Contact: Terry McCarthy
(949) 716-3524
tmccarthy@prodigysearchgroup.com

Position: Vice President of Operations & Engineering
Reports to: CEO
Industry: Medical Device **-** Dental

Company Overview:

Our client is a rapidly growing orthodontic company located in Irvine, CA that offers a revolutionary new paradigm in healthy, automated and invisible tooth movement.

Job Description:

Based in the Irvine office, and reporting to the Chief Executive Officer ("CEO"), the VP of Operations & Engineering will have overall strategic responsibility for all aspects of Operations, including management of manufacturing and supply chain logistics, product engineering and development, technical aspects of regulatory affairs, quality assurance, and facilities. The existing team is comprised of five full-time employee direct reports, including a Director of Engineering, Manufacturing and Software, a QA manager, and an Orthodontic Technologist. The ideal candidate will be comfortable and effective operating at a broad, strategic level as well as at every level of detail required in a design & manufacturing, FDA regulated, company.

Essential Duties and Responsibilities

Manufacturing and Supply Chain Logistics

- Oversight of all manufacturing and production activities, including new production facility layout. This includes driving Turn Around Time and COGS to meet or exceed strategic goals.
- Risk management analysis of alternative manufacturing and supply chain strategies, which may include insourcing or outsourcing certain aspects of the process, and/or initiating search and selection of new and additional manufacturing partners and key suppliers.
- Supervision and improvement of order entry process and all related aspects – partner with Sales to establish customer service excellence.
- Seek continuous improvement of all areas of manufacturing and production.
- Oversight of all business systems involved in manufacturing, production, quality management, complaint handling and product performance, including evaluation of system efficiencies and interface capabilities.

Product, Software, and Manufacturing Engineering

- Oversight of all design engineering responsible for developing both new products and new revisions of existing products in a Class 1 and Class 2 FDA environment.
- Management of all manufacturing engineering necessary to drive operational efficiency, including establishing KPI's and driving Continuous Measurable Improvement (CMI).
- Leadership of the software engineering organization to include customer-facing portals, internal process optimization, and UI/UX of all software systems.
- Continual optimization of insource/outsource and FTE/Contractor resource balance necessary to meet strategic objectives and balance risk.
- Oversight of all engineering functions includes establishing and/or expanding the project management function, utilizing both phase-gate as well as Agile methodologies, as applicable.
- Responsibility includes Facilities engineering (layout, fit-out, management)

Regulatory Affairs and Quality Assurance

- Supervise all control aspects of Quality Management System, including oversight of Quality Control and Document Change Order process, product returns and performance analysis, complaint handling and all other controlled procedures and policies.
- In conjunction with the Quality Manager and Regulatory Affairs personnel, ensure compliance with all applicable FDA (21CFR820) regulations. Prepare company for future compliance with ISO (13485:2016) regulations.
- Work with Regulatory Affairs to prepare all technical aspects of new market regulatory filings, and maintenance of current market filings.

General Leadership and Strategic Planning

- Lead, coach, develop, train, and build a high-performing team of Operations personnel.
- Appropriately balance risk in all technical functions to leverage speed & agility while ensuring regulatory compliance.
- Evaluate company growth plans and strategic goals to ensure Operations and Engineering Strategic plans optimize growth methods to drive highest ROI and exit valuation, including international and strategic partnerships, as necessary.
- Communicate effectively to foster cross-functional, inter-departmental collaboration with other senior leaders.
- Prepare and deliver presentations to the Company's Board of Directors.
- Prepare and submit comprehensive annual operating plan, including budgets and cost forecasts.

MINIMUM REQUIREMENTS AND QUALIFICATIONS

- 20+ years of experience, including 5+ years VP level, in the design & manufacturing industry, including a minimum of 5 years in the dental field. Digital Dentistry experience strongly preferred.
- Broad experience across manufacturing, hardware engineering, software engineering, and QA/QC.
- Track record for personnel excellence, including hiring, termination, and compensation/performance practices to build a high-performing functional team.
- Experience in a business model that works directly with end user customers, vs. through distribution channels.
- Deep experience in program budgeting and fiscal management.
- Board of Directors-level interaction.

PREFERRED EQUIREMENTS AND QUALIFICATIONS

- Experience in both larger corporate and start-up environments.
- Good understanding of current FDA regulations, ISO 13485:2016 qualifications, CE Mark standards and Medical Device Directives; familiarity with international equivalent regulating authorities in APAC and EMEA Regions.
- Familiarity with capital-raising process

COMPENSATION AND TRAVEL REQUIREMENTS

- Competitive salary, opportunity to participate in executive bonus program, and equity ownership.
- Travel requirements may be as high as 15%, with most quarters at approximately 5%.