

Job Title	Project Manager, Systems Engineering
Reports to Title	VP Hardware Engineering and QA
General Accountability	<p>Our mission is to Profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate tissue with precision; a tomorrow where patients have access to safe and effective treatment options, so they can quickly return to their daily lives. Changing the standard of care is part of our fabric. We are a group of energetic, problem-solvers focused on innovation, and looking to change the world. We are changing the paradigm for treating diseases such as prostate cancer by using real-time MR Imaging, thermal ultrasound and close-loop temperature feedback control, to gently ablate the diseased tissue with minimal side effects.</p> <p>If you share our values and want to work in a collaborative results focused culture and want to make a Profound impact in healthcare and your career, here is your chance.</p> <p>This role is responsible for the systems engineering team in Toronto as well as some systems/service resources in the Unites States and EU. The system engineering team is accountable for verification and validation of new projects and maintenance of compatibility with internal and external changes and software releases. Of particular importance is developing new and maintain existing compatibility between Profound’s TULSA-PRO and various MRI systems from GE, Siemens and Philips.</p> <p>This role leads the system team in developing and executing V&V plans, maintaining alignment of team members to plan objectives and milestones to ensure delivery.</p>
Duties and Responsibilities	<ul style="list-style-type: none"> ▪ Overall responsibility for the planning and execution of V&V projects from initiation to commercial release. ▪ Liaise with external MRI OEM representatives to develop and maintain compatibility with TULSA-PRO and remain ahead of new MRI hardware and software upgrades. ▪ Prepare and present status updates and annual report for senior management as requested. ▪ Work cross-functionally (with Hardware, Software, Regulatory Compliance, Operations, Clinical, Sales and Marketing) to drive projects forward and provide optimal value to the organization. ▪ Develop and Maintain a Requirements Traceability system. ▪ Manage the System Engineers. Prioritize work based on business needs, skill set match and resource loading; guides and trains as required. Responsible for performance reviews and career development. ▪ Provides estimates of schedule, tools and equipment required for project activities and ensures that they are requisitioned in a timely fashion. ▪ Organizes test site access, site contracts and usage costs. ▪ Acts as a technical leader and expert resource for other departments; Marketing, Product Development, Project

	<p>Management, and Manufacturing to achieve company strategy and development goals.</p> <ul style="list-style-type: none"> ▪ Participate in the generation of System requirements and specifications ▪ Participate in or lead phase exit reviews by providing expertise in Verification and validation activity. ▪ Follow the company's Design Control Procedure ▪ Develop test methods for getting test agencies approvals and work with the test agencies to qualify products ▪ Ensure that product complaints and other quality events are investigated (including the root cause analysis) in a timely fashion and create plans for remediation.
Competencies	
Education	University degree in Engineering or Science
Key Attributes (experience, skills and technical knowledge)	<p>Required:</p> <ul style="list-style-type: none"> ▪ 5-10 yrs. experience leading development or systems teams. ▪ Ability to thoroughly document and summarize all aspects of testing efforts. ▪ Detail-oriented ▪ Knowledge of medical device standards. ▪ Experience with JIRA Atlassian or similar issue tracking system. ▪ Interest in applications of engineering in medicine. ▪ Able to work well in teams and independently. ▪ Understanding of MRI physics. ▪ Excellent problem solving and troubleshooting skills. ▪ Excellent verbal and written communication skills. ▪ MS Office (Word, Excel, PowerPoint), MatLab. ▪ Valid passport for travel to United States and Europe. <p>Desirable:</p> <ul style="list-style-type: none"> ▪ MRI console operation experience. ▪ Device-compatibility testing with MRI. ▪ Medical device requirement traceability management experience ▪ MR-sequence development. ▪ Experience working with MR compatible devices and/or therapeutic ultrasound devices. ▪ Excellent presentation skills. ▪ Experience interacting with all levels of an organization including leadership teams. ▪ Electrical/RF engineering for MRI compatible electrical devices is an asset. ▪ Experience working within a formal quality system (ISO 13485 preferred) ▪ Familiarity with IEC-60601 is an asset