



POSITION DESCRIPTION

Position Title: Manufacturing Engineer
Supervisor: Director of Supply Chain & Manufacturing Pilot Operations
Issue/Revision Date: February 1st, 2012

PURPOSE OF POSITION: Manage the transfer of medical devices from R&D into manufacturing. Position requires hands-on development of manufacturing processes, automated test systems and development of production procedures within an FDA GMP and ISO 13485 medical device quality system to improve manufacturing productivity and minimize product costs. Position will manage multiple projects (i.e., manufacturing scale-up, cost reductions, process improvements, etc.) to guarantee product availability and reduce product costs.

MAJOR DUTIES AND RESPONSIBILITIES:

- Provide manufacturing engineering support for the daily production output of both in-house and through contract manufacturers by implementing:
 - Engineering Change (ECOs) implementations and training,
 - Deviations and Rework activities, and
 - Methods analysis and process improvements.
- Coordinate the transfer and work with Company's contract manufacturers to setup, transfer, and coordinate production of Company products while acting as the liaison between Company's and the contract manufacturer.
- Plan, schedule and complete the manufacturing transfer of new and existing products by working with R&D, Quality and Regulatory Compliance to produce products on time and meet cost targets. Also when required support R&D prototyping of new product concepts and products under development.
- Create new processes and documents within production procedures as required for FDA cGMP and ISO 13485 cGMP. Resolve Supplier issues, design issues, and documentation issues to support customer shipments.
- Manage Project Planning to have tasks completed on time. Report Project Plan with milestones to management (including problem resolution and recovery schedule). Aggressively drive projects to successful implementation including:
 - Cost Reductions (Both within USA and off-shore),
 - Lead-Time Reductions,
 - Quality Improvements, and



- Capacity Enhancements
 - Document IQ/OQ/PQ validations creating protocols and reports to incorporate new processes/equipment into the production process.
 - Perform Supplier Assessments to develop Outsourcing Partners by coordinating the transfer to Contract Manufacturers (CM) being a liaison between R&D and the contract manufacturer. Support Supply Chain with alternate sourcing of components as needed.
 - Support company goals and objectives, policies and procedures, Good Manufacturing Practices (cGMP), and FDA, MDD and MOH regulations by working within and maintain FDA cGMP and ISO-13485 systems, including pre-production and post-production compliance in coordination with the Document Control, Regulatory and Quality compliance requirements.
 - Travel ($\geq 20\%$) with occasional international travel expected.

DESIRED QUALIFICATIONS & EXPERTISE:

- Proven ability to manage semi-automated assembly/test fixtures projects that utilize electrical, mechanical and software. Experience generating requirements documents (Statement of Work) to have equipment built.
- Technical expertise and knowledge base in plastic molding, sheet metal fabrication, machining, wire harnesses, PCBAs, and Box Build.
- Exposure to Material Requirements Planning (MRP) systems, BOM structuring, and product costing.
- Proficient in Microsoft Office with experience in Visio and Project desired.
- In-depth understanding and experience with FDA, CE and ISO medical device regulatory requirements relative to Class II 510K medical devices.
- Venture backed medical device small company experience.

EDUCATION AND EXPERIENCE REQUIREMENTS: BS Engineering Degree with minimum five years experience with a successful track record of manufacturing FDA Class I/II medical devices.