**Job Title: Medical Device Senior Project Engineer**

**Job Description:**

* Work on one or more projects as directed to assist or lead in the design and development of products per customer need.
* Develop and provide specifications of components for various medical devices.
* Provide documentation of research and development processes through lab notebooks, Work Orders, or other methods.
* Create new and/or revise existing manufacturing documentation for improved materials, components, and/or processes (i.e. Manufacturing Process Instructions, Work Orders).
* Design and build prototype devices and/or lead a team to accomplish the project per customer Purchase Order and specifications.
* Research, specify, and procure material components for project.
* Design and/or conduct DOE (Design of Experiments) and PC (Process Characterization) to determine optimal process parameters, as directed.
* Provide support to and work closely with Project Manager in obtaining optimal process parameters, as well as the assembly of products.
* Train Technicians, Assemblers, and other personnel on multiple processes of projects.
* Conduct GMP (Good Manufacturing Practice) on all projects.
* Develop Process Validation protocols, equipment qualification documents (IQ/OQ/PQ), and process capability studies (e.g. CpK, PpK, etc.), analyze data, and author report, as directed.
* Provide verbal and/or written report of projects (using Word, PowerPoint, MS Project, MiniTab, etc.). Work on multiple projects to resolve issues and/or improve production output.
* Communicate directly with customers, as necessary.

**Job Duties and Responsibilities:**

* Conceive, design, document, procure and fabricate equipment deemed required for aiding production of minimally invasive medical device to Duke Empirical.
* Specify requirements for equipment which may be designed and fabricated by third parties and jointly develop custom tooling
* Perform engineering studies to identify equipment need
* Thoroughly document all aspects of the equipment design process, including its requirements, design, operation, and qualification in compliance with Good Manufacturing Process (GMP)
* Conduct or assist in activity of Process Development/Qualifications (IQ, OQ, PQ) /Validations of current and new equipment
* Perform troubleshooting and repair on broken equipment and assist project engineer on identifying potential risk from equipment usage.
* Provide guidance and support for Engineering staffs and technicians on custom tooling and machine/process design.
* Maintain and improve general documentation process for tooling/equipment.
* Involved with initial customer inquiry, demonstrating machine capabilities by running samples, generation of quotation, designing or re-designing custom machine features, creating the Bill of Materials, assisting Assembly department in fabrication, and travelling to setup or troubleshoot machines in the field.
* Maintain and enforce Machine shop safety practice
* Other duties and responsibilities may be assigned, depending on company needs.

**Minimum Qualifications:**

Bachelor's degree in biomedical engineering, or mechanical

engineering and one year of experience as a manufacturing operator or a project engineer.

Job Location:

Santa Cruz, CA