

Description	
Job Title	Manufacturing Engineer
Reports to Title	Global Director Manufacturing
General Accountability	<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>Support and drive improvements in the manufacturing of medical devices at Profound Medical.</p> <p>Minimize costs and sustain the product through its lifecycle.</p> <p>Continuously strive to increase the product reliability and quality of the products thru working with engineering.</p> <p>Transfer revision updates and new electromechanical designs of medical devices to manufacturing operations (in house and contract manufacturers).</p>
Duties and Responsibilities	<ol style="list-style-type: none"> 1. Oversee the manufacturing processes of assembling medical devices to ensure workflows are smooth and efficient; 2. Design, document, and provision the manufacturing processes for ramping production; 3. Collaborate with design engineers to implement “design for manufacturing”. Participate in Design for Manufacturing/Testability/Reliability reviews; 4. Design/fabricate or select tooling, automation, and test equipment for the manufacturing processes; 5. Establish control and calibration procedures and protocols for tooling, automation, and test equipment to ensure that procedures and protocols are followed to deliver a quality product; 6. Establish process control points in the manufacturing process and establish testing requirements and procedures; develop and ensure maintenance of statistical controls; 7. Train and support production technicians on the day-to-day manufacturing to establish and maintain a smooth and efficient workflow; 8. Identify and collaborate with suppliers of outsourced parts, assemblies, and products. Support the resolution of obsolescence and pertinent quality issues; 9. Participate in Corrective Action and Preventative Action Teams, lead product failure investigations both internally and externally, and design and perform “design of experiments” techniques to establish root cause failure modes; 10. Assist in validation and verification of production processes and

	<p>manage validation resources, prepare and present validation and verification reports to meet ISO 13485 requirements;</p> <ol style="list-style-type: none"> 11. Adhere to and support all ISO 13485 guidelines, support audits, and ensure product compliance to all applicable agency codes; 12. Recommend/evaluate/implement opportunities for continuous process and product improvement and lead “Lean Manufacturing” initiatives to improve production rates, reduce costing, and improve quality of output; 13. Support EHS activities and initiatives to comply with safety regulations; 14. Support any other initiatives or projects as requested
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Competencies	
Education	Bachelor’s degree in Engineering and minimum 3 years relevant experience. Experience with design and testing of electromechanical systems preferred.
Certifications	None
Key Attributes (experience, skills and technical knowledge)	<ol style="list-style-type: none"> 1. Exposure to ISO 9001 quality system minimum. Preferred, exposure to ISO 13485 standard; 2. Employs a results-oriented work style and teamwork-oriented approach to meeting objectives; 3. Demonstrates the ability to prioritize duties, multi-task, and quickly assume new tasks to function productively in a fast-paced environment; 4. Proven ability to establish working relationships with design engineers, operators, and QA personnel. 5. Strong communication skills, written and oral. 6. Possess excellent attention to detail to ensure accuracy; 7. Able to travel infrequently, as required. 8. Ability to interpret technical drawings, dimensions, tolerances, etc. 9. Ability to interpret circuit schematics. 10. Proven ability to design manufacturing tests of subassemblies, electrical and mechanical. 11. Knowledge of test software such as LabView.