Boulder iQ
Innovation to Quality

JOB TITLE: **Document Control Specialist**

DEPARTMENT: Quality

ABOUT BOULDER iQ:

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 ethylene oxide and chlorine dioxide 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 acts under direct supervision and is responsible for providing document control and training support for an ISO 13485 quality management system.

- Print and distribute documents as needed
- Scan and upload documents according to company procedure
- Scan and upload all technical documents such as validation protocols and reports, equipment calibration reports and certificates, product test results and reports
- Review and update documents for the quality management system
- Identify and execute continuous improvements for document and data organization
- Handle records across various departments
- Create templates for use by other personnel
- Maintain confidentiality regarding sensitive documents
- Establish and maintain record retention times
- Establish and maintain document state of the art review schedules
- Assist managers and Quality in creating training curricula, materials, and documentation
- Assist with maintenance of training records and documentation within the eQMS
- Conduct training related to document control and eQMS processes, and as requested by departments

COMPETENCY REQUIREMENTS FOR POSITION:

- Associate degree or higher in a scientific field, preferred
- 0+ years in medical device quality
- Familiarity with ISO 13485 and US FDA QSR, preferred
- Previous experience managing and maintaining document control systems and training programs, preferred
- Computer skills in Microsoft Word, Excel, PowerPoint, and Office
- Experience with an electronic Quality/Document Management System, preferred

QUALIFICATIONS FOR POSITION:

- Attention to detail, critical thinker, and effective organization skills required
- Good organizational skills and the ability to perform varied tasks in a disciplined, consistent manner
- Strong communication skills
- Ability to multi-task and work in a fast-paced team environment
- Be able to work with multiple departments and understand each departments unique needs and requirements
- Ability to sit or stand for long periods of time while doing data entry
- Experienced in Good Documentation Practices

AUTHORITIES FOR POSITION:

- Change Control Approval for document changes
- Document Release through the eQMS change control process
- Training Record approval and release
- Document Control Process

WORKING CONDITIONS:

This position is mainly performed in an office work environment with some work performed in the production work areas.

SALARY RANGE:

- $50,000 - $60,000 annual

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.