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

Description	
Job Title	Regulatory Affairs Specialist
Reports to Title	Quality Assurance / Regulatory Affairs Manager
General Accountability	Responsible for regulatory affairs activities to assist in regulatory submission, annual reports, registrations and listings. Assure compliance with applicable medical device regulations per jurisdiction, guidance and standards. Assist in creation and maintenance of regulatory files.
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 USA, Canada and Europe. 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 for EU, NRTL certifications 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/PhD will be an advantage

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Certifications	RAPs certifications, preferred
Key Attributes (experience, skills and technical knowledge)	▪ Minimum of 2 years regulatory or equivalent experience within a device or pharmaceutical company, CRO, or similar organization ▪ 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