Position Title:	Technical Writer (Medical Device)	Date: 02/22/2021	
Department:	Engineering	Job Status:	Full Time
Location:	Maryland	Travel Required:	10 to 20%
Field Territory:	N/A	FLSA	Exempt
Reports To:	VP of Product Development	Direct Reports:	N/A
Required:	N/A	Experience Required:	4yr Technical Writing
Objective of Position:	The Technical Writer is responsible for developing and writing various types of technical and user documentation including manuals, service bulletins, references, instructions, and technical reports for medical devices.		
Other position notes:	This position is full time (40 hrs/week) and reports the VP of Product Development.		

This job description is not designed to cover or contain a comprehensive listing of activities, duties, or responsibilities that are required of the employee

Job Description

Job Summary: Technical Writer – Medical Device

- Work closely with hardware and software engineers, subject matter experts, marketing managers, project managers, and legal regulatory professionals to establish technical specifications.
- Develop high-quality usable documents and artworks. The documents include the following types: User Guide, Service Manuals, Labelling, Packaging, On-line Help, Install and Support, Quick Reference Guide, and any other product specific ad hoc documents.
- Write clearly and concisely to meet the needs of the target audience.
- Develop and update technical documentation, for example design history files from information provided by engineers, project managers, and other team members.
- Maintain integrity of documents to comply with and be incorporated into the company's quality procedures.
- Create and follow all processes, style guides, templates, and brand guidelines.
- Actively participates as a member of cross-functional new product development teams to ensure compliance with design controls per ISO 13485 and FDA QSR.
- Understand and adhere to the company's Code of Ethical Conduct and ensure that personal actions, and the actions of employees supervised, comply with the policies, regulations, and laws applicable to the business.
- Maintain a professional and credible image with key physicians, consultants, suppliers, and co-workers.
- Perform other duties as assigned.

Essential Functions:

- Excellent written and verbal communications skills.
- Strong organizational skills, attention to detail and proofreading skills.
- Strong ability to interpret and disseminate relevant product information.
- Basic understanding of regulatory compliance for medical devices.
- Ensure all documents conform to FDA requirements for GMP/QSR and ISO13485.
- Support a work environment of continuous improvement that supports Galen's Quality Policy, Quality System and the appropriate regulations for the area supported.

Education Requirements:

- BS in biomedical engineering or related discipline required.

Experience Requirements:

- Minimum 4 years of experience as a medical or technical writer in a regulated environment (Medical Device preferred).

Skills/Qualifications/Competencies:

- Ability to stay organized and detailed oriented while managing multiple tasks.
- Professional experience writing technical documentation for both hardware and software in a regulated environment.
- Read and interpret engineering drawings, design and risk documents, software requirements, bill of materials, system and components specifications, assembly instructions, and test documentation.
- Strong understanding of ISO 13485, ISO 14971, FDA QSR - 21 CFR Part 820, FDA submissions – 510(k), De Novo, PMA, and Pre-Subs.
- Self-motivated, self-directed, and able to thrive in a fast-paced environment.
- Professional and positive approach, self-motivated, team player, creative with the ability to work on own initiative.
- Ability to work cross-functionally with a distributed team across Engineering, Design, Customer Success, Marketing and Business Development.

Physical Factors:

- The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Working Conditions:

- The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Unplanned Activities:

- Other duties as assigned.

Reviewed By (HR):		Date:	
Approved By (MGR)		Date:	
Last Updated By:		Date/Time:	