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Job Description: Sustaining Engineer Cala Health, Inc.

About Cala Health

Cala Health is a world-class medical technology team creating breakthrough devices that are designed first and foremost for the patients that depend on us every single day. Together we are pioneering a new class of electrical medicine called neuroperipheral therapy™. Neuroperipheral therapy treats chronic disease non-invasively, without drugs or surgery, by stimulating peripheral nerves with body-worn electronics. Merging innovations in neuroscience, electronics, and medical devices, Cala Health has recruited experts across these fields to develop new therapies for patients. The company was spun out of Stanford University and we are venture backed by leading investors in technology and healthcare, including Johnson & Johnson, GV, dRx Capital (Novartis/Qualcomm joint investment), Lightstone Ventures, Lux Capital, and Action Potential Venture Capital (GlaxoSmithKline).

The Opportunity

Cala Health is seeking a Sustaining Engineer to join our growing team. The role will report to the Director of Hardware Engineering and is responsible for driving continuous improvements to the expanding line of Cala Trio devices. This includes supporting manufacturing, quality improvements, product analysis on complaints, inventory management, forecast predictions, testing and training. The Sustaining Engineer will also participate on new product development teams. All of these efforts involve research, planning, idea creation and realization, concept development, documentation, generating specifications, writing testing and validation protocols as well as effective communication and project management.

Specific Responsibilities also include:

- Analyze complaint data and generate prioritized actions to address product issues
- Review existing product design, identify weaknesses, propose, implement and monitor effectiveness of improvements.
- Analyze mechanical designs
- Build, and thoroughly test early concepts of corrective designs
- Create strategies for the verification of the corrective designs, and participate in verification activities
- Design, build, test and document electro-mechanical fixtures for testing and manufacturing
- Develop protocols and tests for new product verification
- Produce DHF and DMR documentation for transfer to test/manufacturing
- Source parts as required, manage vendor issues as needed with the operations team
- Contribute to risk management content such as FMEA, hazard analysis and requirements trace matrices

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- Document and resolve quality issues including NCMRs and CAPAs
- Create and route engineering change orders
- Generate and update MPIs, LHRs, and MTs.

Desired Skills and Experience

- Minimum 5 years' experience preferably in the medical device industry
- BS in Mechanical Engineering or equivalent
- Extensive knowledge of Solidworks, PDM and PLM software
- Demonstrated troubleshooting and root cause analysis skills
- Demonstrated success developing ideas into effective designs
- Tenacious problem solver, organized, detail oriented
- In-depth knowledge of manufacturing processes, such as machining, injection molding, PCB fabrication/assembly, 3D printing and sheet metal
- Knowledge of medical device standards such as IEC-60601-1, ISO 10993
- Mechanical aptitude, including ability to use common shop tools and measurement equipment
- Experience working with cable assemblies and PCBs
- Experience with statistical analysis
- Excellent written and verbal communication skills

Cala Health believes our success is based on diversity of people, teams and thinking. We offer all employees the tools, training and mentoring they need to succeed. Our selection process is driven by the key requirements for the role rather than bias or discrimination on the basis of a candidate's sex, gender identity, age, marital status, veteran status, non-job-related disability/handicap or medical condition, family status, sexual orientation, religion, color, ethnicity, race or any other legally protected classification.

If you or someone you know might be interested in this position, please submit a resume & an introductory email to careers@CalaHealth.com.

