Quality System Specialist (Based: Carlsbad, CA - Hybrid)

JOB OPENING

ImpediMed is looking for a **Quality System Specialist** to join our Quality Department team. If you have a passion for engaging in customer-focused quality systems transformations, as well as a driven dedication to assuring compliance to regulatory requirements, then this role is for you! This position offers the opportunity for individual contribution on decision making as well as global collaboration with our team of leaders.

A day in your life as Quality System Specialist at ImpediMed may include:

- Providing clear direction for change and assisting in change management
- Inspecting final products and processes to meet established quality standards
- Identifying and resolving quality issues within the organization
- Identifying areas of improvements in the quality system
- Reviewing and analyzing customer feedback and complaints to identify trends

To be an amazing Quality System Specialist at ImpediMed, you will have:

- Bachelor's degree in engineering, preferable Bioengineering, or equivalent combination of education and 3-5 years of experience in a quality position or related experience in manufacturing
- Strong critical thinking and problem-solving skills
- The ability to work independently and make appropriate analytical and ethical decisions
- Proficient with Microsoft Office Suite, particularly Excel and PowerPoint
- Meticulous attention to detail
- Accept responsibility for our safety and that of others
- Leadership abilities and excellent communication skills
- The ability to prepare and present materials/findings both internally and externally

ABOUT IMPEDIMED

ImpediMed is a medical technology SaaS company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximize patient health.

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.

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).

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ImpediMed devices are currently used in both the clinical and research settings with future applications being developed for home use. ImpediMed has over 20 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 Company Vision: Leave no patient untested who could benefit from our technology.

BENEFITS

Life at ImpediMed

It is fast, it is fun, it is evolving, it is growing, and it is filled with smart, passionate, diverse, friendly people who want to make a difference in healthcare. We are 4 miles from the beach and are located within the Carlsbad Research Park with numerous paths and trails great for walking meetings or enjoying the outdoors during your workday by biking, running, or walking.

Total Rewards

At ImpediMed, we are strongly committed to our employees--their well-being, development, rewards, and recognition opportunities. One way we demonstrate this commitment is by offering a valuable, competitive package of compensation and individualized benefits programs aimed at the varying needs of our diverse and global teams. The sum of our programs is one of the many reasons people choose to work at ImpediMed. We regularly benchmark against other companies in our industry to ensure our Total Rewards package is competitive is competitive and of value.

We offer full healthcare benefits including Medical PPO/HMO Plan Choices, Dental Plan, Vision Plan; 401(k) with employer match. Basic Life, AD&D, STD/LTD, Employee Assistance Program (EAP) and employee discount programs.

Diversity & Inclusion

It is our diverse teams who drive our innovation, creativity, and success. We value the unique backgrounds and experience of all our employees and share a set of core values of ethical behavior for conducting our business. - *Integrity, Accountability, Collaboration, Respect, Quality, Compliance*. We continuously strive to provide an environment where employees not only feel they can succeed, but also where they can thrive.

To Apply

Please apply via LinkedIn or email your resume to employment@impedimed.com with subject heading: Quality System Specialist.

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Equal Opportunity Employment
As part of our commitment to providing equal employment opportunities, we take steps to ensure that all qualified applicants are treated fairly. To that end, our decisions around recruitment, hiring, assignment, promotion, compensation, and other personnel factors are made and administered without regard to race, color, religion, genetic information, national origin, sexual orientation, gender identity, gender expression, pregnancy, childbirth or related medical conditions, age, disability, citizenship status, uniform service member status, or any other protected class under federal, state or local law.

If you have a disability that requires accommodations in order to complete the application process, please contact us at employment@impedimed.com or (760) 585-2100.

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 prepares and implements quality assurance policies and procedures and performs routine inspections and quality tests. Additionally, they provide training on the quality system to key personnel to ensure all employees are fully trained on ImpediMed's quality system requirements, manages the corrective and preventive 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.

Quality System Specialists also elaborate on the sampling and guidelines procedures for collecting and reporting quality data and oversee implementation to ensure inspection efficiency. They analyze customer grievances and other non-compliance issues and make their recommendations based on their findings. They ensure the company continues to comply with industry regulatory and quality requirements, analyze audit outcomes, carry out appropriate corrective procedures, and oversee risk management procedures.

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.
- Instruct staff on ImpediMed's quality system.
- Manage and maintain our corrective and preventive action processes, as per our quality system, and look for continuous improvements and enhancements.
- Take lead on coordinating with Sales, Engineering, Contract Manufacturer, and Customer Service to resolve customer complaints and concerns as they relate to quality issues.
- Perform sampling, inspecting, testing, and evaluating products, including incoming goods inspection and product release.
- Identify gaps in efficient process workflow and suggests steps for supplier quality process improvement.
- Communicate directly with suppliers to assure quality of incoming materials.
- Provide support to operations ensuring consistent application of quality techniques.

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- Analyze customer requirements and respond to all customer complaints by creating and implementing an enhanced customer complaint process.
- Resolve quality issues of capability, tolerance, and material related issues. Identify problems, examine solution options, and implement action plans.
- Support process control, process/product improvement, including data analysis and post market surveillance.
- Manage disposition of nonconforming material and ensure that effective root cause analysis is conducted; track implementation of corrective/preventive actions/deviations.
- Support new product development teams and sustaining manufacturing/operation teams to ensure successful development and transition from design to production, including risk management.
- Preform internal audits of the company's CMS.
- Identify process improvement projects to increase efficiency, reduce costs, simplify processes, and improve quality.
- Write and present reports to management as well as communicate changes to the affected employees.
- Effectively communicate to all levels in the organization to reinforce ImpediMed's commitment to quality.

Supplier Management Responsibilities

- Lead onsite and/or virtual supplier audits for EMEA.
- 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.
- 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

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QUALIFICATIONS GUIDELINES

Typical Knowledge, Skills, & Abilities:

- Training in or good working knowledge of MDD 93/42/EEC, EU MDR 2017/745, ISO 13485, and ISO 14971 or MDSAP and 21CFR820.
- Ability to work independently and balance multiple priorities in a fast-paced highly regulated environment.
- Ability to read, analyze and interpret complex, technical documents to drive improvement or change.
- Ability to work collaboratively across various departments and multiple time zones 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, design controls, blueprint reading, statistics, process capability, and managing a supplier quality.

TYPICAL MINIMUM EDUCATION, EXPERIENCE, or CERTIFICATIONS

- Bachelor's degree in engineering, preferably Bioengineering, or equivalent combination of education and experience and 3-5 years of experience in a quality position or related experience in manufacturing.
- Demonstrated experience in the Medical Device industry, pharmaceutical industry, or a closely related highly regulated industry strongly preferred.
- A minimum of two (2) years with Quality Supply Management or related experience preferred.
- American Society for Quality Certification (ASQ) or equivalent 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 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 20 kgs).
- Mental Demand: Moderate to high degree of concentration due to volume, complexity, and/or "pressure" of work.

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).