**Job Title: Medical Device Project Engineer**

**Job Description:**

Design and develop catheter products for biomedical applications with

in-house extrusion expertise as requested by customers. Work under the direction of the

Manufacturing Manager to meet customer requirements. Communicate with customers

regarding device specifications and performance during the design process while considering

project costs. Prepare project time lines with regular updates. Develop and propose

specifications for components of various medical devices and create the manufacturing bill of

materials for the project. Use service-oriented architecture on assigned projects and order

components on time to meet project time lines.

**Role and Responsibilities:**

Design, develop and manufacture tooling, fixtures, and equipment for manufacturing projects,

as necessary. Use equipment and tools to establish processes and to manufacture products.

Document research and development processes in lab notebooks, work orders, or through

other methods. Design and develop test equipment, as necessary. Create new and/or revise

existing manufacturing documentation for improved materials, components, and/or processes,

for example, manufacturing process instructions, work orders and component specifications.

Design and/or conduct experiments and process characterizations to determine optimal

process parameters, as directed. Participate in technical reviews and receive process approval

from the Process Development Manager. Provide support to and work with managers in

obtaining optimal process parameters and for the assembly of products. Train technicians,

assemblers, and other manufacturing personnel on the processes of various projects and

building prototypes. 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 reports, as directed.

**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