Company:	CeQur Corporation	**Location:**	Marlborough, MA
Status:	Full Time, Employee	**Reports To:**	Head of QA
Job Title:	Senior Quality Engineer		

Company Background:

CeQur® is an innovative company dedicated to helping people with type 2 diabetes manage their disease by developing and commercializing advanced yet simple-to-use insulin delivery devices that make it easier for people to adhere to therapy and stay in control of their disease.

Job Description:

Individual in this role leads CeQur's Quality Control activities and develops & maintains company's Quality Systems in accordance with ISO13485/21CFR820.

Responsibilities:

- Ensure effective and efficient use of Quality Engineering techniques such as risk analysis, test method development, statistical data analysis, and the development of sampling plans.
- Implementing and maintaining the inspection program (including implementations of protocols, methods, SOPs, etc.) for evaluation of raw materials, components, and products at various stages of the manufacturing process are compliant with internal requirements as well as to local standards/regulations. Develop statistically based sampling plans for incoming, in-process and final testing and inspections, and process validations.
- Work with project teams to develop DOEs and statistically sound tests for appropriate support of results.
- Review and coordinate with QA Validation for all test method and design validations. Develop, review and approve validations and completion reports for new and existing products, processes and equipment. Apply statistical analysis to support data-driven decision making.
- Review activities related to Design Verification and Design Transfer of Medical Devices.
- Participate in device risk management activities including UFMEA, DFMEA, PFMEA.
- Verity data integrity, electronic data storage and data sheet validations.
- Develop, implement, and maintain robust Quality Management System (QMS) in accordance with ISO13485/21CFR820 specifically related to Non-Conformances, CAPAs, Complaints Management, Change Control, Document Control, Training, and Quality Management Reviews.
- Lead the development and execution of vendor selection, quality agreements, and establishment/maintenance of vendor qualifications
- Perform analysis of reports and production data to identify trends and recommend updates or changes to quality standards and procedures when necessary.

- Management for NC/Deviations and CAPA (Corrective and Preventive Action) system, ensuring the appropriate use of RCA (Root Cause Analysis) tools, implementation of corrective and preventive actions, and effectiveness of the change
- Establish, execute and maintain internal audit program
- Establish inspection readiness for Audits/inspections (which includes hosting auditors/inspectors, internal training/SME readiness, responses to audit observations, remediation of commitments)
- Utilizes Six Sigma and other quality tools to implement process improvements to enhance product quality and reduce process variance by identifying improvement opportunities in regulation compliance, device, process, and system quality, and cost reductions.
- Proactively research and identify industry trends and keep Quality Systems updated
- Lead new supplier qualification/assessment of finished goods, components, raw materials, and/or services

Background and Qualifications:

- Bachelor's Degree in Engineering or Scientific discipline
- Minimum 7 years of experience in a Quality Assurance role for medical device or pharmaceutical manufacturing, with a minimum of 5 years in Quality Engineering
- Proficient in technical writing (e.g., quality system SOPs, forms, and other documents)
- Ability to work effectively in a cross-functional team environment or independently.
- Proficient with basic computer applications, Microsoft suite of tools (Word, Excel, Power Point etc.), and Minitab for statistical analysis,
- Experience with 510(k) submissions and FDA inspections
- Excellent knowledge of statistical sampling and analysis tools/methods
- Excellent knowledge of risk management per ISO 14971
- Excellent organizational, verbal and written communication skills
- Prior experience in New Product Development and Launch projects
- Six Sigma Green Belt or Black Belt Certification preferred

Send your resume and qualifications to:

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