Principal SupplierEngineer, *Mechanical*

**SAN JOSE, CA /OPERATIONS /FULL-TIME/ ON-SITE**

Company is a surgical*robotics*company enabling better patient care by developing transformative solutions in urology. With an initial focus on BPH, the company’s AquaBeam®*Robotic*System delivering Aquablation therapy, is the first FDA-cleared, automated surgical robot for the treatment of [lower urinary tract symptoms (LUTS)](https://aquablation.com/life-with-bph/#signs-and-symptoms-of-bph) due to benign prostatic hyperplasia (BPH). Aquablation therapy combines real-time, multi-dimensional imaging, automated*robotics*and heat-free waterjet ablation for targeted, controlled, and immediate removal of prostate tissue. Aquablation therapy offers predictable and reproducible outcomes, independent of prostate anatomy, prostate size or surgeon experience.

**SUMMARY**

Responsible for ensuring*suppliers*meet this company’s requirements for *quality*, service, delivery, and *cost*.  Drives*suppliers*to continuously improve business and*manufacturing*processes.  Collaborates with*Supplier Quality* to evaluate and select *suppliers*.  Guides R&D in choosing*suppliers*for new products and provides DFM input to new designs.  Supports both*NPI*and on-going *production*, monitoring and working with*suppliers*to improve*supplier*performance.  Executes detailed projects with*suppliers*to implement changes and improvements affecting *quality*, *cost*, capacity, risk, and sub-*supplier* *management*.

The ideal Candidate possesses broad and deep hands-on*metal machining manufacturing* experience and/or*plastic injection molding*experience along with skills to select and develop *suppliers*.

**CORE RESPONSIBILITIES**

* + Manage*supplier*changes including*manufacturing*process changes,*production*optimization, facility changes, new equipment qualification, and new line validations.
	+ Select the right process and*supplier*for the part, considering long term fit and total*cost*of ownership.
	+ Work with*suppliers*to execute*cost*reductions, capacity improvements, and risk mitigation.
	+ Complete project/ part qualification deliverables including: *Supplier*pFMEA, Process Validations (IQ/OQ/PQ), Inspection Reports, Gage R&R, and Process Capability Analysis.
	+ Build, own, and relentlessly pursue a vision for developing *suppliers*.  This may involve visits and teleconferences with domestic and overseas partners.
	+ Generate key metrics for the team and *suppliers*, and continually drive for timely achievement of those metrics.
	+ Drive*suppliers*to continually improve their*manufacturing*process performance to meet company’s requirements for*supplier*excellence using a collection of best practices in *project management*, Six Sigma, Lean, SPC and negotiation. *Lead*these efforts without managerial guidance at several*suppliers*simultaneously.
	+ Implement corrective and preventive actions for*supplier*processes by driving *supplier*’s investigations and *root cause analysis*.
	+ Develop*supplier*ramp readiness plans by judging business risk based on forecast,*supplier*capacity,*quality*performance, and process capability.
	+ DFM by engaging*suppliers*early in development cycle to provide feedback regarding manufacturability improvements in the designs prior to *production*.
	+ Influence and guide R&D in choosing*suppliers*by determining selection criteria for preferred*suppliers*and leading the team effort to evaluate preferred *suppliers*.
	+ Effectively prioritize and advance multiple concurrent projects and tasks.
	+ Research and recommend new technologies to improve reliability, efficiency and contribute to*cost*reduction.
	+ Communicate business and technical needs, status, results, and observations to operating, technical and business teams.
	+ Maintain trained status for, and comply with, all relevant aspects of the company’s*Quality Management* System to ensure product*quality*and support regulatory compliance.
	+ Understand and adhere to the company*Quality*and EHS policies.
	+ May require up to 20% travel, domestic and international.

**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.
	+ BS in*Mechanical*Engineering or equivalent with a minimum of twelve years experience.
	+ Prior experience in the*medical device*industry is preferred.
	+ Experience in leading highly technical projects in a cross functional environment both internally and with CMs/*Suppliers*.
	+ Demonstrable knowledge in evaluating and challenging*supplier*technical, *quality*, and business capabilities.
	+ Extensive experience with*root cause analysis*and problem solving for both technical and process issues.
	+ Basic working knowledge of*CAD*(*SolidWorks* or other) software.
	+ Ability to read and interpret detailed*mechanical*drawings (GD&T) and communicate technical information.
	+ Experience working in a structured design process such as*ISO9000*or *FDA QSR*, knowledge of regulatory approval process and requirements.
	+ Working knowledge of design control and cGMP requirements for*medical device manufacturing* per*FDA QSR*and *ISO13485*-2003 or*ISO9001*and *EN46001*, including experience in auditing*suppliers*to these standards.
	+ Ability to travel to*suppliers*on an as needed basis – domestic and international.

**PHYSICAL DEMANDS**

* + The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
	+ To perform this duty the employee must have the ability to sit or stand at and operate a computer terminal and walk or travel within the facility. The employee may occasionally lift and/or move up to 50 pounds.

**WORK ENVIRONMENT**

* + While performing the duties of this job, the employee is regularly working in an office environment.
	+ The employee will then occasionally be exposed to engineering labs, a machine shop, and*manufacturing*clean rooms.  This environment is subject to moderate noise from machinery (IE machine shop equipment, the company Aquablation unit, computer equipment, printers, etc.), for which proper hearing protection may be assigned and worn.
	+ The employee may be exposed to hazards including*electrical*sparking, water, and chemicals, for which proper protective equipment may be assigned and worn.

**COVID-I9 Vaccine Requirement:**As of August 19, 2021, all company employees must be vaccinated against the COVID-19 virus. The company will follow an accommodation process for*medical*or religious exemptions.