PROFOUND MEDICAL	**JOB DESCRIPTION – Regulatory Affairs Specialist**

Description	
Job Title	Regulatory Affairs Specialist
Reports to Title	VP Regulatory and Clinical Affairs
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, here is your chance. Responsible for regulatory submissions of class II and III medical devices, globally. Assure compliance with applicable medical device regulations, guidance and standards per jurisdiction where device is marketed. Assist in creation and maintenance of documents required for the regulatory compliance.
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, including investigational device submissions in the USA, Canada, Europe and other countries, as required. Work with other departments and communicate the submission requirements when documents are needed for regulatory submission. 2. Maintain regulatory files. Maintain and update regulatory authorizations, such as IDEs, 510(k)s, Canadian medical device licenses, and CE dossiers 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 response to regulatory authorities questions within assigned timelines. 4. Stay abreast of regulatory procedures and changes in regulatory climate. 5. Assess device related incidents/complaints for medical device reporting requirements. Compile and submit reportable events to relevant regulatory authorities in timely manner. Handle recalls and field actions, if required. 6. Review and create product labels and review promotional material for compliance with applicable regulations and technical standards. 7. Support external regulatory agency audits, providing regulatory input to minimize potential for findings of non-compliance. 8. Assist in preparing clinical trial site ethics review board applications for investigational device trials. Prepare interim or final reports for trial site ethics boards as required

	9. Other duties as assigned.
Competencies	
Education	Bachelor's degree or country equivalent in Engineering or Science or related scientific discipline, or equivalent. Higher degree/Masters will be an advantage
Certifications	RAPs certifications, preferred
Key Attributes (experience, skills and technical knowledge)	▪ Minimum of 5 years regulatory or equivalent experience within a device or pharmaceutical company, CRO, or similar organization ▪ Ability to research and interpret device related regulations, standards and guidance and communicate with internal stakeholders for an adequate and timely implementation ▪ 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