Boulder iQ
Innovation to Quality

Job Title: Quality Associate (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.

What You'll Do:

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

This position acts under direct supervision and is responsible for supporting the quality management system (QMS) activities, maintenance, and records to ensure compliance with regulatory agencies and the Boulder BioMed QMS. Will work within cross-functional teams with quality, R&D, manufacturing, operations, management, outside vendors, clients, and other personnel, as necessary.

- Assist in maintaining the electronic QMS system and review records for adequacy and consistency
- Generate and modify QMS procedures and forms to ensure regulatory compliance
- Review documentation to ensure compliance with internal and external quality requirements
- Participate in design control and development activities, e.g., quality control planning, risk management, hazard analysis, test plans and protocols, inspections, and design reviews to challenge design and compliance requirements (safety, performance, and reliability)
- As required, identify continuous improvement opportunities, generate action plans, and implement
- Participate in closures of CAPAs, Complaints, and NCRs
- Prepare summary and status of the quality system based on quality data/metrics
- Support engineering functions, R&D, and operations, as necessary

What You'll Need:

- BS or higher
- 0+ years in medical device quality
- Familiarity with ISO 13485, US FDA QSR, CE Marking, MDR, and other international regulatory
- requirements
- Strong analytical and problem-solving skills: attention to detail
- Proficient in Microsoft Word and Excel
- Excellent verbal and written communication skills
- Strong interpersonal skills and the ability to work with cross-functional teams

Working Conditions:

- Generally, an on-site desk position using PC laptop computer
- Some functions may be performed remotely

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.