

**Position Title:** Manufacturing Engineer  
**Functional Group:** Production, ME, Materials  
**Reports To:** VP of Operations  
**Employment Status:** Full Time, Non-exempt

**PURPOSE OF POSITION:** The Manufacturing Engineer completes assigned projects as required for Production. Responsibilities include but are not limited to inspection, production, equipment introduction, preventative maintenance, and process validation.

**MAJOR DUTIES AND RESPONSIBILITIES:**

- Support company goals and objectives, policies and procedures that comply with worldwide regulations.
- Develop and perform validations protocols and reports (IQ, OQ, PPQ) in association with production process, equipment and facility needs.
- Help develop processes and procedures for new product lines while solving production related problems and document solutions for existing product lines.
- Become SME on individual production lines providing technical and performance support while also giving regular updates and metrics report outs to management and clients.
- Develop device master records (DMR) for new Client products and improve efficiencies of existing Client product lines.
- Provide DFM/DFA support during development of NPI products.
- Support Prospect ERP system which includes receiving inspection methods, support equipment, labeling, warehousing, and personnel training.
- Review non-conforming product, assess condition and viable rework, and prepare rework instructions.
- Correct quality issues which may include meeting with management to develop quality or process improvement plans for the long term.
- Support management of new and existing equipment files including facilitating calibrations, preventative maintenance, equipment improvements, and procurement.
- Proactively report project activities, issues, and schedule to management.
- Collect, analyze, and interpret manufacturing data to make sound decisions which impact production, personnel, and processes.
- Ensure production equipment is evaluated for safe operation and proper safety measures are in place as needed.
- Support incoming inspection, finish good inspections and final product release for distribution.
- Provide guidance and training to production operators as needed in support of NPI and ongoing production while listening to their feedback regarding process improvements.
- Complete other engineering duties as assigned and provide support for other departments, as necessary.

**MINIMUM REQUIREMENTS:**

- Engineering (BSME, BSEE, BSBE, etc.) degree required.
- Minimum 5+ years engineering experience in medical device manufacturing or contract manufacturing.
- Significant experience with FDA GMP, CE, UL and ISO 13485 preferred.
- Proven professional qualities, including strong initiative, integrity, and the desire/ability to work and grow in a dynamic team environment.

- Proven history of being able to consistently promote a positive, professional atmosphere and support activities that enhance the welfare and morale of PLS employees even during periods of shifting priorities.
- Proven problem solver with excellent track record of providing effective solutions based on data analysis and building strong relationships with key stakeholders.
- Ability to perform excellent work with moderate to medium supervision/direction.
- Experience with transferring products from design through validation into manufacturing.
- Experience with both low complexity/high volume and high complexity/low volume production both in and out of ISO Class 7/8 Cleanrooms.
- Able to create components, assemblies, and drawings as well as understand GD&T.
- Highly experienced user of Microsoft Office Suite to create documentation, spreadsheets, and databases to support Manufacturing operations.
- Excellent written and oral communication skills with excellent attention to detail.
- Possesses advanced mechanical aptitude and understanding of various manufacturing processes.
- Ability to organize and manage multiple projects simultaneously.
- Working familiarity with SPC and process control methodologies.
- Experience with production automation preferred.
- Experience working in lean production environments preferred.
- Technical writing experience preferred.

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Associate Signature

Date Reviewed

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Management Signature

Date Reviewed