



Document Control Coordinator

Position Description:

As a member of the SetPoint Medical Quality team, reporting to the Director of Quality Assurance, the Document Control Coordinator will be responsible for management of the document control and records management process and also ensuring the documentation's accuracy, quality and integrity. The Document Control Coordinator responsibilities include:

- Understands and implements standard business workflows into the Document Control process
- Prepares controlled documents and manages them through each step of the Change Control process including editing, proofreading, scanning, circulating for approval, tracking, releasing and distributing
- Develops standard document formats of varying types and ensures these approved formats are used for all documentation submitted into Document Control
- Provides support and assistance on document generation, as applicable and required
- Manages the generation and distribution of new Document and Part Numbers
- Ensures that all controlled documents are accessible to all employees, both locally and remotely
- Reviews, scans and archives device history records
- Coordinates training as required by approved Change Orders and internal processes
- Provides support during ISO and agency inspections
- Ensures all work is performed and documented in compliance with ISO and FDA cGMP requirements and existing company policies

Location:

Company headquarters in Valencia, CA

Qualifications:

The ideal Document Control Coordinator candidate will have 3 or more years of experience in a fast-paced, technical, regulated Document Control environment. Experience with Class II / III medical device is preferable.

To be successful in this position, the candidate must also have:

- Ability to work effectively with people at all levels of the organization
- Ability to work under time constraints with multiple projects and adapt to change
- Strong attention to detail with each task
- Exceptional ability to deliver consistent results
- Excellent organizational skills
- Self-driven and resourceful to achieve goals independently as well as work well in groups
- Flexibility to adjust to changing requirements, schedules and priorities
- Experience with electronic Document Management System processing
- Solid computer skill using the following programs: Microsoft – Word, Excel, PowerPoint and Visio; Adobe Acrobat DC

Company Description:

SetPoint Medical is an early stage medical device company developing the first implantable neurostimulation device for the treatment of chronic inflammation.

Please address all inquiries to careers@setpointmedical.com.