Position:	Manager, Quality Operations
Company:	CeQur Corporation
Location:	Columbia, SC
Reporting Relationship:	Vice President, Regulatory Affairs & Quality Assurance

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CeQur® is dedicated to helping people with diabetes by developing and commercializing simple drug delivery devices that can be easily integrated into daily life. We are looking for motivated, A+ team players to join our team in a dynamic, rewarding environment as we fulfill the promise of our Quality Policy:

CeQur's mission is to simplify the lives of people with diabetes. We will achieve this by providing convenient, discreet, and injection-free insulin delivery products and support services with a *Quality First* commitment.

Quality First means:

- Providing products and services that meet our customers' requirements, and endeavoring to exceed their expectations
- Continuously improving the processes comprising our quality management system
- Conducting ourselves with integrity and striving for excellence in all we do
- Complying with all applicable regulatory requirements

Job Description

Reporting to the VP RA&QA, the Manager, Quality Operations will have responsibility for assuring that CeQur products and services are manufactured and provided in accordance with our Quality Management System procedures and the requirements of the FDA Quality System Regulation and ISO 13485:2016. As CeQur outsources a large proportion of its manufacturing and other product realization activities, this role will be heavily focused on overseeing CeQur's Supplier Management quality system processes, and will accordingly serve as the primary liaison between CeQur's and our suppliers' Quality Assurance functions. This will be a "hands on" role requiring development and optimization of processes, technical problem solving, and effective collaboration with internal and external partners.

Principal Responsibilities

- Developing/optimizing CeQur product realization quality system processes, with a primary focus on Supplier Management processes.
- Assessing suppliers' compliance with CeQur quality system requirements via audits or other evaluation methods.
- Collaborating with our suppliers and other CeQur functions to process and resolve supplier-reported quality events (e.g., nonconformances, deviations, etc.).

- Reviewing and approving supplier process qualification activities (e.g., IQ/OQ/PQ) as warranted.
- Overseeing product acceptance and release processes.
- Representing CeQur in FDA and other regulatory/certification body inspections and audits.
- Developing, monitoring, and reporting of Quality Operations KPI metrics.
- Supervising and developing Quality Operations personnel.

Education, Experience and Skills Qualifications

- Bachelor's degree in engineering or related field.
- Approximately 10+ years of experience in Medical Device Quality Assurance.
- In-depth knowledge of and experience complying with FDA Quality System Regulation (21CFR Part 820) and ISO 13485:2016 requirements.
- Strong technical writing and verbal communication skills.
- Effective project management experience.
- Successful experience representing companies during FDA inspections and ISO 13485:2016 audits.
- Effective internal and external collaboration skills.
- Experience working within automated manufacturing environments strongly preferred.
- CQE and/or CQA certification is desirable.
- Ability to travel approximately 20% of the year.
- Proficiency in office software (e.g., Word, Excel, Outlook, Power Point, etc.).

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