



Job Description – Project Coordinator

Reports To – Sr. Director, Project Management

Job Responsibilities

This position is part of the Project Management group and will help manage medical device labeling projects in addition to other related projects.

General Description and Duties:

This position will coordinate workflow of various R&D, Operations and Regulatory projects. The job responsibilities include the following:

- Co-ordinate various projects working closely with Regulatory Affairs, R&D, Marketing and Operations teams
- Create project related documentation to meet internal and regulatory agencies requirements
- Co-ordinate with external vendors and internal teams with respect to supply chain issues, parts delivery, and implementation timelines
- Schedule and conduct change reviews
- Participate in risk management activities to address labeling changes
- Review and approve changes including but not limited to drawings, labeling, translations etc.
- Support inventory management
- Ensure compliance with Quality System Regulations
- Establish and maintain team member and project stakeholder relationships, expectations, and communications.
- Manage external vendors and services, as needed for the project.

Position Qualifications

- Bachelor's degree in engineering/sciences.
- Working knowledge of FDA medical device quality system regulations
- Proficient in English language.
- Excellent communication, both written and verbal, skills
- Demonstrates ability to work in a highly cross functional and global environment
- Self-motivated with strong focus on details and accuracy.
- Able to work in fast paced environment

Minimum Experience:

- 1 year of project coordinator experience
- 1 years of Medical Device industry experience in R&D, Operations or Regulatory function
- Experience with project management tools such as MS Project
- Experienced in gathering and tracking metrics

Work Environment & Physical Demands of the Job:

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- The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to remain in a stationary position at least 50% of the time; operate computers and other office equipment; and communicate and exchange information. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.
 - The job requires travel by air, train, and car travel, sometimes for long distances and extended periods of time.

Additional Important Information:
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- Axonics may make reasonable accommodations to enable individuals with disabilities to perform the functions of this job, unless doing so would result in an undue hardship on Axonics.
 - This job description is subject to change and management reserves the right to assign or remove duties and responsibilities of this job at any time.
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