Regulatory Affairs Specialist

We are growing! A key opportunity to be a valuable contributor is available with Velico.

Our team is comprised of talented individuals who draw strength from a highly collaborative and dynamic environment. Based in Beverly, MA we are seeking a highly-motivated RA Specialist who wants to make an impact in the healthcare industry with our groundbreaking technology. We are seeking an individual who has a knack for technology, exceptional communication and training skills who is excited for the opportunity to support the introduction of an innovative, lifesaving technology in the field of transfusion medicine.

Velico Inc. is preparing to launch FrontlineODP™ (On Demand Plasma), a system for spray drying plasma. Spray dried plasma will change the way hemorrhagic trauma is treated by Emergency Medical Services, Hospitals and the military. Velico's mission is to eliminate preventable death from bleeding. This is a rare opportunity to help drive the introduction and adoption of a true innovation in transfusion medicine and trauma care, that could result in saving thousands of lives each year.

Velico is seeking a Regulatory Affairs (RA) Specialist to join our Product Development team who will report to the Vice President of Commercial Operations. The RA Specialist is responsible for supporting the development of the FrontlineODP™ System, a Class III medical device for manufacturing a spray dried plasma product. The RA Specialist will be ensuring compliance with regulatory requirements for medical device, biologics, and drugs in the U.S. as well as developing and authoring regulatory documents for a PMA submission. Interested candidates will be contributing with documentation, as well as, vendor sourcing and approvals, quotes, logistics, managing studies, etc..

The RA Specialist will work cross functionally for the development of single use components per USP/medical device/blood product requirements, conducting stability studies, supporting the execution of Phase I clinical trial, and writing Regulatory submission reports for a PMA submission.

We are seeking candidates with:

- BS or MS in Science, Engineering, or related discipline
- Minimum of 4 years of medical device experience, or advanced degree with a minimum of 2 years medical device experience
- Critical data analysis, problem solving and data interpretation skills
- Excellent verbal and written communication, organizational and technical writing skills
- Proficient in Microsoft Office Suites (e.g., Word, Excel, PowerPoint)
- Works effectively in a small company environment, as well as, self-directed with proven skill to work independently, as well as a part of a cross functional team.
- Proven skill sets that demonstrate initiative, productivity, being team focused, accountable, and adaptable to changing needs in a fast-paced environment
- Experience working with drug programs, biologics, or medical devices needed
- Work with blood products or transfusion products, is a plus

Candidates must possess:

- Excellent verbal and written communication skills, including providing successful presentations.
- Exceptional interpersonal skills and fosters strong positive working relationships.
- Skills to effectively work independently on a variety of projects and as part of a collaborative team in a fast-paced, entrepreneurial environment with a high degree of multi-tasking and prioritizing multiple projects/tasks meeting expected deadlines.
- Task-oriented with strong organizational and attention to detail skills.
- Demonstrated skills to work cross-functionally within the organization and with external customers and vendors.
- Strong analytical and problem-solving skills.
- A strong sense of pace and urgency to ensure work is completed in the expected timelines.
- Process and improvement focused skills to implement new procedures to accommodate growth.
- Promotes and fosters a positive behaviour and work environment.
- Adept at interacting with diverse groups of people.

We are seeking candidates who thrive in a small organization with a "roll-up your sleeves" attitude to better the business, its' customers and team. The right person will perform the responsibilities listed above but must also help the company shape and define our Blood Center Education Program (BCEP).

Velico benefits includes health, dental, vision, short and long-term disability & life insurance, 401k with employer match, vacation time, sick/personal time and paid holidays.

Interested candidates are to send their resume, cover letter and salary requirements to: info@veli.co

Salary is commensurate with experience.