Job Title: Senior Quality Assurance Specialist

Department: Quality Assurance

Reports To: Manager, Quality Assurance

CeQur® Corporation develops and commercializes a discrete, simple-to-use and wearable insulin delivery device that easily integrates into patients' daily lives. CeQur Simplicity™ is a 3 Day Insulin Patch designed to reduce the barriers and challenges of multiple daily injections to enable people with diabetes to achieve glycemic targets.

At CeQur, we aim to provide solutions to people with diabetes that are profoundly simple and clinically effective. We are gaining tremendous momentum already and have built a leadership team and Board that comprises of accomplished and respected industry experts. We are looking for like-minded A+ team players to join our team to help make a difference and build a legacy while driving penetration of our therapies. CeQur values a collaborative and creative mindset, where each team member is encouraged to contribute to our processes, decisions, planning and company culture.

Position Overview:

The Senior Quality Assurance Specialist works within the Quality Assurance team to assist in the management and continual improvement of CeQur's Quality System. The Senior Quality Assurance Specialist's activities are critical to ensure that CeQur meets its quality objectives and maintains compliance to the FDA Quality System Regulation and ISO 13485.

Responsibilities:

The Senior Quality Assurance Specialist will be responsible for:

- Documentation/Changes
  - Create, maintain, update, review, and approve quality records and changes per applicable SOPs within a controlled electronic database.
- Design and Development/Risk Management
  - Help maintain the Design History File and relevant documentation.
  - Support validation activities.
- Supplier Management
  - Onboard new suppliers, evaluate current suppliers, and manage nonconformances, SCARs, etc.
- Nonconformances
  - Coordinate with suppliers to address and document nonconformances.
- Corrective Actions/Preventive Actions
  - Initiate, investigate, oversee, document, and/or maintain CAPAs.
- Customer Feedback
  - Review and approve customer complaints.

- Training/Compliance
  - Ensure proper training and compliance for all CeQur personnel.
- Audits
  - Coordinate, execute, support, and document supplier, internal, and external audits.
- Track/trend data, develop metrics, develop/improve process maps, and assist/lead projects.

Other duties may be assigned as deemed necessary by the manager.

Education and Experience Minimum Requirements:

- Bachelor's degree in engineering or related discipline.
- Minimum of 3 years of Quality Assurance or Quality Engineering experience.
- Experience in Medical Device or Pharmaceutical industries strongly preferred.
- Strong computer skills, including working knowledge of MS Office (specifically Word and Excel) and electronic database, document, training, and/or electronic quality management systems.

A successful candidate is:

- Experienced in applying requirements of the FDA Quality System Regulation and ISO 13485.
- Experienced in manufacturing or supplier quality control, particularly in the Medical Device Industry.
- Experienced in managing Customer Feedback, Suppliers, NCMRs, CAPAs, etc.
- Familiar with common engineering practices and techniques such as Root Cause Analysis, FMEA, etc.
- A strong verbal and written communicator with effective time management skills.
- Extremely attentive to detail, highly organized, innovative, proactive, and logistical.
- Self-motivated, team-oriented, and collaborates and communicates effectively with local and international team members in a cross-functional, multi-cultural, interdisciplinary environment.
- Comfortable working in an extremely dynamic and fast paced start-up environment, and able to meet aggressive and realistic development milestones.