impedimed

Quality Systems Manager - based in Carlsbad, California, United States

JOB OPENING:

The position of **Quality Systems Manager** at ImpediMed will be an impact player within the Company and will be responsible for elevating and supporting ImpediMed's Quality System. A key responsibility of the role will be to lead onsite supplier audits and to analyze and drive quality for key optimal performance throughout ImpediMed.

This opportunity will allow you to work with a top-of-class, quality team at a company that has a cohesive, corporate culture that places value on work-life balance. You will be able to influence the overall direction of ImpediMed's Quality System with opportunities to develop as a leader within the company.

To be successful in this role, this person needs to be both a great listener and influencer and should be able to understand our product requirements from both our customers' and suppliers' perspectives. This person must be able to communicate effectively to all levels of the organization, have a thorough knowledge and understanding of testing/auditing principles and practices, and be proactive to change to minimize any effect to our products.

We are interested in candidates coming from a Medical Device company. Their experience should also include successfully working with cross-functional teams (domestic and international) and promoting collaboration. Our company mission is to improve patients' lives by providing solutions that will allow for a deeper understanding of the human body and the importance of fluid status and body composition in all living things. If you have a 'continuous quality improvement' mindset, wish to improve patients' lives and believe that you meet the qualifications described below, we encourage you to apply!

About ImpediMed
ImpediMed is a medical device world leader with a focus on providing fluid and body composition measurements that are non-invasive, highly accurate and simple to operate. Our bioimpedance spectroscopy (BIS) technology is unique in that it scans a wide frequency up to 1000kHz taking readings from 256 points- making this device the most accurate bioimpedance spectroscopy device available. Our 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's FDA cleared device is used in a variety of settings to aid surgeons, oncologists, therapists, and radiation oncologist. ImpediMed's devices are currently used in both 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.

With offices in Australia, Greece, and the United States, and our corporate headquarters in Carlsbad, California, ImpediMed is a global company pioneering the next generation of medical devices using BIS technology. As ImpediMed expands, we require new employees to help develop and market our compelling product range. ImpediMed is currently in the process of developing its BIS technology for additional medical indications and is developing SOZO™, a BIS technology medical device. During all development, ImpediMed strives to uphold its Company Mission: To improve patients' lives by providing solutions that will allow for a deeper understanding of the human body and the importance of fluid status and body composition in all living things.

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: **Quality Systems Manager**

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POSITION SUMMARY:
The **Quality Systems Manager** is responsible for driving customer-focused, quality systems transformations and will assure compliance within ImpediMed and maintain regulatory quality requirements. The **Quality Systems Manager** 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.
- Track and log all quality and delivery data.
- Instruct technical 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 of products and processes from design to production.
- Provide support to operations ensuring consistent application of quality techniques.
- Initiate process improvement projects to increase efficiency, reduce costs, simplify processes, and improve quality.
- Effectively communicate to all levels to reinforce ImpediMed's commitment to quality.
- Resolve quality issues of capability, tolerance, and material related issues. Identify problems, examine solution options, implement action plans, and provide resources.
- 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 customers and vendors to provide technical support for our products and assures quality of incoming materials.
- Analyze customer requirements and respond to all customer complaints by creating and implementing an enhanced customer complain process.

Supplier Management Responsibilities

- Lead onsite supplier audits.
- Initiate and monitor supplier performance through Nonconformance Reports (NCR) and assist in defect identification and troubleshooting.
- 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.
- 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.

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- Implement real-time work in process (WIP) and failure tracking process at supplier sites.
- Establish component level ongoing reliability testing (ORT) at suppliers 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.
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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, blue print reading, statistics, process capability, and managing a supplier quality

TYPICAL MINIMUM EDUCATION, EXPERIENCE, or CERTIFICATIONS:

- Bachelor 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, with at least two (2) years at a manager level.
- 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.
- Project Management Professional (PMP) certification preferred or demonstrated experience as a Project Manager preferred.
- Lean/Sigma Green Belt or Black Belt preferred.
- American Society for Quality Certification (ASQ) as a Quality Auditor or Quality Engineer highly recommended.

WORK ENVIRONMENT & PHYSICAL REQUIREMENTS:

- Travel: Position will require business travel, both domestic and occasionally international, up to 30%. 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.

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- Basic Life, AD&D, STD/LTD, EAP Program

ImpediMed is an Equal Opportunity/Affirmative Action Employer