PROFOUND MEDICAL Inc.	**JOB DESCRIPTION – Quality Engineer**

Description	
Job Title	Quality Engineer
Reports to Title	Manager QA RA
General Accountability	Applies engineering principles to address product and process issues, ensure reliable new and/or changed product development, lead investigations, and provide general support of the quality system. Works on a wide range of quality problems related to Product and Process Quality, including Supplier Management
Duties and Responsibilities	• Stay up-to-date and follow all Quality System procedures, which can affect the quality of products or services provided to our customers. • Work closely with design team in considering manufacturability, reliability and testability of products. • Support prototype activities of new products for quality and efficiencies as well as inspection and test activities • Lead development of D-FMEAs and P-FMEAs • Works with R&D and Manufacturing Teams to ensure that manufacturing and design documentation is accurate, complete, and fully conforms to specifications/procedures, including approval of verification and validation deliverables. • Provide manufacturability feedback for improvement of product design, processes, and final installation of product • Apply engineering principles/methods to manage and document product failures/quality investigations including driving to root cause and corrective action. • Apply risk analysis methodology for both new design and product/process changes. Conduct and lead risk management process by utilizing tools such as FMEAs, Hazard Analyses, Control Plans, and Risk Management Plans/Reports etc. • Provide input/support for development of new product design and product/process changes. Support development of test/evaluation test protocols. • Establish requirements placed on suppliers. Contribute to generate and update inspection instructions for purchased parts. • Participate in Change Control Board meetings. Assess impact of change orders on quality deliverables. • Manage all aspects of complaint investigations, including application of statistical methods and analysis and trending of complaint data as a vehicle for ensuring effectiveness of corrective action(s). • Develop quality metrics for product realization, customer complaints, and product repairs. Report to the management on these metrics. Initiate corrective or preventative actions as required.

	• Must work effectively both independently and within a multi-functional team (eg. R&D, Clinical, Regulatory, Manufacturing, Marketing and Customers) to resolve manufacturing issues or field complaints. • Provides support in the evaluation and management of supplier quality. • Supports internal/external audits/assessments.
Competencies	
Education	Bachelor's degree in Engineering or Science and minimum 5 years device experience; or equivalent combination of education and experience. Experience with design and testing of electromechanical systems preferred
Certifications	ASQ or equivalent Certification preferred
Key Attributes (experience, skills and technical knowledge)	1. Knowledgeable in project planning, statistical analysis of Quality data, software validation, FDA QSR, International Standards i.e. ISO 13485, ISO 14971, Medical Devices Directive (MDD), Canadian Medical Device Regulations (CMDR). 2. Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram or schedule form. 3. Ability to work with mathematical concepts such as probability and statistical inference and fundamentals of plane and solid geometry and trigonometry. Ability to apply concepts such as fractions, percentages, ratios and proportions to practical situations. 4. Ability to read, analyze and interpret common scientific and technical journals, financial reports and legal documents. Ability to write comprehensive reports and articles for publication that conform to prescribed style and format.