POSITION SPECIFICATION

POSITION	Quality Systems Engineer
COMPANY	CeQur Corp
LOCATION	Marlborough, Massachusetts
REPORTING RELATIONSHIP	Reports to VP Quality Assurance

COMPANY BACKGROUND/CULTURE

CeQur is a startup venture that has spun out of Danfoss Bionics and leverages their core competency in fluidics. The company is funded by a small group of Angel and VC investors. The company is dedicated to the design, manufacture and commercialization of a very small and disposable wearable insulin infuser that is geared specifically to the needs of diabetes type II patients and offers a range of advantages to patients, physicians and other caregivers relative to conventional insulin delivery platforms.

The CeQur™ insulin infuser is a plastics, elastomer, and glass capillary-based technology with a disposable reservoir and a reusable electronic monitor. The infuser is equipped with an adhesive for easy attachment to the patient's abdominal area. Insulin is delivered subcutaneously through a cannula which is changed by the patient every three days. The device is needle-free and, in addition to delivering predetermined basal rate of insulin, is equipped with a push-button for the administration of bolus amounts.

The company's engineering and component manufacturing is located in Nordborg, Denmark. While the company's operational headquarters and pilot manufacturing is established in Massachusetts, volume manufacturing will be done in a location and country yet to be selected. This position requires infrequent travel to the Danish location.

KEY RESPONSIBILITIES

The CeQur Quality Systems Engineer will manage the execution of the quality system including the administration of the CAPA system, Internal audit system, training system, the complaint handling system and preparation for the Management Review process. The responsibilities will include establishing and coordinating changes,

improvements and additions to the CeQur Quality Management System and will share in the overall system compliance to ISO and national regulations. The engineer will also have supervisory duties for document control personnel.

Areas of specific responsibility and attention include:

- Recommend, coordinate and implement changes to the Quality Management System based on sound process judgment and experience
- Coordinate Corrective Action and Preventive Action activities
- Coordinate and participate with Internal Audit activities
- Coordinate and monitor training activities
- Organize and prepare key process metrics for management review
- Coordinate and participate in product returns and complaints
- Supervise and provide backup for document control including the Compliant Pro automated record system

YEAR ONE CRITICAL SUCCESS FACTORS

- The effective management and compliance of the quality system.
- Completed internal audit schedule and timely completion of CAPA metrics.
- Effective preparation for the Management Review process.

EXPERIENCE

The successful candidate will bring the following background and experiences to CeQur:

- Proven knowledge and experience with a quality system in an FDA or ISO medical device environment.
- Proficient in a variety of software applications such as Microsoft Office products, Adobe, and knowledge of CAD packages.
- Experienced with electronic data management systems.
- Experience auditing ISO and FDA regulated processes.

SKILL AND TALENT REQUIREMENTS

- Proficient in computer applications such as MS Word, Excel, and PowerPoint.
- Detail oriented, highly responsible for their quality of work.
- Understands quality system concepts and can recommend solutions that maintain effective compliance in the CeQur environment.
- Understands and is proficient and interpreting ISO and FDA medical device regulations.

EDUCATION AND EXPERIENCE

3 – 5 years experience in Medical Device Quality System Management equivalent role is required. Audit certification required. College degree is preferred.