QA DOCUMENT CONTROL SPECIALIST

The ***Quality Assurance Document Control Specialist*** assists in the administration and improvement of the site's Quality Management System (QMS) and works with interdisciplinary teams to help ensure processes and procedures are established, implemented, maintained and in alignment with 21 CFR Part 820 and ISO standards. The position will be responsible for maintaining the electronic document management system in a finished medical device and medical device component manufacturing environment. The designated role supports the quality, engineering and manufacturing departments with all document control functions, while complying with record retention and archival policies. Position will report to the Director QA/RA.

RESPONSIBILITIES:

- Organize and maintain hard copy and electronic controlled records
- Enter, update, and edit controlled documents and coordinate requirements for new documents with internal customers
- Maintain historical records (manual and electronic): archive hard copy records, manage outside archival resources, and manage Document Control Room. Coordinate off-site document storage
- Assure that site document management strategies and regulatory requirements for electronic documents are upheld
- Serve as the site system administrator for the electronic Document Management
- Manage the daily flow and final release of controlled documents through the document management system
- Maintain chain of custody on requested records
- Maintain backups of logs and records
- Provide assistance for document research projects and support for client audits
- Acts as the designated Archivist for maintaining accountability and control (storage and retrieval) of quality records, data, and/or SOPs
- Support site training initiatives
- Record, track and handle departmental metrics
- Contribute data to routine company-wide metric reports
- Report CAPA's, NCP's and or OOS incidents as encountered
- Work closely with all operations support functions (Quality Assurance, Quality Control, Facilities, Engineering, Validation, Project Management and Materials Management groups) to ensure that Company objectives are met on schedule
- Interact with material/equipment vendors and commercial partners
- Responds to client document requests
- Author and revise SOPs and batch records as appropriate
- Coordinate the revision process of Standard Operating Procedures (SOPs), forms and other controlled documents
- Participate in internal meetings, client audits, and conference calls
- Assist Quality Assurance Analysts with administrative support
- Contribute to the overall operations and to the achievement of departmental goals
- Other duties as assigned

QUALIFICATIONS:

- Bachelor's Degree in a Life Science discipline is preferred.
- 0-3 years of QA experience in a regulated or ISO industry

- Basic knowledge of medical device industry terminology preferred.
- Attention to detail and the ability to organize and prioritize work and meet deadlines required
- Must be diligent, organized, and dependable
- Good working knowledge of SOPs
- Proficient in Oral & Written communication skills. Needs to read, write and understand English
- Proficient in computer programs (e.g., Microsoft office)
- Proficient in an electronic document control system
- Must be able to work in an office environment with minimal noise condition
- Ability to work in a team environment and independently as required
- Thorough understanding of Good Manufacturing Practices, including Good Documentation Practice. Equivalent training and experience may be considered to meet the above requirements.