Job Title: Senior Manager, Supplier Development

Department: Operations

Reports To: Senior Director, Operations

CeQur® Corporation develops and commercializes a discrete, simple-to-use and wearable insulin delivery device that easily integrates into patients' daily lives. CeQur Simplicity™ is a 4 Day Insulin Patch designed to reduce the barriers and challenges of multiple daily injections to enable people with diabetes to achieve glycemic targets. CeQur Simplicity™ is FDA cleared and CE marked.

At CeQur, we aim to 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.

Position Overview:

The Senior Manager, Supplier Development is a key leadership role responsible for developing, executing, and sustaining robust supplier qualification, performance management, and continuous improvement programs. This individual will partner cross-functionally with Quality, Operations, R&D, Regulatory Affairs, and external suppliers to ensure that all sourced materials and components meet CeQur's high standards for quality, reliability, and compliance. This is a highly strategic and hands-on role, ideal for someone who excels in a fast-paced, innovative medical device environment and is passionate about building strong supplier relationships and operational excellence.

Key Responsibilities:

- **Lead Supplier Qualification and Development Activities:**
  Develop and execute qualification plans for new suppliers, components, and materials. Collaborate with internal teams to define critical requirements and ensure robust validation protocols are met.
- **Supplier Performance Management:**
  Create, manage, and communicate supplier scorecards and performance metrics. Lead regular supplier business reviews to address quality trends, performance gaps, and improvement opportunities.
- **Nonconformance and Root Cause Investigation:**
  Own the process for investigating and resolving raw material/component nonconformances, ensuring timely root cause analysis and effective corrective/preventive actions (CAPAs).
- **Audit and Compliance Support:**
  Plan and participate in supplier audits to ensure ongoing compliance with FDA 21 CFR 820, ISO 13485, and other applicable standards. Support internal and external audits as a subject matter expert on supplier quality.
- **CAPA and Continuous Improvement:**
  Drive continuous improvement initiatives within supplier operations. Lead or support CAPAs related to supplier issues and collaborate cross-functionally to resolve recurring quality challenges.

- Cross-functional Collaboration:
  Serve as the primary liaison between CeQur and its suppliers. Partner with Engineering, Operations, Quality, and Regulatory Affairs to ensure alignment of supplier capabilities with business and product needs.
- Inspection and Quality Support:
  Support incoming inspection strategies by working with internal teams or external inspection services to ensure proper verification of incoming components.

Education:

- BS/BA in Engineering, Quality, or related technical field; advanced degree preferred.
- CQE and/or CQA certifications are highly desirable.

Experience and Skills:

- 10+ years of experience in a quality or supplier development role in the medical device industry.
- Strong working knowledge of FDA 21 CFR 820, ISO 13485, and relevant international regulations.
- Proven experience in supplier qualification, auditing, and quality issue resolution.
- Experience with wearable or combination medical products and their manufacturing processes (e.g., injection molding, automated assembly) is preferred.
- Deep understanding of risk management tools (e.g., FMEA, fault tree analysis).
- Strong statistical analysis and problem-solving skills.
- Proficient in Microsoft Office Suite (Excel, Word, PowerPoint, Outlook).
- Excellent verbal and written communication skills.
- Demonstrated ability to manage multiple priorities in a dynamic, fast-paced environment.
- Strong interpersonal skills with the ability to work cross-functionally and influence at all levels.

Requirements:

- Light lifting may be required
- Up to 25% travel