

NeuroSystec Corporation (www.neurosystec.com), is located in Valencia, California. Our goal is to combine modern device technologies with potent neurologically active therapeutics to treat diseases of the nervous system, beginning with hearing-related disorders. The company will combine the power of tissue-specific drug delivery from partially or completely implantable drug-delivery devices with potent neurologically-active therapeutics. This targeted, local delivery will allow for treatment with more effective agents while minimizing the risk of side effects associated with systemic delivery.

Our initial program focuses on disorders of the inner ear including tinnitus, Ménière's Disease, and progressive hearing loss.

Senior Mechanical Engineer

The Senior Mechanical Engineer leads the biomedical product development efforts for all aspects of implantable and external devices. The successful candidate should be able to design and analyze prototypes, as well as perform the required testing, documentation and manufacturing releases needed in regulated and quality controlled environments. The position requires a problem solving person with demonstrated analytical skills, able to supervise and guide engineering personnel in all stages of product development, with excellent organization, planning and project management skills. On hand experience with computer aided design or 3-D modeling software such as AutoCAD or SolidWorks and familiar with biomedical devices, moving device prototypes from bench into production and pumps and filters for biological and human use is preferred. Demonstrate excellent oral, written and presentation skills.

EDUCATION / EXPERIENCE

Doctorate in engineering (Ph.D. preferred) or Master's degree (M. S.). Ten or more years related experience and/or training; equivalent combination of education and experience will be evaluated.

Regulatory-Quality Specialist

The Quality-Regulatory Specialist is responsible for assisting in the regulatory and quality aspects of drug and device development projects including the preparation of and maintenance of various quality and regulatory documents including IMPD/CTA, IND/NDA and CMC. The position will be responsible for ensuring that the quality, accuracy and format of regulatory submissions comply with applicable laws, regulations and corporate standards. The position will also require the ability to organize and compile IMPD and IND submissions to regulatory agencies to ensure regulatory compliance, conduct Quality & Regulatory training, active participation in the CAPA program, ensure conformance to 21 CFR and ICH regulations, and assist in development of relevant regulatory and quality SOPs. As time is available, assist in the project management of key company programs.

Qualifications and Competencies:

The position requires a bachelor degree in science and/or a related field. Five to ten years of quality-regulatory experience in biopharmaceutical environment and/or training; equivalent combination of education and experience will be evaluated. The candidate must be able to work in a team-based environment. Excellent interpersonal, oral and presentation skills are crucial for this position as well as strong English written language skills and computer skills, including the suite of Microsoft Office.