POSITION: **Senior Quality Engineer** **DATE: March 2021**

REPORTS TO: **VP, Quality** **FLSA STATUS: Exempt**

DEPARTMENT: **Quality**

ACCOUNTABILITY OBJECTIVE:
The Senior Quality Engineer is responsible for following Impel Quality policies to sustain product quality and ensure compliance. Utilizing sound statistical and engineering techniques and tools, this incumbent will investigate non-conformances. As Quality Reviewer, s/he performs document reviews to support design and labeling change controls. In addition, s/he will formulate and recommend engineering technical work and contribute to design changes or enhancement of products and processes, in accordance with business objectives. S/he will also be asked to participate in Supplier Management and/or other Quality related projects.

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

- Participates as Quality representative on select product development teams which includes providing guidance for Market Specification, Functional Specification, Design Verification, Design Validation, Test Method Validation, Risk Assessments, and Design Reviews
- Provides guidance and decisions on product development activities to ensure continued compliance with internal procedures and applicable ISO and FDA regulations and guidance
- Provides oversight for validation activities that are conducted at Impel's manufacturing partners
- Analyzes and trends data from various sources (Non-Conformances, Field Corrective Actions, and Complaints) to drive decisions
- Provides team leadership with respect to Project Documentation, DHF and compliance with appropriate SOPs guiding product development
- Resolves issues of experimental design and data discrepancy in both intra and interdepartmental experiments
- Develops sampling, testing, and inspection plans for development and/or manufacturing with statistical justification
- Conducts statistical analysis of device data and coordinates implementation of necessary CAPA activities
- Participates in risk analysis and the comprehensive approach to risk management activities
- Assists in review of design changes and quality planning
- Assists in responding to inquiries or complaints from customers, regulatory

- Participates in internal, supplier and regulatory audits and inspections

EDUCATION, EXPERIENCE AND/OR SKILLS REQUIRED AND PREFERRED

- A bachelor's degree in Mechanical or Manufacturing Engineering or comparable scientific discipline
- 8-years of experience in Quality Engineering, preferably in the Medical Device industry
- Knowledge of CFR 21 Part 820 (QSR), ISO 13485, ISO 14971
- Experience in implementing design control and risk management activities
- Experience with MasterControl or other electronic Quality Management System
- Project management and/or experience operating in a matrix-based project team
- Solid understanding of statistical techniques
- Familiarity with Minitab 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 their actions.
- **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 ensures 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. Travel up to 20% to meet the ongoing needs of the business, some of which may be international, so a current passport is required.