PROFOUND MEDICAL

JOB DESCRIPTION – QUALITY SYSTEM SPECIALIST

Description	
Job Title	Quality System Specialist
Reports to Title	Manager Quality Assurance
General Accountability	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. Control and maintain current version on Device Master Documents on the production floor. 4. Oversee generation and maintenance of Design History Files and ensure compliance to applicable regulations. 5. Participate in risk management meetings and related activities such as verification of risk mitigation implementation in products and processes. 6. Provide support for the supplier management program. Evaluate suppliers, monitor supplier quality issues, and coordinate failure investigations in a timely manner. Create reports on supplier performance. 7. Assist with design transfer to manufacturing, including quality control activities from production processes to shipment of the final product. 8. Participate in process validation activities. 9. Participate in documentation and investigation of customer complaints. 10. Perform product inspections to specified requirements. 11. Review, maintain and archive Device History Records. 12. Handle customer returns according to Return Goods procedure. 13. Handle nonconforming products, documentation and reports as per current Non-Conformance procedure. 14. Conduct Internal Quality Audits and support the audit program as needed. 15. Other duties as assigned.

Competencies	
Education	University or College degree, preferably in sciences or quality/ regulatory
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 13485:2003, ISO 14971:2000; Medical Devices Directive (MDD), 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.