



Title: Regulatory Affairs Specialist

Job Description:

A Regulatory Affairs (RA) Specialist position is available at Quantum Applied Science & Research (QUASAR).

QUASAR is an R&D company specializing in non-invasive electrophysiological measurement systems. Our work builds on our revolutionary wearable biosensors and advanced algorithms to produce systems that monitor cognitive and physiological states for medical, military, and consumer applications.

QUASAR is a small company with less than 20 employees, most of whom are Ph.D. level scientists and engineers.

The successful candidate will be responsible for managing QUASAR's quality system and filing 510K applications to the FDA for QUASAR's EEG headsets. He or she will participate in all aspects of the submission, from document control, to finalizing documents describing procedures and biocompatibility results, to discussions with the FDA, with the support of a high-level RA consultant.

Possible activities include, but are not limited to, the following:

- Preparation of 510K application package
- Assistance in defining RA strategy for current and next products
- Compilation and completion of suitable document control
- Interfacing with engineers to document manufacturing procedures
- Interface with 3rd parties providing biocompatibility testing
- Participation in design reviews
- Interfacing with FDA

Essential Requirements:

- Bachelor's Degree and 2+ years relevant work experience
- Experience with class II/III medical devices
- Prepared a 510(k) application for a medical device
- Clear understanding of regulatory affairs workings and methodologies
- Leadership capabilities with demonstrated project management skills
- Good communication skills, including demonstrated fluency in English writing, grasp of pertinent terminology and understanding of proper document preparation requirements
- Capacity for independent work with a sense of urgency to resolve issues and complete project goals on time.
- US persons (citizens and permanent residents) only

Application:

The position is available to start immediately. Salary is commensurate to experience. To apply, please email resume and a paragraph stating interest and availability to jobs@quasarusa.com.