

Performance White Paper ~ Interim Executive Engagement

Opportunity

Establish formal business operations and infrastructure for startup medical device company (Class III, Pre-market Approval). Acting Chief Operating Officer.

Challenge

Quickly and efficiently develop business operations for release of first tranche of financing.

Constraints

The company's device is a relatively complex platform requiring substantial development time, financial resources and FDA clinical trials prior to commercial launch.

Execution

Created company's inaugural Strategic Business Plan and five year pro forma financial budget. Established Strategic Commercialization Plan identifying roadmap to market, key influencers and potential early adopters.

Established FDA-compliant Quality Policy and quality system documentation and procedures.

Created investor communication documents and attended investor pitches in support of CEO.

Evaluated and initiated working prototype development with outsourced engineering firm.

Results

Achieved release of first and second tranche of investment funds.

China development and manufacturing facility established.

Ongoing advisory engagement on an *as needed* basis (due to long development cycle).

Patents issued.

Company on the threshold of closing B Round of equity financing. Company valuation now at \$28 million from pre-money valuation of under \$10 million (in less than two years).