impedimed

Quality System Specialist - based in Brisbane, Queensland, Australia

JOB OPENING

ImpediMed is striving every day to "Leave no patient untested who can benefit from our technology". By designing extraordinary solutions, we believe that we can change the future of healthcare! You will see the tangible results of your contributions, through a device that is benefiting thousands of patients!

We are looking for a **Quality System Specialists** to be based in our Brisbane (Queensland), Australia office. As part of a global quality team, you will share your expertise with your colleagues in Australia, the United States and Greece. Your focus will be on continuous improvement of our design process through supplier audits and quality design control. You will continue to uphold our product standards.

The ideal candidate will have a passion for driving quality at all levels of the organization to achieve the highest standards. To achieve this, you will be a highly motived self-starter, have a strong work ethic and have a desire to share your knowledge with others through various forms of training and awareness programs.

We look for candidates who demonstrate our Core Values of: Integrity, Accountability, Collaboration, Respect, Quality, and Compliance.

This is a terrific opportunity to join a ground-breaking, growing and innovative medical device / medical technology company!

About ImpediMed
Based in Brisbane, Australia with its principal office located in Carlsbad, CA, USA and a European office in Thessaloniki, Greece, ImpediMed is the world leader in the design and manufacture of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of tissue composition and fluid status. ImpediMed Limited is a public company listed on the Australian Stock Exchange (ASX: IPD).

ImpediMed devices are currently used in both the clinical and research settings with future applications being developed for home use. ImpediMed has over 15 years of clinical experience supporting healthcare professionals in the assessment of secondary unilateral lymphedema of the limbs. ImpediMed's devices are used in a variety of settings to aid surgeons, oncologists, therapists, and radiation oncologists. Our research devices are thought of as a gold standard measurement system for non-invasive fluid and body composition measurement, used in both animals and human research.

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO®, sold in select markets globally. For more information, see our website at www.impedimed.com.

ImpediMed's management team includes executives who have international experience in successfully introducing innovative medical products to global markets. The organization is dynamic and professional and has been built from the ground up with a strong team of enthusiastic and dedicated senior managers, researchers and employees. The company is on a dramatic growth path with the strong demand for its unique product offerings and offers exciting career opportunities.

ImpediMed's Company Vision: *Leave no patient untested who could benefit from our technology.*

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POSITION SUMMARY

The Quality System Specialist is responsible for driving customer-focused, quality systems transformations and will assure compliance within ImpediMed and maintain regulatory quality requirements. The Quality System Specialist provides training on the quality system to key personnel to ensure all employees are fully trained on ImpediMed's quality system requirements, manages the correction action systems ensuring proper execution, leads supplier quality audits, participates in quality audits with regulatory agencies, manages the quality document control project and associated activities, and provides quality leadership for issues not addressed by formal quality systems.

PRIMARY DUTIES & RESPONSIBILITIES

(Essential Functions of the Position) include but are not limited to the following. Other duties may be assigned.

- Support the Director of Quality in planning and driving completion of all project milestones.
- Manage and maintain our correction actions processes, as per our quality system, and look for continuous improvements and enhancements.
- Write and present reports to management as well as communicate changes to the affected employees.
- Instruct staff on ImpediMed's quality system.
- Develop and implement methods and procedures for disposition of nonconforming material and ensure that effective root cause analysis is conducted; track implementation of corrective/preventive actions/deviations.
- Develop and implement methods for sampling, inspecting, testing, and evaluating products.
- Design 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 from design to production.
- Provide support to operations ensuring consistent application of quality techniques.
- Identify process improvement projects to increase efficiency, reduce costs, simplify processes, and improve quality.
- Effectively communicate to all levels in the organization to reinforce ImpediMed's commitment to quality.
- Resolve quality issues of capability, tolerance, and material related issues. Identify problems, examine solution options and implement action plans.
- Take lead on coordinating with Sales, Engineering, Contract Manufacturer, and Customer Service to resolve customer complaints and concerns as they relate to quality issues.
- Communicate directly with suppliers to assure quality of incoming materials.
- Analyze customer requirements and respond to all customer complaints by creating and implementing an enhanced customer complaint process.

Supplier Management Responsibilities

- Lead onsite supplier audits.
- Initiate and monitor supplier performance through Nonconformance Material Reports (NCMR) and assist in defect identification and troubleshooting.
- Assist Operations and Engineering to identify and source new suppliers that conform to ImpediMed's quality system requirements.
- Drive supplier quality development by evaluating supplier processes (supplier surveys) and/or product tooling validations. Provide process improvement assistance to supplier to meet ImpediMed's quality standards by conducting supplier review meetings and supplier training.

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- Provide Manufacturing, Quality, and other departments with timely investigations into supplier quality issues, including coordinating material purges, participating in CAPAs and inspections.
- Write and revise policies and procedures and create forms to support our supplier development process.
- Work with Suppliers to implement real-time work in process (WIP) and failure tracking processes and drive quality improvement as required.
- Drive failure analysis and corrective actions/supplier corrective action requests (SCAR) within assigned suppliers.
- Write effective and compliant internal specifications, work instructions, supplier part specifications, and internal test methods.

SUPERVISORY RESPONSIBILITIES

- None

QUALIFICATIONS GUIDELINES Typical Knowledge, Skills, & Abilities:

- 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 and 21 CFR 820) is required.
- Ability to work independently and balance multiple priorities in a fast-paced FDA regulated environment.
- Ability to read, analyze and interpret complex, technical documents to drive improvement or change.
- Ability to work collaboratively across various departments throughout the organization.
- Ability to effectively communicate with all levels of employees including presenting to management.
- 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.
- Proficient computer skills and demonstrates competence to include Word, Excel, PowerPoint, Visio.
- Working knowledge of inspection methods, blueprint reading, statistics, process capability, and managing a supplier quality.

MINIMUM EDUCATION and/or EXPERIENCE

- Bachelor's degree in engineering, preferably Bioengineering, or equivalent combination of education and experience and five plus (5+) years of experience in a quality position or related experience in manufacturing.
- Demonstrated experience in a Class II Medical Device industry or closely related industry strongly preferred.
- A minimum of two (2) years with Quality Supply Management or related experience preferred.
- American Society for Quality Certification (ASQ) as a Quality Auditor or Quality Engineer highly recommended.

WORK ENVIRONMENT & 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.

- Travel: Position will require business travel, both domestic and occasionally international, up to 15%. 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.

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This position may require access to patient Protected Health Information (PHI) and may also involve access to electronic Protected Health Information (ePHI). Those in this position are required to comply with all final regulations including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

TO APPLY

Please email your resume to employment@impedimed.com. Please include the 'Quality System Specialist' in the subject line of your email.