

<b>Description</b>	
<b>Job Title</b>	Mechanical Developer
<b>Reports to Title</b>	Mechanical Engineering Manager
<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, here is your chance.</p> <p>This position is for a seasoned mechanical developer with at least 5 years' experience designing medical devices or other similar instruments. This mechanical developer would own the design and future development of the ultrasound applicator device and other future treatment-delivering devices. The mechanical developer would seek input from customers, sales and marketing, and manufacturing and use it to drive future design of devices in such a way that maximizes value by improving manufacturability, usability and quality while reducing costs. The mechanical developer is expected to show great technical leadership, to take part in project management and to interact with and answer directly to the various stakeholders.</p>
<b>Duties and Responsibilities</b>	<p>Duties and responsibilities will include (but are not limited to):</p> <ol style="list-style-type: none"> <li>1. Analyze user needs and generate requirements for the company's disposable products</li> <li>2. Create design specifications for the mechanical aspects of the company's products</li> <li>3. Create aesthetic, functional, and reliable product designs</li> <li>4. Review existing product design, identify weaknesses and propose improvements</li> <li>5. Analyze mechanical designs</li> <li>6. Build early concepts of new designs and prototypes</li> <li>7. Design and build fixtures for product manufacturing and testing</li> <li>8. Create strategy for the verification of the design, and participate in verification activities as required</li> <li>9. Produce DHF and DMR documentation for transfer to test/manufacturing</li> <li>10. Support in-house production as needed</li> <li>11. Interact with customers, marketing, and sales as required to capture user needs and look for opportunities to improve products</li> <li>12. Investigate product complaints at clinical/customer sites, perform root cause analysis of failures, and propose remediation in a timely fashion</li> <li>13. Develop clinical workflow, author content for the user manual, incorporate human factors into designs and train other employees on product use</li> </ol>

	<p>14. Contribute to risk management content such as FMEA, PFMEA and hazard analysis</p> <p>15. Perform all duties in compliance with the quality management system; actively contribute to the continuous improvement of the QMS</p> <p>16. Perform project engineering roles as needed.</p>
--	---

<b>Competencies</b>	
<b>Education</b>	Mechanical Engineering or similar undergraduate degree
<b>Certifications</b>	None
<b>Key Attributes (experience, skills and technical knowledge)</b>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>▪ A minimum of 5 years of experience designing medical devices or similar high-technology instrumentation.</li> <li>▪ At least 1 year experience in designing and developing catheter, guide wire, needle-type or similar medical products and processes.</li> <li>▪ In depth knowledge of manufacturing processes such as injection molding, urethane casting, extruding, coating etc.</li> <li>▪ Competency in mechanical analysis skills such as solid and fluid dynamics, heat transfer, material strength</li> <li>▪ Hands-on experience working with epoxy for gluing, sealing, coating</li> <li>▪ Extensive knowledge of SolidWorks</li> <li>▪ Excellent drafter</li> <li>▪ Excellent verbal and written skills. Ability to quickly, clearly, and concisely communicate.</li> <li>▪ Mechanical aptitude including ability to use common shop tools and measurement equipment</li> <li>▪ Tenacious problem solver, organized, detail oriented</li> <li>▪ Knowledge of medical device standards such as IEC-60601-1, ISO 10993</li> <li>▪ Demonstrated ability to translate user needs into design specifications</li> <li>▪ Demonstrated ability to troubleshoot problems and perform root cause analysis</li> <li>▪ Demonstrated ability to communicate with customers and with all employees of the company.</li> <li>▪ Knowledge of ASTM standards and testing methods</li> </ul> <p><b>Desired:</b></p> <ul style="list-style-type: none"> <li>▪ Experience working with MR compatible devices and/or therapeutic ultrasound devices.</li> <li>▪ Knowledge of finite-element analysis</li> <li>▪ Working knowledge of industrial design</li> <li>▪ Experience with statistical analysis</li> <li>▪ Experience working with sterilization and disinfection methods</li> </ul>