



## VICE PRESIDENT OF OPERATIONS - POSITION PROFILE

### COMPANY OVERVIEW:

OrthAlign, Inc. is a privately held medical device company that was established in the summer of 2008 and based in Irvine, CA. The company is developing a line of computer assisted surgical devices that distill the critical features and benefits of large surgical navigation systems in a non-invasive, disposable, palm-sized solution with accompanying instrumentation. OrthAlign's goal is to create a new standard of care in total joint replacement, making consistent and measurable results accessible to surgeons and patients.

In December 2008, OrthAlign secured its Series A financing round. The capital is being deployed to confirm the practicality of the technology, the applicability to the surgical suite and to bring the first generation of products to market. Initial prototypes have been received favorably by leading orthopedic surgeons in the US. The company expects to start commercialization of its first products in the second half of 2009. The initial product targeting knee replacement surgery has been developed and the 510K application was filed in May 2009. OrthAlign contracted with a local contract product development and pilot production house specializing in the design and development of electronic and electro mechanical devices for medical use. The contracted engineering firm has assisted in bringing the prototype to the pre-manufacturing stage.

### BACKGROUND:

The 510K for the initial product offering from OrthAlign was filed in May 2009 and is awaiting approval. The company is targeting transition from pilot production which has been accomplished in a non-automated production process at the contracted engineering firm to a true manufacturing facility capable of developing production process design and initial scale-up automation to achieve cost efficient production and rapid order fulfillment with a secure supply chain in place and achieving minimal parts and finished product inventory. OrthAlign desires to retain in-house capability (or utilize the contracted engineering firm or similar) to develop product modifications, prototypes, and first run capability and initial production process design prior to transitioning to production and scale-up.

OrthAlign, in collaboration with the contracted engineering firm, has developed an initial supply chain, assembly processes, sterilization process, and quality assurance. The company is aware that transitioning to manufacture of larger lot sizes to meet initial market requirements and later scale up as demand increases may require changes at established vendors, additional sources of supply, changes to production and sterilization processes, and a comprehensive quality assurance system capable of manufacturing in a scaled up and semi-automated manufacturing environment. It should also be anticipated that, once the product is in production and in the market, revisions to the product design may require further manufacturing changes in terms of both suppliers and production processes to achieve optimal market acceptance and production economics. The VP of Operations will need to factor in that the product is in development and may be superseded by improved product in the near future. Furthermore, the manufacturing planning should also consider the typical cash flow constraints of a start-up and the possibility that the company will be acquired by an entity with its own manufacturing pipeline.

### VP OF OPERATIONS:

OrthAlign is currently seeking a **Vice President of Operations**, who will report to the President and CEO. The VP of Operations is a new position expected to plan and execute a transition to initial manufacturing. The VP of Operations will have a significant opportunity to positively impact the company by successfully planning and implementing contract manufacturing and supply chain management, resulting in state-of-the-art and sustainable product quality, consistently delivering on commitments to customers, all the while reducing product cost. The VP of Operations will be responsible for manufacturing planning and execution, sourcing of contractors and materials, manufacturing engineering, inventory management and shipping.

**PERFORMANCE OBJECTIVES:** To achieve the mission for this position, the VP of Operations must produce the following critical actions and results:

Initial Deliverables:

1. Assess and identify potential contract manufacturers with the capabilities required to produce qualified product and reduce costs
2. Work with selected contract manufacturers to identify optimal supply chain partners and alternates to achieve cost reduction
3. Identify OrthAlign organizational resource requirements
4. Develop and analyze product(s) volume and cost models to optimize gross margin over time, including developing a strategy for overseas manufacturing and purchasing after the initial phase
5. Coordinate contract manufacturing start and ramp up to marketing and sales requirements
6. Identify manufacturing process improvement strategy as sales ramp up.

Ongoing Deliverables:

1. Deliver on commitments, in a timely and flexible manner
2. Continuous cost improvements
3. Improve Product Quality

**BACKGROUND AND EXPERIENCE REQUIREMENTS:**

The ideal candidate will have the following education, work history, knowledge and skills:

- BS degree – Electrical Engineering preferred, or degree in another engineering discipline; solid technical training in medical devices and electrical products.
- 15 years of increasingly responsible management experience in manufacturing and/or operations in a similar environment: requirement for outsourced manufacturing management experience, preferably including overseas manufacturing of low cost, high volume medical devices with a significant electronics component to their precision and functionality.
- Hands on experience with and proven success in logistics, purchasing and shipping as well as quality control and running operations in a regulated environment will be considered an asset.
- Evidence of improvement of groups/processes/profits/etc. in a similar environment is important. The ideal candidate has learned in a larger company and been successful in similar roles in at least one startup company.
- Career progression ideally will include a combination of engineering, design for manufacturing, manufacturing engineering, production and/or manufacturing management.
- Exposure to the FDA and ISO 13485, MRP/ERP systems, etc. is very helpful. P&L understanding is important.

**PERSONALITY AND CHARACTER:**

The ideal candidate will have most of the following traits:

- Passion for success
- Customer driven
- Produces results with people (not through people)
- Establishes trust and credibility
- Projects confidence and competence

For more information and applications, contact Sandy Guzman at:

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