



JOB DESCRIPTION

Job Title: Operations Engineer

Department: Operations

Reports to: Director of Operations

Direct Reports: None

JOB SUMMARY:

Works with and across the various disciplines of the assembly floor personnel, machine shop personnel, Operations team, Quality team, and Engineering team for project realization, manufacturability, inspection, and assembly of product. One of the primary functions of the position is to create, develop, and establish cost effective processes and procedures for manufacturability, inspection, and assembly to reduce cost and improve fabrication methods that meet the product specifications and requirements.

JOB DUTIES:

- Provides technical support to Assembly, Machine Shop, Purchasing, Quality, and Engineering as needed or when requested.
- Evaluates designs to develop, create, verify, and validate effective and cost-efficient manufacturing, inspection, and assembly processes that meet product specifications and requirements.
- Evaluates and troubleshoots problems, issues, or challenges in the manufacturing, inspection, and assembly processes to provide solutions.
- Must be able to perform and demonstrate all developed and existing manufacturing, inspection, and assembly processes in a general hands-on approach.
- Gathers information for analysis to provide data on existing as well as proposed manufacturing, inspection, and assembly processes for good decision making. This may include calculating production costs through labor, methods/processes, time, equipment, and materials.
- Works and collaborates with outside suppliers in acquiring information for new development requirements or in working through problems, issues, and/or challenges.
- Complies with regulations and established company policies, procedures, and processes to ensure best practices are followed that ensure all products or processes meet specifications and/or requirements.
- Attend or lead meetings as necessary as a part of team collaboration.
- Performs other duties as assigned.

SKILLS AND QUALIFICATIONS:

- A bachelor's degree of Science in Mechanical Engineering or related field is required.
- 3-5 years of related industry experience is required.
- Design and development in regulated industries required, preferably medical device background and working knowledge of IEC 60601-x, ISO 13485.
- Experience with design controls for medical devices Title 21 CFR 820 and ISO 13485 is preferred.
- Experience with Risk Management ISO 14971 is preferred.
- Experience with 3D Solid Modeling CAD software is required – SolidWorks preferred.
- Hands on experience with the design and development of small electromechanical systems/devices is preferred.
- Must be familiar with Microsoft Project.

- Experience and general understanding of operation and programming of Computer Numerically Controlled (CNC) equipment is required.
- Experience with Design For Manufacturability/Inspection/Assembly (DFMIA).
- Good understanding of ASME Y14.5 Geometric Dimensioning & Tolerancing (GD&T) and how it relates to the design, manufacturing, inspection, and assembly processes or procedures.
- Able to conduct tolerance stack-up analysis is required.
- Able to conduct stress analysis or analysis of the loading conditions on a design for assembly or manufacturing processes.
- Able to understand and implement principles of Lean Methodology for improvements and gain efficiency.
- Able to apply statistical methods to analyze data for testing, manufacturing, inspection, and assembly processes. Able to gather information and data quickly and efficiently for analysis to provide direction and guidance for good decision making.

ACCOUNTABILITY:

- Assume responsibility and ownership with minimal direction and guidance.
- Exercise initiative and judgement with data driven decision making.
- Provide support to team members, customers, and others in the company as required.
- Assure all regulations, policies, procedures, or processes are followed as specified by the company.
- Utilize standards and best practices where appropriate.
- Maintain a safe working environment.
- Hands on approach to problem solving.
- Expected from time to time to put in extra time and effort to complete critical tasks to meet deadlines or objectives for the company.

INTERPERSONAL AND COMMUNICATIONS SKILLS:

- **Team Environment:** Must be able to work in a fast-paced team environment and collaborate in a positive and professional manner. This may include taking on tasks and responsibilities overlapping with other team members.
- **Conflict:** Must be able to negotiate and resolve issues with team members and management in a positive and professional manner.
- **Communication:** Must be a strong communicator able to convey clear and concise information to team members, management, or customers. Good listening skills are required.
- **Ownership:** Must be able to take ownership of problems, issues, or challenges with minimal guidance to troubleshoot and work through them.

LANGUAGE SKILLS:

Must possess the ability to read, write, speak, and comprehend the English language. Must be able to read, analyze, and interpret documents such as safety rules, operating and maintenance procedures.

SUPERVISION RECEIVED:

Receives direction and guidance based on determined work objectives and priorities mandated by the company and/or its officers or supervisors. Participates and collaborates in the approach to assignments based on objectives and priorities. Plans, organizes, schedules, and arranges activities based on objectives and priorities with minimal supervision.

SUPERVISION EXERCISED:

No direct subordinates.

MENTAL, PHYSICAL, AND VISUAL DEMANDS:

The physical requirements listed in this section include but are not limited to the motor/physical abilities and skills required of this position to successfully undertake the essential duties and responsibilities of this position. In accordance with the Americans with Disabilities Act (ADA), reasonable accommodations may be made to empower individuals with disabilities to undertake the essential duties and responsibilities of the position.

While undertaking the essential duties and responsibilities of the position, the employee must repeatedly sit, listen, speak type and move throughout the facility and must be capable of using a keyboard for computer purposes. This role may require the employee to stand for long periods of time while setting up and monitoring equipment. The employee is required to go to all areas of the company. The employee may be required to periodically lift and/or move up to 50 pounds. The employee may be required to conduct inspections under magnification.

The ability to utilize a computer, telephone, fax and copy machine are required as well as other general office equipment. In addition, general shops, inspection tools, and CNC machinery may be required from time to time.

ADVERSE WORKING CONDITIONS

The adverse working conditions listed in this section include, but are not limited to, those environmental conditions to which the employee may be exposed while undertaking the essential duties and responsibilities of this position, which is that of a general plant environment.

There are no adverse working conditions outside of a general plant environment.

SELECTION GUIDELINES

Formal application, rating of education and experience; oral interview and reference check; job related tests may be required.

DISCLAIMER

The duties listed above are intended only as illustrations of the various types of work that may be performed. The omission of specific statements of duties does not exclude them from the position if the work is similar, related, or a logical assignment to the position.

The job description does not constitute an employment agreement between the employer and employee and is subject to change by the employer as the needs of the employer and requirements of the job change.

Approved by: _____ Date: _____
Manager of Human Resources

Approved by: _____ Date: _____
Department Manager

Employee: _____ Date: _____
Print Name

Employee: _____ Date: _____
Signature