Senior Manager of Regulatory Affairs **(Based: Carlsbad – Hybrid)**

JOB OPENING

ImpediMed is looking for a **Senior Manager of Regulatory Affairs** to join our team. If you have a passion for executing worldwide regulatory strategies in medical devices, then this role is for you! This position offers the opportunity to direct and oversee short-term and long-term planning of regulatory submission initiatives as well as global collaboration with our team of leaders.

A day in your life as a Senior Manager of Regulatory Affairs at ImpediMed may include:

- Develop and implement strategies for the earliest possible approval of regulatory submission.
- Be responsible for regulatory submissions, license renewals, periodic updates, and registrations to regulatory agencies.
- Review product changes for impact on regulatory filings worldwide.
- Collaborate with the software development and clinical teams to meet the company's objectives. This includes regulatory oversight of new indications to ensure appropriate labeling and clinical data to support regulatory clearances.
- Work with Director, Clinical Research for data analysis and report results and conclusions to management, and as required, to investors, physicians, patients, regulatory agencies, reimbursement parties, and medical journals.

To be an amazing Senior Manager of Regulatory Affairs at ImpediMed, you will have:

- A minimum of 5 years' experience in Medical Devices
- Must understand, follow, and comply with FDA Quality System Regulations and ISO Standards (ISO13485).
- Must have filed at least two 510(k) applications with the FDA
- 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.
- Must be able to perform tactical hands-on work and have the ability to negotiate with the FDA.
- Must have Medical Device software development experience

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.

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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 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/HSA 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.

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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: Senior Manager of Regulatory Affairs.

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 Senior Manager of Regulatory Affairs will assume responsibility for formulating and executing worldwide regulatory strategies and clinical research activities in order to obtain effective and timely regulatory submissions/approvals and the management/compliance in all aspects of clinical trials to ensure corporate objectives are met.

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

- Lead the short-term and long-term planning of regulatory submission initiatives.
- Develop and implement strategies for the earliest possible approval of regulatory submission.
- Be responsible for regulatory submissions, license renewals, periodic updates, and registrations to regulatory agencies.
- Organize regulatory information and track and control submissions.
- Review and advise on labeling for compliance with regulatory filings.
- Review product changes for impact on regulatory filings worldwide.
- Research regulatory issues and provide guidance and advice to colleagues.
- Provide updates to changes in legislation as they become available.

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- Work with the Product Development team to ensure new product is compliant to regulatory requirements.
- Work with Director, Clinical Research for data analysis and report results and conclusions to management, and as required, to investors, physicians, patients, regulatory agencies, reimbursement parties, and medical journals.
- Maintain required privacy and security of all PHI and ePHI used to fulfill job duties in compliance with HIPAA and all other applicable laws and regulations.

SUPERVISORY RESPONSIBILITIES

- None

QUALIFICATION 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) is required.
- Must have experience in filing 510(k) submissions with the FDA, on medical devices that contain software.
- 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.
- Must possess a sound knowledge of product launch, labeling, advertising and promotion, product vigilance, and medical device reporting.
- Should have an understanding of Medical Device Regulation (MDR).
- Should have experience with Agile methodology for product development.
- Ability to work with and safely handle all PHI and ePHI information per HIPAA regulations and requirements.
- In depth understanding of medical devices, ideally, bioimpedance spectroscopy and its applications in the medical market.

Must Be Proficient in the Following Software or Systems:

- Microsoft Office, Microsoft CRM, Microsoft Office SharePoint Server (MOSS)

MINIMUM EDUCATION, EXPERIENCE OR CERTIFICATIONS

- Tertiary qualification (Bachelor's degree or equivalent)

WORK ENVIRONMENT & PHSYICAL REQUIREMENTS

This job operates in a professional office environment. This role routinely uses standard office equipment such as computers, phones, photocopiers, filing cabinets and fax machines.

- 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. Light physical effort. This job requires the employee to lift at least 15 lbs infrequently.
- Mental Demand: Moderate to high degree of concentration.
- Travel: Position requires some business travel and valid driver's license.

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).