Job Title: Quality Assurance Engineer
Department: Quality
Reports to: Manager, Quality Assurance

CeQur® Corporation develops and commercializes a convenient, discrete, and simple-to-use wearable insulin delivery device that easily integrates into patients' daily lives. CeQur Simplicity™ is a 4 Day Insulin Patch designed to revolutionize insulin delivery and simplify the lives of people with diabetes by providing injection free dosing. CeQur Simplicity™ is FDA cleared.

At CeQur, we aim to provide solutions for 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 Quality Assurance Engineer is responsible for ensuring the quality, safety, and compliance of the CeQur Simplicity product line by supporting design control, risk management, manufacturing, supplier management, and post-market activities.

Key Responsibilities and Essential Functions:

- Support and maintain the QMS in compliance with FDA 21CFR820, ISO 13485, and other applicable regulatory requirements.
- Collaborate with cross-functional teams, including R&D, Operations, Marketing, and Suppliers to ensure quality and compliance throughout the product lifecycle.
- Participate in design control activities, including risk management, verification and validation, and design reviews.
- Update, review, and maintain Design and Development Files.
- Review and approve quality records such as nonconformances, deviations, complaints, change orders, and validation documentation.
- Support supplier quality management including audits and supplier qualifications.
- Assist in the preparation and execution of internal and external inspections and audits (e.g., FDA, ISO).
- Conduct root cause investigations and implement effective Corrective and Preventive Actions (CAPA).
- Lead or participate in continuous improvement projects to enhance product quality and process efficiency.
- Monitor and analyze quality metrics to identify trends and drive improvements.

Background Requirements and Qualifications

- BS in Engineering; Master's in Engineering preferred.
- 3+ years in a Quality Engineering department for the development/manufacture of medical devices.
    - Experience with wearable or combination products is preferred.

- Deep knowledge of FDA 21CFR820, ISO 13485, and relevant regulations/ standards.
- Basic knowledge and proficiency in the application and principles of Quality Engineering and Validation.
- Good understanding of Quality Management Systems, design control, risk management, and related risk management tools (e.g., FMEA, fault tree analysis, etc.)
- Strong verbal and written communication skills.
- Self-motivated, team-oriented, analytical, and detail-oriented.
- Comfortable working in an extremely dynamic and fast paced environment.