Job Title: Quality Systems Engineer
Location: San Diego, CA
Type: Salary

Qualifications

- Bachelor's degree in engineering or related field plus minimum 5 years of industry experience
- 3-5 years of direct work experience in QA, including aspects of quality systems creation and management
- 3-5 years of work experience with design and manufacture of electroporation-based drug delivery devices
- 3-5 years of work experience in quality with device/drug combination products
- Experience in drafting and execution of test methods and protocols in support of medical device design, development, and manufacturing
- Well organized and detail-oriented with the ability to interpret and follow instructions provided in various forms (written, oral, work schedule, etc.)
- Familiarity with Good Manufacturing Practices (GMPs) and 21 CFR Parts 210 and 211 and Quality System regulations (QSR) per 21 CFR Part 820
- Working knowledge of FDA regulations and ISO/IEC standards, including ISO 11608, IEC 62304, and IEC 6061
- Effective interpersonal and communication skills and capable of supporting cross-functional project goals
- Self-starter with the ability to take direction and complete tasks in a timely manner
- Requires the ability to produce results in a fast-paced environment to meet client deadlines

Job Description & Responsibilities:

The Quality Systems Engineer is responsible for creating and supporting the core quality systems, including creating SOPs, CAPA & complaints tracking, change control, risk management, and compiling, trending and reporting key quality metrics. The Quality Systems Engineer is responsible for manufacturing support, DHR review, in addition to creating test methods and test protocols for verification and validation of medical devices. The individual will coordinate with quality and engineering personnel to assure compliance to internal policies and procedures as well as to applicable external standards (GMP, QSR, ISO 13485, MDD, etc.). Additional responsibilities include:

- Perform quality review and approval of regulated documentation including, but not limited to, part/component/system inspection reports, nonconforming material reports, deviations, engineering change orders, engineering change reports, and engineering work orders
- Draft test methods and test protocols for design characterization and verification of medical devices. Provide support to engineering for statistical methods selection
- Participate in design reviews for design changes at key milestones
- Manage or support the document control program as well as suggest and implement improvements to the existing quality system policies and procedures
- Support inventory control
- Support internal audits, vendor/supplier audits and audits from external parties
- Perform related tasks as assigned