Job Description

Job Title: Director, Regulatory Affairs	**Department:** Regulatory Affairs
Reports To: VP, Quality	**Date:** April 20, 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.

Position Overview

The Director of Regulatory Affairs will possess solid post-market/commercialization experience in all regulatory and quality processes. The pro-active, intellectually curious candidate will implement, champion, coordinate and document regulatory processes within the company, as well as prepare reports for submission to regulatory agencies.

Essential Job Functions

- Works with a talented multi-disciplined engineering group to document, validate, and verify product designs and design changes and confirms compliance with Design Control regulations. Candidate will have the judgement and presence to participate on product development team and weigh in on design changes and the corresponding required verification and regulatory assessment.
- Reviews test protocols and test reports to confirm updated designs and corresponding testing, conform to relevant requirements.
- Recommends changes to company procedures in response to changes in regulations and standards.
- Writes and updates standard operating procedures, work instructions, and policies.
- Analyzes product and field complaints and makes recommendations regarding their reportability.
- Drafts key regulatory submissions and ensures the successful clearance and/or approval of those submissions.

Requirements/Qualifications

- 10+ years of successful regulatory experience with a commercialized medical device.
- Desired but not required - direct experience with drafting 510(k) Submissions that were successfully navigated through the approval process at FDA.
- Desired but not required - has had direct experience drafting original IDE Submissions and relevant Supplements, Annual reports, and other Amendments.
- Desired but not required - experience with CE Mark process including authoring Clinical Experience Summaries, as required by MDD.

- Has a deep enough knowledge of regulations so that judgements and creative solutions can be considered and discussed.
- Is a clear and independent thinker.
- Has a personality that is focused, driven, ambitious and seeks out innovative approaches to challenges.
- Possesses exceptional communication skills and whose daily actions are culture building.
- Has the ability to interface effectively with all levels and functions within the organization.
- Strongly preferred, but not mandatory, experience with capital equipment devices that include hardware, firmware, and software.
- Has an undergraduate degree in a field relevant to a regulatory position in the medical device industry.