



Title: Quality Systems Engineer
Reports to: Director of Quality Assurance and Regulatory Affairs

Job Summary:

This position is responsible for the development, maintenance and improvement of the Quality System to ensure compliance to applicable national and international regulations and standards.

Qualifications:

1. Bachelor's degree in an engineering, technical or scientific discipline
2. In-depth knowledge of FDA QSRs and ISO13485 for medical devices
3. Experience with ISO 9001:2000
4. Demonstrated proficiency working with computers and the MS operating systems
5. Ability to write technical documents
6. Strong interpersonal skills, written and oral communication skills and analytical skills
7. Excellent leadership skills leading multiple discipline teams
8. Ability to work independently, but also functions well in a team setting
9. A working knowledge of quality improvement tools and techniques
10. Three (3) to 5 years experience in software- and electronic-based engineering in a medical device development and manufacturing environment

Essential Duties and Responsibilities:

1. Manage a comprehensive Quality System audit program
2. Develop and maintain appropriate metrics to assess the effectiveness of the Quality System
3. Lead the Quality System management reviews
4. Maintain and improve Quality System procedures
5. Support employee training on the Quality System
6. Facilitate continuous improvement throughout the organization
7. Maintain and improve the Corrective and Preventive Action Process
8. Manage interdepartmental resources to maintain and improve the Quality System
9. Manage the complaint handling process
10. Prepare for and participate in customer and certification audits
11. Manage the customer satisfaction process

Quality Assurance personnel are encouraged to be creative and innovative, while at the same time are expected to learn and follow our structured processes. They will take direction from engineers and other technical personnel and will assume appropriate level of responsibility for technical work to assist in the development or manufacturing of products and assemblies.

Quality Assurance personnel are expected to contribute to our team while enhancing their own technical expertise and increasing their responsibilities.



Our company offers excellent benefits including medical, dental, life and disability insurances, 401k plan, paid time off, and tuition reimbursement among others. Additionally, our company has a fun, flexible and challenging work environment that fosters innovation and growth for all employees.

Minnetronix, Inc. is an Affirmative Action Equal Opportunity Employer
Must be authorized to work in the United States
NO AGENCIES / NO PHONE CALLS

To reply to this posting, please send a cover letter and resume to:

hr@minnetronix.com (*preferred*)

or:

Human Resources - Minnetronix, Inc.
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