

POSITION SPECIFICATION

POSITION	<i>Senior Manufacturing/Process Engineer</i>
COMPANY	CeQur Corp
LOCATION	Marlboro, Massachusetts
REPORTING RELATIONSHIP	Reports to Manufacturing Engineering Manager

COMPANY BACKGROUND/CULTURE

CeQur is a growing startup 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® PaQ® device consists of a sterile disposable insulin reservoir and a reusable electronic monitor. The device eliminates the need for multiple daily injections; replacing them with just one needle stick every 3 days and in addition to delivering a predetermined basal rate of insulin, is equipped with a push-button for the administration of bolus amounts.

KEY RESPONSIBILITIES

The CeQur Senior Manufacturing/Process Engineer will be responsible for the development and optimization of processes and systems to support the overall Business Objectives.

Areas of specific responsibility and attention include:

- Use engineering skills to:
 - Develop and implement manufacturing processes and measurement methods to meet tight tolerance manufacturing requirements
 - Conduct process evaluations and lead process optimization initiatives utilizing tools such as SPC, DOE, and, MSA
 - Evaluation and improvement of process capabilities
 - Develop and lead projects to improve quality and reduce costs
 - Conduct root cause failure analysis and corrective action

- Establish sampling plans / Quality plans
- Participate / lead risk management activities including FMEA
- Lead development of fixtures and equipment with outsourced assistance
- Support reliability engineering activities
- Participate / lead validation activity for design, process or products
- Development and qualification of test methods for verifications and validations
- Lead, support, and/or coach improvement projects throughout the life cycle of CeQur products including:
 - Manufacturing
 - Procurement

YEAR ONE CRITICAL SUCCESS FACTORS

- Improve process capabilities for specific manufacturing processes.
 - plastics laser welding
 - pick and place assembly
 - heat welding
 - packaging
- Complete process and test method validations for manual and semi-automated assembly processes for the CeQur insulin patch product.
- Establish reliable and high quality commercial supply of CeQur insulin patch pump products

EXPERIENCE

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

- Proven ability to solve problems and improve manufacturing processes that use high precision mechanical components
- Experience in the scale-up of high volume consumable products, preferably medical
- Strong working knowledge and experience with injection molding processes and plastic components.
- Successful implementation and use of statistical based quality improvement tools such as Design of Experiments, Statistical Process Control, and Gage R&R.
- Project leadership in multi-disciplined projects.
- Experienced in quality system requirements for the medical device industry
- Minimum 5 years experience

COGNITIVE AND TECHNICAL SKILLS

Conceptual Skills

- Ability to apply technical knowledge to the specific scenario within CeQur, creating value by recommending and implementing solutions to complex problems.
- Proven ability to motivate and lead others, often without direct control, such as suppliers.
- Strong verbal and written communication skills.

Analytical Skills

- Ability to understand and break down complex situations and problems.

Process Engineering and Statistics

- Understands specifications in drawings and blueprints.
- Translates product specifications into manufacturing processes, test and inspection methods.
- Specifies equipment capable of producing or measuring product design requirements.
- Design fixturing and tooling to support assembly, inspection and testing.
- Specifies testing requirements and methods to test product and process outputs.
- Develop recommended courses of action utilizing statistical techniques.
- Understands and applies basic uses of statistics in the manufacturing environment including gage R&R, sampling plans, design of experiments, process capability and control charting.

Continuous Improvement

- Understands six-sigma or other systematic methodology for effecting change and measuring improvement
- Practitioner of structured problem solving techniques

EDUCATION

A BS in Mechanical or related Engineering field is required, MS preferred.

Qualified candidates should send a cover letter and resume to careers@cequr.net.