GRAVITAS MEDICAL, INC.

Job Description

Position Title: Senior Quality Assurance Specialist

Reports To: VP of QA and RA

Department: Quality

Location: In person at 2332 4th St, Berkeley, CA

FLSA Status: Exempt

PURPOSE OF JOB:

Perform Quality Assurance activities in accordance with 21 CFR 820, ISO13485 including Document Control, Training, Inspection and Testing, Equipment Control, Review of Lot History Records and Product Release, and supporting various Quality System and Office Management activities.

RESPONSIBILITIES:

- Responsible for Document Control activities including processing DCOs and maintaining controlled and archived documents in the company's electronic Document Control System.
- Support the training program to ensure compliance including sending training reminders and entering training records int the company's electronic Training System as needed.
- Incoming Inspection activities including material inspection, release of material, and maintenance of Incoming Inspection records.
- Product lot release activities including pre and post-sterile inspection and testing including performing visual, dimensional label and packaging inspections and functional testing.
- Performing completed Lot History Record reviews and product release activities.
- Generating Non-Conforming Material Reports (NCR) and supporting NCR investigations.
- Complete Design Verification and Validation Testing.
- Maintaining Quality System Databases and Logs (NCMR, CAPA, Approved Supplier List).Support equipment calibration and maintenance program.
- Create new and revise existing Quality System procedures as required.
- Assist with Test Method Development and Validation.
- Assist with Quality metrics trending for the Management Reviews.
- Participate in regulatory body inspections and audits (e.g. FDB, FDA, Notified Body).
- Support other Quality System areas as needed.
- Support Office Management activities including ordering supplies, receiving and other miscellaneous activities.

REQUIREMENTS:

- 5+ years of work experience in start-up medical devices
- Prior experience working in a GMP Quality System supporting inspection, testing and various quality system support activities.
- B.S. in Biomedical Engineering, Chemistry, or Life Science discipline is preferred.
- A willingness to work hard, with a driven outlook and with a strong desire to succeed as a Quality professional, as part of a team.
- An inventive aptitude balanced with discipline and high level of attention to detail.

DESIRABLE SKILLS:

- Experience working on the development of medical device products from concept through commercialization. Experience with hardware and software systems, and single use sterile products highly desirable.
- Good working knowledge of domestic and international regulations and guidance documents (i.e. 21 CFR 820, 820, ISO 13485, CGMP)
- Experience in a start-up environment wearing multiple hats.
- Excellent communication and intrapersonal skills.
- Strong Quality Systems and technical background with a thorough knowledge of applicable regulations and standards.
- Working knowledge of statistical techniques (e.g. sample size determination, tolerance intervals, capability analysis) using statistical software packages (e.g. Excel, Minitab, JMP).

Contact hr@gravitasmedinc.com for more info