Job Description

Job Title: Supplier Quality Engineer	**Department:** Quality
Reports To: Principal Quality Engineer	**Revision Date:** November 9, 2016
Classification: Temporary / Contractor	**Position Location:** San Jose, CA

Company Overview

Outset is a pioneering medical technology company that puts the patient before the machine. Our human-centered model is designed to dramatically improve not only the care experience – for patients, families, providers and physicians alike – but also cost-efficiency of dialysis delivery. We believe in introducing technology innovation in order to drive service model innovation. And in doing so, we intend to profoundly and permanently impact what, where and who can dialyze.

Position Overview

The Supplier Quality Engineer will join the Quality organization in managing approved suppliers, scheduling and performing supplier audits, and supporting refinement of the quality system. The successful candidate will have audit experience and an in depth understanding of medical device quality system requirements.

Essential Job Functions

- Coordinates with suppliers relating to quality performance, trends, and corrective action. Verifies compliance and effectiveness of supplier quality systems by performing supplier audits and surveys. Initiate programs to improve supplier quality performance.
- Work with suppliers to refine and enhance products and processes by applying continuous improvement principles and techniques to assure quality of goods and services provided.
- Will be responsible for ensuring that nonconforming material is dispositioned in a timely manner and analyze defect trends in order to initiate appropriate corrective action with the supplier.
- Develop second sourcing strategy based on risk assessments of suppliers' stability and capability.
- Champions problem solving and root cause analysis activities with suppliers to eliminate recurrence of non-conformances.
- Works with Operations and R&D to ensure supplied components, subassemblies, and modules have clearly defined specifications and inspection requirements.
- Works with Operations and R&D to ensure the correct components are chosen based on their clinical and functional use.
- Works with Supply Chain to create a strategic sourcing plan.
- Applies sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues.
- Creates Supplier Quality Audit Plans, Leads Supplier Quality audits, and authors audit reports.
- Initiates Supplier Corrective Action Reports (SCARs) and tracks them to completion.

Requirements/Qualifications

Required:

- BS degree in engineering or technical field or equivalent experience; M.S. or PhD preferred.
- 5+ years of related experience with medical products.
- Previous audit experience.
- Detailed knowledge of medical device regulation and standards such as 21 CFR 820, GMP, ISO 13485, ISO 9001 and ISO 14971.
- Solid communication and interpersonal skills.
- Able to travel 25-75%, domestically and internationally

Preferred:

- Previous training and / or experience as a Lead Auditor.
- Manufacturing experience with medical devices is preferred.
- Engineering experience and demonstrated use of quality tools/methodologies.
- Strong project management and leadership skills, including the demonstrated ability to lead multi- departmental project teams and resolve quality-related issues in a timely and effective manner.
- Advanced computer skills, including statistical/data analysis and report writing skills.