impedimed

Senior Quality Engineer - based in Bloomington, Minnesota, United States

JOB OPENING:

The **Senior Quality Engineer** at **Impedimed** will be responsible for supporting and maintaining Impedimed's Quality System, analyzing customer complaints, conducting internal and external audits, and will play a key role in driving quality throughout the company.

This person will need to be a great listener and able to understand our product requirements from the end-user perspective. The person occupying this position must be able to communicate effectively to all levels of the company, have a thorough knowledge and understanding of testing/auditing principles and practices, and be proactive when there are changes to the product that impact results.

We are interested in candidates from a Medical Device company. Their experience should also include successfully working with cross-functional teams (domestic and international) and promoting collaboration. Creatively striving for 'improvement over perfection' and a mindset of continuous improvement are foundational to the success in this position.

Impedimed is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. Impedimed's primary product range consists of several medical devices that aid surgeons, oncologists, therapists, and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphedema. Impedimed has the first medical device with an FDA clearance in the United States to aid health care professionals clinically assess secondary unilateral lymphedema of the arm and leg in women and the leg in men. As we expand we will require new employees to help develop and market our compelling product range.
Impedimed also markets devices for body composition assessment and fluid status monitoring in a variety of research settings. Impedimed is developing its BIS technology for use in many other clinical settings.

Impedimed is an ASX 300 company, and one of the fastest growing small companies on the Australian Stock Exchange. Visit our website at: www.Impedimed.com and www.HelloSOZO.com and our stock at ASX: IPD

TO APPLY: Please send your resume to: employment@impedimed.com, subject line reading: **Senior Quality Engineer**

ATTENTION APPLICANTS: Along with your resume, please provide a cover letter explaining your interest in this job opportunity and why you are interested in working at Impedimed.

POSITION SUMMARY:

This position supports projects, activities, and processes to improve systems and quality. He/she collects and analyzes data and generates performance reports. This position will initiate steps in continuous improvement and report findings to the Director of Quality. This position will play a key role in driving quality throughout the organization.

PRIMARY DUTIES & RESPONSIBILITIES (Essential Functions of the Position include, but are not limited to the following. Other duties may be assigned.):

- Provide engineering support to operations ensuring consistent application of quality techniques.
- Resolve quality issues of capability, tolerancing, and materials related issues.
- Resolve quality issues by identifying problems, examining solution options, implementing action plans, and providing resources.

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- Effectively communicate and reinforce Impedimed's commitment to quality improvement efforts.
- Coordinate with Sales, Engineering, Contract Manufacturer, and Customer Service to resolve customer complaints and concerns.
- Drive supplier quality development through the facilitation of supplier surveys and onsite supplier audits, monitor supplier performance through NCR and delivery schedule and partner for continuous improvement activities.
- Interface with customers and vendors to provide technical support for our products and assures quality of incoming materials.
- Initiate nonconformance reports and corrective action for nonconforming material and assist in defect identification and troubleshooting where necessary with suppliers.
- Develop and implements methods and procedures for disposition of nonconforming material and ensures that effective root cause analysis is conducted; track implementation of corrective/preventive actions.
- Working with ISO 13485 standards and 21CFR 820 regulations for medical device products.
- Develop root cause for non-conformances and deviations.
- Develop and implement methods for sampling, inspection, testing and evaluation of products.
- Develop and implement statistical methods and design experiments to support process control, process/product improvement.
- Support research and development and contract manufacturing to ensure successful transition of products and processes from design to production.
- Initiate process improvement projects to increase efficiency, reduce costs, simplify processes, and improve quality.
- Support process and test method validation activities by developing and executing protocols for new or existing processes.
- Develop and initiate standards and methods for inspection, testing and evaluation.
- Develop and write internal specifications, work instructions, supplier part specifications, and internal test methods.
- Trained as an internal auditor and perform quality audits.

SUPERVISORY RESPONSIBILITIES:

- None

QUALIFICATIONS GUIDELINES (Typical Knowledge, Skills, & Abilities):

- Ability to work independently and balance multiple priorities in a fast-paced FDA regulated environment.
- Ability to read, analyze and interpret complex document to drive improvement or change.
- Ability to work collaboratively across various department throughout the organization.
- Must understand, follow, and comply with regulatory requirements as applicable to various processes. An understanding of FDA Quality System Regulations and ISO Standards (ISO 13485) is required.
- Must possess a thorough understanding of work related standards and regulations, including but not limited to Standard Operating Procedures (SOPs) and Quality System Regulations (QSRs), both US and international.
- Strong organization and planning skills with an attention to detail and accuracy.
- Strong verbal and written communication skills; ability to write technical reports, specifications and work instructions and convey technical information.
- Proficient computer skills and demonstrates competence to include Word, Excel, PowerPoint, Visio.
- Working knowledge of inspection methods, blue print reading, statistics, process capability, and managing a supplier quality

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TYPICAL MINIMUM EDUCATION, EXPERIENCE, or CERTIFICATIONS:

- Bachelor's degree in Engineering, preferably Bioengineering.
- Five (5) plus years of experience in the medical device industry.
- Two (2) to four (4) years of related experience with Quality and Supply Chain preferred.
- American Society for Quality Certification as a Quality Auditor or Quality Engineer preferred.

WORK ENVIRONMENT & PHYSICAL REQUIREMENTS:

- Travel: Position will require business travel, mainly domestic and occasionally international, up to 10%. A valid driver's license and passport will be needed.
- Physical Demand: Light physical effort. For example, standing, bending, or stooping for extended periods, operating light office equipment, e.g., personal computer, copier, fax machine, etc., manually handling medium weight materials and/or equipment (0 to 10 pounds).
- Mental Demand: Moderate to high degree of concentration due to volume, complexity, and/or "pressure" of work.

BENEFITS:

- Full healthcare benefits include: Medical PPO/HMO/HSA Plan Choices, Dental Plan, Vision Plan; 401(k) with employer match for full-time employees once vested in plan.
- Basic Life, AD&D, STD/LTD, EAP Program

Impedimed is an Equal Opportunity/Affirmative Action Employer