Boulder iQ
Innovation to Quality

Job Title: Project/Quality Engineer (Full-Time)

Location: Boulder, CO

Who we are:

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.

The engineering division of Boulder iQ helps companies from the napkin sketch to prototyping to designing for manufacturing to verification and validation testing. This position offers cross-functional experience relating to manufacturing, engineering, quality, and sterilization.

What You'll Do:

Be a team member of a small dynamic engineering and manufacturing team focused on bringing innovative solutions to the market

- Participate and/or lead quality design control and development activities (quality control planning, risk management, hazard analysis, test plans and protocols, inspections, design reviews, etc.) to challenge design and compliance requirements (safety, performance, and reliability)
- Participate and/or lead Root Cause and Corrective/Preventive Actions for CAPAs, Complaints, and NCRs
- Review documentation to ensure compliance with internal and external quality and regulatory requirements
- Manage supplier audits for the sterilization, engineering, and manufacturing team
- Generate and modify QMS procedures and forms to ensure compliance within operations and manufacturing
- Build and setup equipment including developing, conducting, and writing equipment installation, operation, and performance protocols and reports
- Support receiving, in process and final inspection activities
- Evaluate process, methods and equipment for adherence to good manufacturing practices (GMP) and other regulatory agencies for compliance

What You'll Need:

- BS or higher in Engineering or related field (Required)
- 3+ years of experience performing quality/project activities, preferably on new products
- Medical Device industry and Quality Management System experience preferred (ISO 13485, FDA CFR 820, MDD 93/42/EE, etc.)
- Compliance and testing experience
- Knowledge of quality control processes and statistical techniques
- Manufacturing experience (hands-on building)

- Understanding of manufacturing processes and techniques
- Strong analytical and problem-solving skills; strong attention to detail
- Proficient in Microsoft Office product
- Strong interpersonal skills and the ability to work with cross-functional teams
- Good verbal, and written communication skills

Working Conditions:

- Required to be on-site
- Work is performed in an office, clean room, R&D lab, and production floor
- Minimal travel necessary for this role

Benefits:

Boulder iQ is located in the city of Boulder, CO, an area known for smart and ambitious people who also value work-life balance. We are located close to many outdoor activities including hiking, biking, skiing, climbing and camping. Our team is focused on providing the best services we can to our clients in the best location. Additional benefits Boulder iQ provides:

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

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