



**POSITION:** Product Engineer

**DATE:** November 2020

**REPORTS TO:** Chris Fuller

**FLSA STATUS:** Exempt

**DEPARTMENT:** Operations

**ACCOUNTABILITY OBJECTIVE:**

The successful Product Engineer is responsible for enhancing the lifecycle, quality, and profitability of Impel's commercial products. This role will help ensure production operations meet defined objectives by addressing design, manufacturing, and quality issues and opportunities identified during production at Impel's contract manufacturing organizations and worldwide supply base.

**ESSENTIAL DUTIES AND RESPONSIBILITIES** includes the following. Other duties may be assigned.

- Propose and initiate design changes in a regulatory compliant (21CFR 820) manner to resolve Impel and supplier identified issues
- Participate in product cost assessments and propose improvements that reduce product cost
- Participate in product quality assessment and propose improvements that enhance product quality
- Investigate design, production, and quality issues to determine root cause
- Analyze customer complaints and investigate product returns to determine root cause
- Analyze trends from multiple data sources to propose corrective actions and improvements
- Play an active role in Impel's material review board to address and resolve issues and drive assigned actions to completion
- Participate in the development and review of rework instructions to verify conformance to specification
- Drive and document both design verification and validation and process validation activities that result from proposed improvements or manufacturing changes
- Provide technical assistance to Impel's worldwide supply chain
- Create and review documentation to support regulatory compliance (21CFR820)
- Effectively communicate at all levels of the organization both orally and in writing
- Follow up on corrective actions and evaluate effectiveness

**EDUCATION, EXPERIENCE AND/OR SKILLS REQUIRED AND PREFERRED**

- A bachelor's degree in Mechanical Engineering is required.

- Five-years of experience in a progressive, fast paced commercial manufacturing/production support role is required
- Experience with injection molding, semi-automated and manual assembly processes and equipment is required.
- Experience with MasterControl or equivalent, Minitab or equivalent, Solidworks or equivalent is required.
- Experience with risk management and advanced problem-solving techniques is preferred.
- GMP or ISO 13485 manufacturing experience is preferred.

#### CULTURAL COMPETENCIES

- **Collaborative:** Works together in an intersection of common goals by sharing knowledge, learning and building consensus with others.
- **Flexibility:** Develops new or diverse strategies to achieve organizational goals. Able to lead in a changing and challenging work environment. Manages competing demands and unexpected events.
- **Ownership:** Demonstrates full ownership and takes accountability for the actions and execution of both self and the department.
- **Leadership:** Ability to be dynamic and visionary, and able to define clear and specific objectives, tasks and responsibilities.
- **Initiative:** Measures self against a standard of excellence. Demonstrates persistence and overcomes obstacles, takes calculated risks to accomplish goals. Ability to work a demanding, primarily self-directed work schedule.
- **Professionalism:** Works well in a fast-paced environment; treats others with respect and consideration; accepts responsibility for own actions. Understands business implications of decisions, aligns work with strategic goals. Meets deadlines and commitments.
- **Communication Skills:** Clearly and persuasively communicates verbally and in writing. Listens and seeks clarification; manages difficult situations; maintains confidentiality.
- **Problem Solving:** Conducts appropriate analysis and makes clear, consistent, and timely decisions.
- **Detail minded:** Demonstrates accuracy and thoroughness; monitors own work to ensure quality and organization. Strong attention to detail while multitasking.

#### PHYSICAL DEMANDS

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. Must have demonstrated ability to multitask in high pressure, changing conditions.



Sitting, standing, stooping, and lifting of packages/laboratory equipment up to 30 pounds may be required.

**WORKING CONDITIONS**

When based in the office, expect a noise level typically moderate for offices and labs.

**PRIMARY LOCATION & TRAVEL**

Seattle Washington. Impel is currently dealing with Covid-19 utilizing a remote work from home approach, working in office only as required. The candidate is expected to be in the office 2-3 days per week, or as required to ensure operations objectives post Covid-19. Travel up to 30% to meet the ongoing needs of the business, some of which may be international, so a current passport is required.