ability to train and lead staff
- Experience with ISO 13485 and 14971 preferred

To apply for this position, please submit a cover letter and resume to Melissa Tindall at melissa.tindall@monarchmedtech.com.