

Second Sight

Second Sight (www.2-sight.com), located in Sylmar, California, was founded in 1998 to create a retinal prosthesis to provide sight to patients blinded from outer retinal degenerations, such as [Retinitis Pigmentosa](#). Through dedication and innovation, Second Sight's mission is to develop, manufacture and market implantable visual prosthetics to enable blind individuals to achieve greater independence.

Device: The device consists of a tiny camera and transmitter mounted in eyeglasses, an implanted receiver, and an electrode-studded array that is secured to the retina with a microtack the width of a human hair. A wireless microprocessor and battery pack worn on the belt powers the entire device.

Field Clinical Engineer:

A clinical engineer is responsible for providing regulated clinical research and field support to internal and external customers, including assisting customers in the management of clinical cases, performing patient and device testing, surgical support including pre- and intra-operative device testing, and advanced diagnostics for hardware/software issues, analyzing trends from the issue tracking process related to patient, hardware and software issues and investigating these trends. S/he is also responsible to provide clinical and technical update to external customers and field feedback to the R&D and other cross-functional teams. A clinical engineer may also be responsible for monitoring study documentation for compliance to governmental regulations.

EDUCATION/CERTIFICATION: Min. BSc degree in life sciences, electrical or biomedical engineering. Master's degree is a plus.

EXPERIENCE REQUIRED:

- Must have 3-5 years of experience in a medically-related setting, preferably in the implantable medical device industry.
- Field experience is a plus.
- Must have an understanding of the application of electrical stimulation for biomedical prostheses.
- Must be able to work in a fast paced environment and foster constructive relationships with internal and external customers.
- Strong written and verbal skills.
- Must be able to travel extensively.

Patent Agent/Technical Writer:

SUMMARY

Develops, writes, and edits technical specifications for patent applications.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

In the fields of chemistry and materials sciences:

- Reviews invention disclosures, engineering notebook entries, product specifications, patents, journals, papers, and other technical documents;
- Observes research production, developmental, and experimental activities;
- Interviews production and engineering personnel to determine technical details of an invention,
- Organizes material and completes patent specification writing assignments in a clear and concise manner according to patent office rules and standards.
- Analyzes and respond to patent office actions for related patent applications

EDUCATION and/or EXPERIENCE

Bachelor's degree (BS) or equivalent in chemistry or materials sciences; or five to seven years related experience and/or training; or equivalent combination of education and experience. Patent experience, and patent agent registration is very helpful.

Clinical / Regulatory Affairs Specialist:

Responsibilities include the following:

- Assists with the preparation of submissions for US and International regulatory agencies to gain approvals to conduct clinical trials and to request approval to market the company's products
- Maintenance of regulatory and clinical files including product catalog, complaint files, adverse events, and submissions
- Provides support function for state, federal and notified body inspections of company's operations
- Prepares and updates product labeling that meets regulatory requirements
- Interacts and interfaces with regulatory agencies
- Assists with Safety Board oversight of clinical studies
- Contributes to clinical and regulatory in-house procedure development
- Implements complaint handling system and the returned goods authorization system
- Provides assistance in product notification and recall activities
- Works with cross functional teams to meet the company's regulatory and clinical needs

REQUIREMENTS:

- BS degree required, preferably in Engineering, Physical or Biological Sciences
- 2-3 years experience in US regulatory affairs, preferably with Class III devices or equivalent combination of education and experience