Senior/Principal System Engineer

Our success comes from our Velico Team who are **global thinking** (to save many lives worldwide), **visionary** (as we are future focused industry leaders, **collaborative** (we deliver the best results through inclusion and diversity), **professional** (as are our highly qualified team of experts) and **honorable** (we work ethically and look to do the right thing). **We seek like-minded individuals to join us.** Velico's mission is to eliminate preventable death from bleeding. This is a rare opportunity to contribute to a true innovation in transfusion medicine and trauma care, that could result in saving thousands of lives each year.

Based in Beverly, MA we are seeking a highly-motivated person who wants to support an organization who is involved in groundbreaking technology with the skills, education & experience needed. We are seeking an individual who will be responsible for the design, development, and maintenance of our advanced medical device systems.

Responsibilities include:

- Leads and participates in the design and development of complex medical device systems from concept to commercialization.
- Defines system requirements, specifications, and architectures based on user needs, industry standards, and regulatory requirements.
- Collaborates with hardware and software teams to integrate components and subsystems into a cohesive medical device system.
- Conducts system-level testing, verification, and validation activities to ensure compliance with design inputs and performance expectations.
- Performs and develops methods to objectively quantify system performance/function.
- Analyzes and troubleshoots system-level issues, identifying root causes and then implementing effective solutions.
- Ensures the medical device system meets regulatory standards (e.g., FDA, ISO, IEC) and participates in the preparation of documentation for regulatory submissions.
- Works with the notified bodies (e.g. UL, TUV) to demonstrate product compliance.
- Coordinates testing to be performed to ensure compliance with all ISO, IEC, and regulatory standards required for a given product or assignment.
- Collaborates with quality assurance teams to develop and execute system-level test plans and protocols.
- Works collaboratively with cross-functional teams, including hardware engineers, software developers, quality assurance specialists, and regulatory experts, to ensure the successful creation of safe, effective, and compliant medical devices.
- Participates in risk management activities including identifying potential hazards and mitigations for the medical device system.
- Maintains a strong awareness of industry trends, best practices, and emerging technologies related to medical device engineering.
- Provides technical support and expertise to cross-functional teams throughout the product lifecycle.
- Identifies and pursues novel technology to support future strategic opportunities.
- Supports Quality System Audits conducted by external agencies, such as FDA, Notified Body, and/or Regulatory Agency audits.
- Ensures alignment of internal and external customers.
- All other duties, as assigned.

We are seeking individuals with:

- Bachelor's of Science degree BS in Biomedical/Mechanical Engineering or directly related scientific discipline, MS preferred.
- Applied understanding of mechanical, electromechanical, and systems design.
- 5+ years of experience in medical device system engineering or a related role.
- Solid understanding of medical device regulations and standards (e.g., FDA QSR, ISO 13485, IEC 60601).
- Proficiency in system-level design, requirements management, and architectural development.
- Excellent working knowledge of computer systems including MS Office Suites with advanced knowledge of Excel.

Interested candidates are to have:

- Strong analytical and problem-solving skills, with the ability to troubleshoot complex issues.
- Excellent communication skills, both written and verbal, to effectively collaborate with cross-functional teams and stakeholders.
- Excellent verbal and written English communication skills.
- Problem-solving skills including identifying, troubleshooting, recommending and implementing of solutions.
- Task oriented with strong organizational and attention to detail skills.
- Required to work cross-functionally within the organization and with external customers and vendors.
- Self-directed and proven skill to work independently, as well as, part of a team.
- Ensures work is completed in the expected timelines and is adept at resolving competing priorities.
- Results-oriented with strong analytical skills and exercises appropriate judgment and make decisions based on accurate and timely information.
- A high level of integrity and dependability.
- Maintains a high level of confidentiality.
- Demonstrated skill in managing multiple projects to drive results.
- Process and improvement focused skills to implement new procedures to accommodate growth and adaptable to change priorities, as needed.
- Demonstrated exceptional interpersonal skills and fosters strong working relationships and is adept at interacting with diverse groups of people.
- A self-motivated approach to work efficiently in a team-oriented environment with a high degree of multi-tasking and prioritizing multiple projects/tasks meeting expected deadlines.
- A positive behavior which promotes and fosters our work environment.
- A strong work ethic; comfortable in a fast-paced, entrepreneurial company environment.

Work is usually performed in a sitting position and may require stooping, kneeling, reaching, lifting and carrying during the course of the work shift. Required to solely lift and safely move material of up to approximately 25 lbs. during the course of the work shift.

May be required to work nights or weekends to meet monthly, quarterly and/or annual compliance deadlines.

May require traveling up to 10% of the time via car and air in the U.S. and Europe.

Interested candidates are to send their resume, cover letter and salary requirements.