Sr. Quality Engineer

Sr. Quality Engineer will be responsible for working with and supporting the Company's Product Development team to validate and verify all aspects of Design Control for the PAQ® devices, including Design Verification, Design Validation, and Design Transfer activities, and to ensure that requirements are being met.

Job Duties:

- Writing and coordinating efforts for the development and implementation of new and updated Quality System procedures for ISO/QSR, such as verification protocols, validation protocols, manufacturing procedures, product and material specifications, design and development documentation, SOPs, and development and task force projects;
- Supporting the 510(K) filing for new products;
- Supporting launch of approved devices, including transfer of technology from development to commercialization from a quality and a manufacturing perspective;
- Facilitating the execution of Risk Management and Usability Engineering process activities;
- Developing statistically-based sampling plans for incoming, in-process and final testing and inspections, and process validations;
- Leading new supplier qualification/assessment of finished goods, components, raw materials, and/or services;
- Working with internal or external inspection resources to fulfill incoming inspection requirements for device components;
- Working with project teams to develop Design of Experiments and statistically sound tests for appropriate support of results;
- Developing, reviewing and approving validations and completion reports for new and existing products, processes and equipment;
- Applying statistical analysis to support data-driven decision making;
- Ensuring that all projects are in compliance with GMP, QSR, ISO or other applicable requirements;
- Participating in FDA inspections, ISO Certification and overseeing audits and customer audits;
- Identifying and implementing opportunities for continuous improvement in product quality and the quality system;
- Interacting and coordinating activities with other departments, external vendors and customers;

- Leading the prompt execution of root cause analysis of various failure investigations and leading and supporting Corrective & Preventative Action(s) implementation and/or review;
- Performing other Quality Systems related duties as required; and
- Reporting directly to CeQur's Quality Assurance Manager.

Min Reqs:

- Bachelor's Degree in Mechanical, Industrial or Manufacturing Engineering (or its foreign equivalent), plus
- 6 years of experience in a Quality Engineering/Quality Assurance role in the medical device or pharmaceutical manufacturing industry;

OR

- Master's Degree in Mechanical, Industrial or Manufacturing Engineering, plus
- 4 years of experience in a Quality Engineering/Quality Assurance role in the medical device or pharmaceutical manufacturing industry;

AND/OR INCLUDING

- Prior experience in product development projects in the medical device industry;
- Experience with 510(k) submissions and/or FDA inspections;
- Excellent knowledge of risk management per ISO 14971;
- Strong knowledge of MS Office Suite and statistical sampling and analysis tools/methods (including Minitab);
- Six Sigma Green Belt or Black Belt Certification; and
- Excellent organizational, verbal and written communication skills.

Full-time; position is located at 734 Forest Street, Suite 100, Marlborough, MA. Apply on-line at https://cequrcorp.com/team#careers; no phone calls please.