Position:	Supplier Quality Engineer
Company:	CeQur Corporation
Location:	Columbia, SC
Reporting Relationship:	Engineer Manager - Operations

CeQur® is dedicated to helping people with diabetes by developing and commercializing simple drug delivery devices that can be easily integrated into daily life. The company has a platform of an extremely simple, discrete, and wearable, 3-day device, with the first-generation being FDA cleared and CE marked.

At CeQur, we aim to challenge the status quo mindset and provide solutions to people with diabetes that are profoundly simple and clinically effective. 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.

Job Description

The Supplier Quality Engineer will be responsible for the qualification and management of raw material/component suppliers to ensure product/service quality meets CeQur requirements. Interfaces with other CeQur departments (Operations, Information Technology and Regulatory Affairs) as well as with suppliers and other external parties on issues related to product quality. Effectively communicates Quality metrics through supplier scorecards and management review to the organization, suppliers and Executive Management.

Principal Responsibilities

- Develop a process and lead internal component and raw material non confirming investigations.
- Assist with the qualification of new suppliers, new components, and changes by developing and executing, in conjunction with other internal groups, a robust and complete set of plans and requirements for such qualifications.
- Communicate quality issues to suppliers as needed and help develop corrective actions.
- Initiate and follow up on supplier corrective actions related to non-conformances to ensure timely closure.
- Generate monthly, quarterly and annual Supplier Performance Reports for Management visibility.
- Track and trend supplier performance via supplier scorecards, taking remedial action as needed.
- Assist or lead CAPA evaluation and closure as related to the supplier quality processes and/or supplier performance.
- Work with internal or external inspection resources to fulfill incoming inspection requirements for device components.
- Performs other duties as required.

Education, Experience and Skills Qualifications

- BS/BA Degree or Equivalent.
- 2 - 4 years of experience in Quality in the medical device industry.
- Medical device or related industry experience in a technical position.
- Working knowledge of the Quality System Regulation (FDA 21CFR Part 820) and ISO 13485 quality system standards.
- CQE and/or CQA certification is desirable.
- Strong verbal and written communication skills, internal and external to the company.
- Good interpersonal skills in dealing with suppliers, peers and other functional areas.
- Ability to prioritize multiple competing deliverables simultaneously.
- Must be proficient in Word, Excel, Outlook and Power Point.
- Familiar with NPI/Launch Strategy. Familiar with injection molding process and automated assembly process.
- Statical analysis a plus.

This description reflects management's assignment of essential functions; it does not proscribe or restrict the tasks that may be assigned.