avinger	Job Description Form

Job Title: Senior Regulatory Affairs Specialist

Department: RA/CA/QA

Reports to: Director of Regulatory Affairs (TBD)

Status: X Exempt ☐ Nonexempt

As a **Senior Regulatory Affairs Specialist** with this fast growing, Class II medical device company, you will be responsible for product submissions, license renewals, periodic updates and registrations to regulatory agencies. You will organize regulatory information and track and control submissions, review and advise on labeling for compliance with regulatory filings, review product changes for impact on regulatory filings worldwide, and research regulatory issues and provide guidance and advice to colleagues.

Specific Duties and Responsibilities :

*Collect and coordinate information and prepare regulatory documentation for submission to regulatory agencies or to commercial partners, advise on the submission strategy
*Timely compile materials for license renewals, updates and registrations
*Maintain regulatory files/database and chronologies in good order. Establish and maintain system for tracking changes in documents submitted to agencies or partners
*Review labeling and labels for compliance with regulatory requirements
*Review changes to existing products and SOPs to define the requirements for regulatory submissions
*Provide the regulatory reviews of customer complaints and define the regulatory reportability
*Responsible for timely registration of the facility
*Maintain current knowledge of FDA and international regulation, guidance and standards applicable to company products
*Actively participate in evaluation of regulatory compliance of document / product / process /test methods changes
*Participate in research of regulatory issues and dissemination regulatory information to Production, QA, QC and R&D departments and senior management as required.

Core Job Responsibilities:

- Represent Regulatory Affairs on R&D product development project teams to ensure all regulatory requirements are met throughout the development process.
- Complete submissions to FDA, EU regulatory entities.
- Create and maintain product EU technical files.
- Review advertising and marketing material for appropriateness and compliance to regulatory requirements and laws.
- Supervise Regulatory Affairs consultants as required.
- Other duties as assigned

Other Responsibilities:

- Understand the job specific quality system procedures and processes as defined in the Training Matrix and adhere to the requirements listed in those documents. If any of the procedure or process requirements are unclear or ambiguous, it is the responsibility of the employee to notify his/her supervisor or Quality Assurance
- Maintain corporate confidentiality at all times.

Living Avinger's Culture:

As a member of the Avinger team, the Senior Regulatory Affairs Specialist agrees to embrace and live out the core values of Avinger, specifically to:

- Put patients first
- Fail fast
- Be open-minded
- Collaborate
- Maintain a sense of urgency

Requirements:

- Requires BA degree in a science or related field
- At least 5 years relevant experience within the regulatory affairs discipline
- Knowledge of US and international medical device regulatory requirements
- Experience with Class II devices is mandatory
- International experience is a plus

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities.