

<i>Description</i>	
<b>Job Title</b>	Regulatory Affairs Specialist
<b>Reports to Title</b>	VP Regulatory Affairs & Product Management
<b>General Accountability</b>	<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. If you want to make a Profound impact with your career, while making a difference in other people’s lives, here is your chance.</p> <p>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.</p>
<b>Duties and Responsibilities</b>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. Assist in preparing response to regulatory authorities’ questions within assigned timelines.</li> <li>4. Stay abreast of regulatory procedures, guidance documents, standards, and changes in regulatory climate.</li> <li>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.</li> <li>6. Review and create product labels and review promotional material for compliance with applicable regulations and technical standards.</li> <li>7. Support external regulatory agency audits, providing regulatory input to minimize potential for findings of non-compliance.</li> <li>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.</li> <li>9. Assess and document regulatory impact of product design changes in jurisdictions where product is licensed. Participate in design projects as an independent reviewer.</li> </ol>

	<ol style="list-style-type: none"> <li>10. Review and approve product change orders and deviations, considering regulatory impact of proposed changes.</li> <li>11. Participate in post-market surveillance activities for licensed products.</li> <li>12. Assist in fulfilling requirements of the Person Responsible for Regulatory Compliance under the EU MDR 2017/745.</li> <li>13. Other duties as assigned.</li> </ol>
<b>Competencies</b>	
<b>Education</b>	Bachelor’s degree or country equivalent in Engineering, Science, or related scientific discipline, or equivalent. Higher degree/Masters will be an advantage
<b>Certifications</b>	RAPS certification, preferred
<b>Key Attributes (experience, skills and technical knowledge)</b>	<ul style="list-style-type: none"> <li>▪ Minimum of 5 years regulatory or equivalent experience within a medical device company or similar organization</li> <li>▪ Ability to research and interpret device related regulations, standards and guidance and communicate with internal stakeholders for an adequate and timely implementation</li> <li>▪ Scientific knowledge, must be able to digest complex data while keeping the big picture through good analytical skills</li> <li>▪ Excellent written and Verbal communication skills with the ability to listen, articulate and advocate</li> <li>▪ Proactive, high performance, result oriented and manage projects with ethical integrity</li> <li>▪ Technical system skills (e.g. MS office applications, databases, efficient online research)</li> <li>▪ Manage multiple projects and deadlines</li> <li>▪ Ability to identify compliance risks and escalate when necessary</li> <li>▪ Demonstrate both creative and critical thinking skills</li> </ul>