



Job Description – VP, Clinical Affairs

Reports To – Chief Medical Officer

Job Responsibilities

The VP, Clinical Affairs will provide leadership, guidance, and direction to clinical team. This key member will plan and execute clinical trials while ensuring compliance with applicable regulations, standards and procedures, company SOPs, and project plans and timelines.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required to perform this job effectively.

- Responsible for developing and overseeing the research strategy and agenda for the Clinical Affairs department.
- Responsible for overseeing the design, implementation and reporting of clinical trials that meet the highest standards of excellence for ethics, scientific merit, and regulatory compliance, as well as satisfying corporate goals for study completion and reporting.
- Assist regulatory affairs with completion of required regulatory reports for the FDA, and regulatory agencies outside the US. This will also include overseeing annual clinical literature review updates.
- Plan and execute clinical trials while ensuring compliance with applicable regulations, standards and procedures, company SOPs, project plans and timelines.
- Full management for clinical trials - data analysis, monitoring, in person management, manuscript writing
- Supervises the development of protocol, implementation, and management of the process.

Projects and Other Duties:

- As assigned by manager

Position Qualifications

- Experience developing educational strategies and conducting clinical trials
- Knowledge of current and new healthcare industry trends, technologies, competitors, and place in the market
- Knowledge in women's health and experience with physicians in FPMRS, Urology and Colo-rectal surgery
- Demonstrates a continuous desire to understand, learn and implement industry best practice and trends
- Strong leadership and communication skills
- High-performer and results driven
- Ability to foster strong relationships with internal and external stakeholders
- Personifies Axonics' Mission, Vision, and Values

Minimum Education:

- BA or BS degree in a health-related field
- Master's degree preferred

Minimum Experience:

- Minimum 6 years healthcare experience
- Minimum 5 years of medical device experience

Work Environment & Physical Demands of the Job:

- 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:

- 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.