PROFOUND	**JOB DESCRIPTION – QUALITY SYSTEM COORDINATOR – 1 YEAR INTERNSHIP**

Description	
Job Title	Quality System Coordinator 1 year Internship – Vantaa, Finland
Reports to Title	Senior Quality and Regulatory Specialist
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. 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. Support the Quality/Regulatory department as required in all aspects of quality control, quality assurance and regulatory compliance activities.
Duties and Responsibilities	1. Stay up-to-date and follow procedures related to the job. 2. Assist with monitoring and maintenance of the applicable procedures and instructions. 3. Assist with design transfer to manufacturing, including quality control activities from production processes to shipment of the final product. 4. Participate in equipment qualification activities. 5. Control and maintain current version of Device Master Record documents on the production floor. 6. Manage the equipment calibration program, including preventive maintenance and tracking of facility maintenance. 7. Provide support for the supplier management program. Evaluate suppliers, monitor supplier quality issues, and coordinate failure investigations and supplier corrective action requests in a timely manner. Create reports on supplier performance. 8. Administrator of non-conforming product reports. Control movement of non-conforming product and ensure adequate investigation and reports are documented as per non-conforming products procedure. 9. Perform inspection of finished devices to ensure conformity with the quality management system and applicable regulatory requirements before a device is released. 10. Review, maintain and archive Device History Records. 11. Handle customer returns according to Return Goods procedure.

	12. Track manufacturing data metrics such as yield rates, failure modes, and scrap rates. 13. Support Internal Quality Audits audit program and conduct audits, as needed. 14. Participate in and support 3rd party audits and inspections (ISO, Notified Body, Health Canada, FDA, etc.) 15. Other duties as assigned.
Competencies	
Education	Bachelor's degree or country equivalent in Engineering, Science, related scientific discipline, or equivalent. Higher degree will be an advantage.
Certifications	None required
Key Attributes (experience, skills and technical knowledge)	▪ Minimum 3 years medical device experience; or equivalent combination of education and experience. ▪ Knowledge of device regulations and its applications such as FDA QSR, International Standards i.e. ISO 13485; EU Medical Device Regulation (MDR), Canadian Medical Device Regulations (CMDR). ▪ Language Skills: Ability to read, analyze and interpret common business documents. Ability to respond to inquiries or complaints from customers, suppliers, and business partners. Ability to write well. Ability to effectively present information to management. ▪ Excellent knowledge of Microsoft Office applications such as Excel, Power point, Visio, Word, Access, etc. ▪ Organized, detail-oriented, and able to multi-task and prioritize responsibilities. ▪ Experience in engineering and manufacturing environments preferred. ▪ Methodical, neat and clean work habits. ▪ Strong attention to details. ▪ Experience in quality audits preferred.