Position Title:	Product Development Engineer	Date:	
Department:	Engineering	Job Status:	Full Time
Location:	Maryland	Travel Required:	5 to 10%
Field Territory:	N/A	FLSA	Exempt
Reports To:	Director of Verification and Validation	Direct Reports:	N/A
Required:	N/A	Experience Required:	
Objective of Position:	The Product Development Engineer is responsible for product development activities throughout the design control process from concept to commercialization. The activities include product and test tool development, creating and maintaining DHF documentation, and developing and executing testing essential to the successful verification and validation of complex medical devices to meet patient, customer, and regulatory agency requirements.		
Other position notes:	This position is full time (40 hrs/week) and reports the Director of Verification and Validation.		

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: Product Development Engineer

- Work closely with manager and software and hardware teams to understand requirements, contribute to design activities, and develop associated test criteria and test procedures to demonstrate required V&V endpoints.
- Provide pre-verification testing support for device design and test method development.
- Collect and analyze data, generate summary reports, and review and document results.
- Maintain traceability between test reports and requirements, specifications, and failure modes analysis throughout design controls.
- Preform all aspects of product testing and execution within pre-specified program plans to support regulatory submissions (including documentation such as protocols, reports, statistical analysis, deviations, root cause investigations).
- Ensure that the product meets performance requirements, intended use, and user needs by conducting engineering tests, inspections, stability testing, human factors evaluations, and preclinical animal studies to evaluate individual components, subsystems, or the overall design.
- Build and maintain development medical devices, automated test equipment, and test tools.
- Establish and maintain schedules to meet critical milestones.
- Work with 3rd party vendors and cross-functionally to advance product development and testing.
- Conduct failure investigations/root cause analysis for issues identified during testing and development and summarize evaluations and results through written or oral presentations.
- 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:

- Write and maintain design history file documentation.

- Write test protocols, conduct feasibility, verification, and validation testing, and record results in a clear, concise, and compliant manner.
- Keep manager informed of all test failures and risks to testing or schedule.
- Assist in hands-on assembly, testing, and qualification of test fixtures and medical devices.
- Investigate and troubleshoot test failures, document findings, and propose solutions.
- Ensure all activities 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 Engineering or related discipline

Experience Requirements:

- Minimum 2 years of experience developing products or performing verification and validation testing under design controls or similar regulated environment (Medical Device preferred)

Skills/Qualifications/Competencies:

- Ability to stay organized and detailed oriented while managing multiple tasks.
- Experience writing design documentation and conducting testing in a compliant manner in a regulated environment.
- Understanding of statistical techniques and data analysis.
- Ability to condense complex requirements into specific and measurable test objectives.
- Read and interpret engineering drawings, design and risk documents, software requirements, bill of materials, system and components specifications, assembly instructions, and test documentation.
- Effective troubleshooting skills to isolate test failures/anomalies and recommend solutions.
- Excellent oral and written communication skills.
- Experience using automated test fixtures and test equipment.
- Knowledge of and ability to read and interpret engineering design and test standards (e.g. ISO 62366, ISO 10993, IEC 60601, IEC 62304, etc.).
- 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:	