JOB DESCRIPTION

Job Title: **Quality Engineer**

Department: **Quality**

Reports To: **Quality Assurance Department Head**

JOB SUMMARY:

The Quality Engineer is responsible for supporting manufacturing, receiving inspection, reviewing and analyzing complaint data, performing root-cause-investigations to establish corrective action plans and implement corrective actions, developing and performing test methods for product testing and investigations, writing and updating procedures as required to ensure the quality system is compliant with regulations including the FDA Quality System Requirements (QSR), ISO 13485, Canadian Medical Device Regulations (CMDR), and the Medical Devices Directive (MDD). Perform all job duties while adhering to HIPAA requirements.

Specific Duties and Responsibilities:

The Quality Engineer is responsible for the day to day support of the QMS and supporting Manufacturing. Will assist Quality management on specific tasks as assigned to facility the effectiveness of the Quality Management System. BrightWater Medical is a small start-up company and other tasks may be assigned as needed.

Job Qualifications

Leadership:

- Recognized as a technical leader within the company and engenders trust when working with customers or suppliers
- Capable of leading a Continuous Improvement Team, CAPA team, or working with a customer or supplier to resolve product quality issues
- Works effectively on cross functional teams to establish appropriate processes pertaining to quality

Communication

- Excellent written and oral communication skills
- Ability to formulate responses to common inquiries or complaints from customers and regulatory agencies
- Ability to review, analyze, summarize, and interpret data; draw conclusions and make appropriate recommendations and decisions; write reports; and give oral presentations

Minimum Education and Experience:

- BS or BA in Science or other technical field
- Minimum of 5 years of experience as a Quality Engineer in the medical device industry

Job Skills:

- Medical device Quality System Knowledge including 21CFR Part 820 (QSR) and ISO 13485, CMDR and MDD
- Demonstrated skills in statistical analysis
- Hands on approach
- Experience participating in internal and external audits
- Ability to work with multiple departments (e.g. Receiving Inspection, R&D, Operations, Regulatory) to optimize processes
- Experience with production support, complaint investigation, risk management, validations, CAPA, NCMR
- CQE preferred

Working Conditions *(OSHA requirement)*

This position is a full time position. The Quality Engineer is expected to be on site during normal business hours.

This position profile identifies the key responsibilities and expectations for performance. It cannot encompass all specific job tasks that an employee may be required to perform. Employees are required to follow any other job related instructions and perform job related duties as may be reasonably assigned by his/her supervisor.

The above statements are intended to describe the general nature and level of the work being performed by people assigned to this job. They are not an exhaustive list of all of the duties and responsibilities associated with it.

BrightWater Medical is an Equal Employment Opportunity and Employer

Document History

Document Title: Job Description Template				
DCO	**Revision**	**Description of Change (Revision History)**	**Released By:**	**Date**
1146	A	Initial Release	R MacKinnon	20161021
Document Owner: Quality Assurance				