JOB TITLE: **Manufacturing Engineer II**

DEPARTMENT: Operations

REPORTS TO: Operations Management

ABOUT BOULDER IQ:

Boulder iQ: Bringing Products to Market from Product Concept through Manufacturing

Boulder iQ is an expert contract consulting firm providing all the services a life science company needs to get its product to market. With years of experience in regulatory, quality, product development, manufacturing, and contract EO sterilization, our single-source solution speeds the product development and regulatory submissions process. Our experts help companies navigate through the process of getting medical device, diagnostic and combination products to the market quickly.

ESSENTIAL DUTIES & RESPONSIBILITIES:

This position is responsible for the execution of manufacturing engineering and project management activities including process design, process testing, and related quality requirements.

Primary Responsibilities:

- Provides leadership, support, and guidance to medical device product manufacturing projects.
- Executes manufacturing development activities including protocol and process development.
- Designs and develops medical device production processes.
- Manages projects using company Standard Operating Procedures with sound project management principles.
- Adheres to company objectives and company milestones with a focus on meeting schedules and milestones.
- Develops concepts and designs using latest in engineering principles and technologies.
- Interfaces with external suppliers including identification, assessment, and selection as required, identifies technologies and processes for the development activities.
- Responsible for adherence to Good Manufacturing Practices (GMP) and other regulatory agencies for compliance.
- Writes test protocols and reports to support development of project processes. Carries out validation and verification activities.
- Generates and maintains required manufacturing protocols, reports, and records as applicable.
- Supports equipment calibration and preventive maintenance.
- Supports equipment installation, operation, and performance.

Additional Responsibilities:

- Responsible for training per company requirements.
- Provides updates for project review meetings.
- Provides mentoring to less experienced engineers.
- Additional Quality, Regulatory, and QMS needs may arise and will require support.

AUTHORITIES FOR POSITION:

- Develop manufacturing processes and create work instructions.
- Prepare test protocols and reports.
- Execute test protocols.
- Prepare other manufacturing documents as needed.

QUALIFICATIONS/COMPETENCY REQUIRED FOR POSITION:

- BS in engineering
- 3+ years of engineering experience, medical device experience preferred
- Good understanding of FDA regulations, QMS, GMP, ISO standards
- Proficiency in Excel, Word, MS Project, and statistical methods
- Proficiency in SolidWorks or other CAD software and FEA a plus
- Experience operating under a Quality Management System and within regulatory requirements (ISO 13485, FDA CFR 820, MDD 93/42/EE, etc.)
- Quality standards within the company
- Demonstrated understanding of various types of mechanisms, materials, proper tolerance, drafting standards, design for mold ability, and GD&T
- Compliance and testing experience
- Statistical analysis expertise for creating sampling plans and summarizing test results
- Knowledge of dFMEA principles, component manufacturing processes, tooling methodologies, material properties, and regulatory compliance
- Experience utilizing computer aided design (CAD)
- Technical writing: protocols, testing results, procedures, status, and special reports
- Scheduling work to achieve goals
- Good interpersonal, verbal, and written communication skills
- Self-starter with little supervision required for day-to-day activities
- Ability to work safely in laboratory and shop environments
- Clean room experience is preferred
- Experience with aseptic techniques is a plus

WORKING ENVIRONMENT:

- Primarily a desk position utilizing a personal computer
- Will include regular use of an engineering laboratory and workshop as well as operating in a clean room environment

SALARY RANGE:

- $75,000 - $95,000 annually

BENEFITS:

Boulder iQ is located in the city of Boulder, CO, an area known for its outdoor lifestyle and appreciation for work-life balance. Being located at the base of the foothills of the Colorado Rockies, Boulder offers easy access to many outdoor activities including hiking, biking, skiing, climbing and camping.

Additional benefits Boulder iQ provides:

- Health, Dental and Vision insurance
- 401(k)
- Paid Time Off
- Company Holidays

NOTE: Please be aware that **relocation assistance is not a negotiable benefit** for this position.

Boulder iQ is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, religion, color, national origin, sex, sexual orientation, gender identity, age, status as a protected veteran, among other things, or status as a qualified individual with disability.