PROFOUND	**JOB DESCRIPTION – QUALITY ASSURANCE AND REGULATORY AFFAIRS SPECIALIST**

Description	
Job Title	Quality Assurance and Regulatory Affairs Specialist – up to 6 month contract. Possible opportunity for a full-time position
Reports to Title	Quality Assurance Manager (Primary) and VP Regulatory Affairs and Product Management (Secondary)
General Accountability	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. If you want to make a Profound impact with your career, while making a difference in other people's lives, here is your chance. Responsible for activities for a legal manufacturer of class II and III medical devices. Activities include regulatory submissions, registrations and listings, globally. Assure compliance with applicable medical device regulations, guidance and standards for jurisdictions where devices are marketed. Assist in creation and maintenance of documents required to demonstrate compliance to medical device regulations.
Duties and Responsibilities	1. Write, analyze, and edit technical documents to support country-specific regulatory submissions and compile submissions in a format consistent with applicable guidance documents. Work with internal and external stakeholders ensure regulatory submission are of high quality. 2. Maintain regulatory files. Maintain and update regulatory authorizations, such as IDEs, 510(k)s, Canadian medical device licenses, and CE dossiers for EU, etc. Assure that appropriate maintenance of registrations occurs including renewals, device listings, site registrations, supplements for changes and annual reports. Support approval in other regions as required. 3. Assist in preparing responses to regulatory authorities' questions within assigned timelines. 4. Stay abreast of regulatory procedures, guidance documents, standards, and changes in regulatory climate. 5. Assess device related complaints for medical device reporting requirements. Compile and submit reportable events to relevant regulatory authorities in a timely manner. Handle recalls and field actions, if required. Review and approve complaint files. 6. Review product labels and review promotional material for compliance with applicable regulations and technical standards. Maintain product UDI listings in country-specific databases. 7. Support external regulatory agency audits, providing regulatory input to minimize potential for findings of non-compliance.

	8. Assess and document regulatory impact of product design changes in jurisdictions where product is licensed. Participate in design projects as an independent reviewer. 9. Review and approve product change orders and deviations, considering regulatory impact of proposed changes. 10. Participate in post-market surveillance activities for licensed products. 11. Assist in fulfilling requirements of the Person Responsible for Regulatory Compliance under the EU MDR 2017/745. 12. Maintain QMS procedures related to regulatory responsibilities, product licensing, and regulatory reporting. 13. Participate in internal audit program. 14. Support other projects, as required.
Competencies	
Education	Bachelor's degree or country equivalent in Engineering, Science, related scientific discipline, or equivalent. Higher degree will be an advantage
Certifications	RAPS certification, preferred
Key Attributes (experience, skills and technical knowledge)	▪ Minimum of 2 years regulatory or equivalent experience within a medical device organization ▪ Documented training on current medical device standards and regulations is an asset (e.g. MDSAP, EU MDR, ISO 13485, etc.) ▪ Scientific knowledge, must be able to digest complex data while keeping the big picture through good analytical skills ▪ Excellent written and Verbal communication skills with the ability to listen, articulate and advocate ▪ Proactive, high performance, result oriented and manage projects with ethical integrity ▪ Technical system skills (e.g. MS office applications, databases, efficient online research) ▪ Manage multiple projects and deadlines ▪ Ability to identify compliance risks and escalate when necessary ▪ Demonstrate both creative and critical thinking skills