Senior Director, Disposable & Accessories – Onsite San Jose

Surgical robotics company enabling better patient care by developing transformative solutions in urology. Location: Onsite San Jose

**SUMMARY**
The Senior Director, Disposables & Accessories will manage a team of Engineers who are responsible for the research and product development of our high-volume and high-margin disposable products. As a leader within COMPANY, you will play an active role in helping us achieve and maintain our vision to be the treatment of choice for all BPH patients world-wide. She/he will provide leadership to the disposable and accessories areas in the development and implementation of new solutions and will manage support from various skills. The position requires a solid understanding of COMPANY’s internal design controls, while working cross-functionally advancing development, prototypes, testing, documentation, and production transfer as well as management of external development and manufacturing resources. This is your dream role if you are excited about developing innovative and groundbreaking medical devices, solving complex engineering and commercial challenges, and have excellent interpersonal and leadership skills. The position will apply your mastery of first-rate program management abilities and technical skills to the worldwide growth of the AQUABEAM® Robotic System.

**CORE RESPONSIBILITIES (Other duties may be required as assigned)**
The Senior Director, Disposables & Accessories will be responsible and accountable to lead activities and outcomes in a high growth environment that is both highly technical and highly collaborative. Responsibilities include:

* Leading cross functional skills of mechanical, electrical, and software skill for complex new-to-market product development programs or new major initiatives that serve to enhance the reliability and efficacy of the product.
* Ability to drive unique design requirements for sterile high-volume single-use medical device products
* Planning resource requirements and negotiating team resource assignments with functional leaders within COMPANY.
* Leading the creation of the cross-functional project plan, including budget and resource planning, to fulfill the product concept.
* Aligning and managing all cross-functional activities to deliver the product on time and on budget while meeting all agreed upon technical, operational, business and customer requirements.
* Negotiating and resolving personal and team conflicts and project and functional conflicts and driving consensus among team members to accomplish project and business goals.
* Refining, and understanding customer requirements.
* Successfully tracking progress to requirements, plan and resolve deviations.
* Architecting or refining the high-level product concept to fulfill the customer requirements.
* Providing work definition and direction to the assigned cross-functional Core Team Members.
* Supports the growth of engineers; advances the tools and processes utilized by the engineering team. Recommends and implements changes to methods. Makes final decisions on administrative or operational matters and ensures effective operations and achievement of objectives.
* Instrumental leader for resource management, staffing, and identifying and assigning resources across all projects, and defining resource needs.
* Sets, manages, and reports on project budgets and departmental budgets.
* Drives collaboration between multidisciplinary stakeholders and subject matter experts; leads projects requiring inputs and deliverables from adjunct department contributors.
* Solicits inputs from the development team and stakeholders on project and product risks; anticipates, captures, and dispositions risk through the project risk registry or RAID (risks, assumptions, issues, and dependencies) log; contributes to risk management activities and documentation.
* Collaborates with clinical, quality, regulatory, and marketing to understand and develop product specifications.
* Understands testing requirements to assess the feasibility of new products; works cross-functionally on the development of protocols, builds, procurement, testing, reporting and documentation release.
* Aware of all project schedules, progress, and resources. Works with stakeholders and development team on Agile and Phase Gate development planning. Drives team to use Agile methods, daily scrums, reviews, and retrospectives in accordance with COMPANY BioRobotics’ design controls procedures.
* As needed, supports management of engineering projects through on-boarding, executing, monitoring, and reporting on projects including adherence to the schedules and milestones.
* Experience with Design History File (DHF) and Device Master Record (DMR), supporting compliance to the QMS and regulations, design reviews, controlled documentation and supporting audits.
* Conducting successful project reviews; making leaders aware of, and proposing solutions to, unanticipated or potential issues/concerns as soon as they are known.
* Driving successful product design and quality.
* Providing accurate and timely reporting, e.g. project portfolio server, resource allocation, dashboard updates.
* Contributing to the continuous improvement in organization's ability to execute programs and projects from initiation through launch.
* Quality Management System – Maintains trained status for, and complies with, all relevant aspects of the COMPANY BioRobotics Quality Management System to ensure product and support regulatory compliance.
* Environmental Health and Safety (EHS) Policy - Understands and adheres to the COMPANY BioRobotics EHS Policy.
* Must carry out the managerial responsibilities listed under the “Managerial Responsibilities” section.

**QUALIFICATIONS (Education, Experience, Certifications)**
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

* Bachelor’s Degree in Engineering or a related field required, advanced degree preferred.
* 20 years’ experience required in increasingly advanced engineering assignments, at least 10+ years of which are in functional management with a medical device company leading and managing end-to-end projects and cross-functional project teams
* Successful track record of developing and launching commercially viable complex medical device technologies (FDA Class 2 minimum with Class 3 highly desired) and delivering to market.
* Highly proficient in collaborating with project stakeholders (client and internal), end-users, business partners, and technical team members to ensure proper plan alignment and deliver high quality projects
* Deep understanding of disciplined product/technology development processes (Phase/Gate product development method), regulatory and quality requirements, high-volume manufacturing.
* Successful experience working with outside contract development groups and transfer to internal resources for a successful product launch.
* Must be a skilled and determined communicator with strong leadership and negotiation skills and a naturally collaborative relationship-builder.
* Awareness of regulatory standards (e.g. IEC 60601, ISO14971, ISO 13485); system level V&V planning and execution.
* Excellent verbal and writing skills as well as presentation expertise to senior level leadership.
* Organizational awareness and ability to garner support at all levels for a course of action.
* Strong fit with COMPANY values: Excellence, Commitment, Ingenuity, Teamwork, Ethics and Drive.
* Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, or governmental regulations. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from other internal groups, clients, customers, and the general public.
* Ability to work as part of a multi-disciplinary team in a small, fast-paced company

**MANAGERIAL RESPONSIBILITIES**
Directly manages employees in the R&D Department. Carries out managerial responsibilities in accordance with the organization’s policies and applicable laws. Responsibilities include interviewing, hiring, and training employees; planning, assigning, and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and resolving problems.