| PROFOUND | **JOB DESCRIPTION – Document Control Specialist – 1 year contract** |
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| ***Description*** | |
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| **Job Title** | Document Control Specialist – 1 year contract |
| **Reports to Title** | Quality Assurance Manager |
| **General Accountability** | 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.<br><br>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.<br><br>Support the Quality department through control of documents and records required in all aspects of quality control, quality assurance and regulatory compliance activities. |
| **Duties and Responsibilities** | 1. Control and maintain quality system documentation in accordance with internal procedures and external regulatory standards and guidance.<br>2. Administrator for all document and product change orders. Review submitted change orders for completion and work with other departments as required to ensure timely review of changes. Organize and run weekly Change Control Board (CCB) meetings and manage meeting action items.<br>3. Ensure that all employees are familiar with and follow document control procedures and good documentation practices. Perform training on these activities for new employees.<br>4. Control and maintain current version of Device Master Record documents on the production floor.<br>5. Organize and store quality records, enabling timely retrieval when necessary.<br>6. Create and revise company documents as requested.<br>7. Administrator for customer complaints, including monitoring open complaints, ensuring timely completion of investigations and action items, and reviewing complaint records for completion.<br>8. Stay abreast of new regulatory procedures, guidance documents, and standards. Manage external document listing and the process for changes to those documents.<br>9. Participate in 3rd party audit and inspection activities (ISO, Notified Body, FDA, Health Canada, etc.).<br>10. Participate in the Internal Quality Audit program and conduct audits as needed.<br>11. Other duties as assigned. |

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| ***Competencies*** | |
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| **Education** | University or College degree, preferably in sciences or quality/ regulatory |
| **Certifications** | None required |
| **Key Attributes (experience, skills and technical knowledge)** | ▪ Minimum 1 year medical device experience; or equivalent combination of education and experience.<br>▪ Knowledge of device standards and regulations such as ISO 13485, FDA Quality System Regulation, EU Medical Device Regulations, Canadian Medical Device Regulations.<br>▪ Language Skills: Ability to read, analyze and interpret common business documents. Ability to communicate clearly to personnel in other departments. Ability to write well. Ability to effectively present information to colleagues and management.<br>▪ Excellent knowledge of Microsoft Office applications such as Word, Excel, Power Point, Visio, etc.<br>▪ Organized, detail-oriented, and able to multi-task and prioritize responsibilities.<br>▪ Experience in engineering and manufacturing environments preferred.<br>▪ Experience in quality audits preferred. |