Job Description

Job Title: Director, Quality Assurance	**Department:** Regulatory & Quality
Reports To: VP, Quality & Regulatory Operations	**Revision Date:** November 11, 2016
Classification: Exempt, Full-Time	**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.

Essential Job Functions

- Maintain Quality and Regulatory compliance through the development and oversight of appropriate strategies, tactics and related activities and by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; providing input on internal audits, complaints, licensing, document control, change control, good distribution practices, temperature monitoring, process validation, computer validation, and DEA.
- Provide counsel, training and interpretation of FDA and other regulatory requirements to all company employees.
- Responsible for company's product quality and reliability to meet or exceed customer expectations.
- Responsible for company's Quality Compliance to ensure compliance with regulatory agencies and all applicable standards worldwide.
- Develop quality assurance plans by conducting hazard analyses, identifying critical control points and preventive measures, establishing critical limits, monitoring procedure execution and corrective actions.
- Oversee the preparation of quality records by collecting, analyzing, and summarizing information and trends including failed processes, corrective actions.
- In support of the quality system, provide effective leadership support, training and guidance to all company personnel.
- Support both hardware and software quality assurance.
- Provide technical guidance to the Quality Engineering team.
- Provide input to product requirements and features.
- Contribute to software release process and release notes documentation.
- Host regulatory external inspections and audits.

Requirements/Qualifications:

- BA/BS undergraduate degree in life sciences, engineering, business or equivalent experience.

- 15+ years medical device quality, regulatory and clinical experience in a medical device or life sciences technology driven company.
- Progressive & proven record of leadership and managing quality/regulatory/clinical organizations.
- Experience with all phases of the product development lifecycle, including concept, design, implementation, verification and validation activities necessary for product commercialization.
- Extensive experience in cGMP and other Regulatory compliance requirements. Experienced in regulatory filings for US (510(k), IDE and PMA) and other key countries/regions.
- Validation experience required.