RA/QA Documentation Specialist Job Description:

The role of RAQA Documentation Specialist is an integral part of any organization. This contributor applies extensive organizational skills and knowledge both as an individual and as part of a team, to assure that documents meet the needs of the organization as well as meeting regulatory requirements (in terms of standards and regulations) and quality assurance requirements (in terms of good engineering).

The RA/QA Documentation Specialist is expected to provide significant guidance as well as hands on support in the development of new documents, procedures, and changes to existing procedures, processes, plans, and other quality system documentation.

The RA/QA Documentation Specialist will support the creation of regulatory submissions [510(k), PMA and Technical Files] and/or updating documents as well as actively participate in the creation, implementation and continuous improvement of the quality system including developing, maintaining and reporting quality system metrics.

The RA/QA Documentation Specialist manages changes to documentation/PLM(Product lifecycle management) system. New documents and document changes are entered into the documentation system, approvals are obtained, and documents are distributed in a controlled manner. Applicable data/records are processed into a documentation system on a daily basis and reports are generated. All documents must be stored and organized to facilitate efficient and timely retrieval via the documentation system

Specific job responsibilities:

- Coordinate, develop, and maintain quality system documents: formatting documents, reviewing documents, assigning approvals, producing effective documents through PLM system
    - Own the documentation system such that metrics on document review cycle times, document throughput quality, training, current validation of the documentation system repository can be produced.
    - May act as independent reviewer during design reviews or as an auditor of paperwork prior to upload into the repository system.
- Generate document reports for use by requesting departments
- Ensure integrity of all QA files for the purpose of efficient and timely retrieval of generated documents
- Perform audits of the documentation system to identify any documents that need to be written, revised, or obsolete, work with appropriate staff to assure relevant documents reside in appropriate locations
- Solve administrative issues such as lock-outs, training new employees on the system, assuring employees have appropriate access to the system
- Assist in the updating of documents as requested
- Write audit reports, review /edit documentation, scribe during FDA audits and provide front room/back room support during 3rd party audits.
- Will direct reviews related to appropriate parties per review procedure
- May help trend corrective and preventive action
- Will provide guidance and instruction to engineering and manufacturing personnel on quality system/quality assurance/regulatory requirements and documentation
- Will actively participate in the maintenance and continuous improvement of the quality system.

MINIMUM REQUIREMENTS:

- Education – 2 year degree minimum, 4 year degree preferred
- Experience – minimum of 3 years with a document system or other relevant catalog/filing system
    a. Must have excellent computer skills
        i. Microsoft office suite, visio, sharepoint, and dropbox
    b. Must speak, read and write in the English language
- Understand basic principles of all phases of the PLM system
- Understand and comply with all quality procedures
- Understand basic QA/RA principles
    a. Must be aware of and have worked in a system using FDA GMP requirements noted in 21 CFR 820, especially design controls.
    b. Must be aware of ISO 13485 Quality System Requirements, Medical Device Directive
    c. Must be aware of ISO 14971 Risk Management for Medical Devices
    d. Must be aware of IEC 60601 Safety requirements
    e. Must be aware of IEC 62304 Medical Device – Software Life Cycle Processes
    f. Must be aware of Global Harmonization Task Force Guidance documents applying to medical devices
    g. Minimum of 1 year of experience with electromechanical devices that include hardware, firmware, computers
    h. Must have strong communication skills, both verbal and written.
    i. Must have strong attention to detail
- Prior Medical Device work experience will be given preference
- Prior work experience with MasterControl will be given preference
- Prior Quality Assurance Document Control experience, working with Quality documents will be given preference
- May work on other projects as assigned by the VP of RAQA and the Seno management team.