

<b>Description</b>	
<b>Job Title</b>	Quality Control Technician
<b>Reports to Title</b>	Global Director Manufacturing
<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. We are changing the paradigm for treating diseases such as prostate cancer by using real-time MR Imaging, thermal ultrasound and close-loop temperature feedback control, to gently ablate the diseased tissue with minimal side effects.</p> <p>If you share our values and want to work in a collaborative results focused culture and want to make a Profound impact in healthcare and your career, here is your chance.</p> <p>Support the Manufacturing and Quality department as required in all aspects of quality control, quality assurance and regulatory compliance activities.</p>
<b>Duties and Responsibilities</b>	<ol style="list-style-type: none"> <li>1. Provide support to manufacturing and purchasing through receiving, FAI, and inspection of incoming material for conformance to product specification, purchasing specifications, Food and Drug Administration GMPs and ISO 13485;</li> <li>2. Perform timely First Article Inspections and Incoming Inspections using mechanical and measuring equipment to ensure conformance to part/product specifications and requirements;</li> <li>3. Document failures thru the NCR process and root cause. Communicate and resolve failures with Suppliers as applicable;</li> <li>4. Write, review, improve, and create Incoming Inspection plans, first article inspection plans, work instructions, procedures, and special instructions as required based on experience executing plans, NCR results, Corrective Actions and Preventive Actions;</li> <li>5. Perform supplier evaluation through data collection of inspection results. Manage and Monitor Supplier Quality. Review and approve new Suppliers;</li> <li>6. Print labels for manufacturing;</li> <li>7. Review process Device History Records;</li> <li>8. Trend production quality metrics;</li> <li>9. Develop and maintain an incoming inspection lab, associated equipment and facility.</li> <li>10. Maintain control of equipment requiring calibration and preventive maintenance. Coordinate calibration of equipment with</li> </ol>

	<p>manufacturing engineers and procurement team. Coordinate preventive maintenance work with manufacturing engineers;</p> <ol style="list-style-type: none"> <li>11. Prepare and review shipment of product to sterilization;</li> <li>12. Assist in In-process/Final Inspection as required;</li> <li>13. May be required to do special testing, engineering support work, and other quality control and quality assurance activities;</li> <li>14. Actively support quality control and continuous improvement through participation in engineering changes and other improvement programs;</li> <li>15. Adhere to and support the Quality Policy as well as all ISO-13485 Quality System procedures and guidelines;</li> <li>16. Support Lean activities and initiatives;</li> <li>17. Support EHS activities and initiatives;</li> <li>18. Perform other duties/special projects as assigned.</li> </ol>
<b>Competencies</b>	
<b>Education</b>	College or University Degree or at least 3 years of experience with inspecting parts using measurement equipment in an ISO 9001 environment;
<b>Certifications</b>	None
<b>Key Attributes (experience, skills and technical knowledge)</b>	<ol style="list-style-type: none"> <li>1. Exposure to ISO 9001 quality system minimum. Preferred, exposure to ISO 13485 standard;</li> <li>2. Ability to read and understand part drawings and written specifications;</li> <li>3. Ability to interpret technical drawings, dimensions, tolerances, etc;</li> <li>4. Ability to interpret circuit schematics;</li> <li>5. Employs a results-oriented work style and teamwork-oriented approach to meeting objectives;</li> <li>6. Demonstrates the ability to prioritize duties, multi-task, and quickly assume new tasks to function productively in a fast-paced environment;</li> <li>7. Proven ability to establish working relationships with design engineers, sustaining engineers, manufacturing engineers, production technicians, procurement team, QC personnel, and QA personnel;</li> <li>8. Strong communication skills, written and oral;</li> <li>9. Possess excellent attention to detail to ensure accuracy.</li> </ol>