

Galen Robotics Job Description

Position Title:	V&V Group Lead	Date:	
Department:	Product Development	Job Status:	Full Time Employee
Location:		Travel Required:	Approximately 10-20%
Field Territory:	N/A	FLSA:	Exempt
Reports To:	VP Product Development	Direct Reports:	N/A
Required:	N/A	Experience Required:	Product Engineering Management
Objective of Position:	The V&V Group Lead will be responsible for all aspects of the company's V&V activities. This is a hands-on position where the V&V Group Lead will be responsible for leading the verification and validation efforts providing technical direction, strategy, and mentoring to V&V group.		
Other position notes:	This position is full-time (40hrs/week) and reports to the VP Product Development.		
<i>This job description is not designed to cover or contain a comprehensive listing of activities, duties, or responsibilities that are required of the employee.</i>			
Job Description			
Job Summary: V&V Group Lead			
<ul style="list-style-type: none"> • Develop planning control of verification and validation activities. • Hire and direct staff to meet scheduled commitments. • Evaluating and understanding our current state of testing and driving change to increase test automation and improve our overall testing practices. • Developing test strategies for test automation and manual verification and external validation. • Develop the test development processes including: designs, reviews, implementations, and test execution. • Continuously improving testing methodology, best practices, and standards to provide consistent testing across products. • Work closely with other teams to build and maintain testing infrastructure and tooling. • Work collaboratively with others to drive best practices and reduce cost of SW V&V effort. • Assist engineering team in failure investigations/ root cause analysis for problems identified during lab testing and field issues. • Periodically review how the test strategy aligns with the latest available technologies and industry trends • Ensure that V&V testing is focused on meeting the customer requirements. • Write test reports that summarize the compilation and analysis of basic reliability data from field studies. • Need to clearly articulate design verification and stability process concepts to the business community through written and oral presentations. • Ensure that personal actions, and the actions of employees supervised, comply with the policies, regulations and laws applicable to the business. • 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:			
<ul style="list-style-type: none"> • Ensure all activities conform to FDA requirements for GMP/QSR and ISO13485. 			

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- Support a work environment of continuous improvement that supports Galen’s Quality Policy, Quality System and the appropriate regulations for the area supported.
- Provide direction for improving the customer experience.

Education Requirements:

Minimum BS in Engineering, Software preferred, 6 years of industry engineering experience

Experience Requirements:

Minimum 3 plus years related experience in the medical device industry.

Skills/Qualifications/Competencies:

- Demonstrated team building and leadership skills.
- Working knowledge of engineering design and test standards (e.g. IEC 60601, IEC 62304, etc.)
- Strong track record of independently analyzing test data and assessing compliance with performance requirements.
- Effective troubleshooting skills to isolate test failures/anomalies and to develop recovery action plans.
- Computer skills sufficient to retrieve, manipulate, analyze, interpret, and present data.
- Knowledge of FDA design control requirements
- Demonstrate ability to condense complex requirements into specific and measurable test objectives.
- Professional and positive approach, self-motivated, team player, creative with the ability to work on own initiative.
- Demonstrated strong oral and written communication skills.
- Proven leadership capabilities including strategy development, effective decision making, and the ability to drive results.
- Self-motivated, self-directed, and able to thrive in a fast-paced environment.
- 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:	