Director, Clinical Trials – Carlsbad, CA

JOB OPENING:

Driven by a passion for our company vision, "Leave no patient untested who could benefit from our technology", ImpediMed is a 'Med Tech' company comprised of a highly dedicated team of software developers, clinical affairs, regulatory and quality professionals, R&D professionals and many other business professionals from world-class companies and institutions who care deeply for our work, product and each other. When you join ImpediMed, you will learn and grow quickly. You will work along side the elite of the industry in the fields of cardiology, oncology and lymphedema and you will be able to take pride in being part of a company that has technology that is changing the future of healthcare!

We are looking for a confident, hands-on, clinical professional who has experience managing the clinical trial process. This person would describe themselves as tactical as well as an influencer, who can train, monitor and manage clinical trials. The ideal candidate will have an established professional network in the cardiology, preferably CHF and/or cancer survivorship/ oncology within the medical community.

You will be joining a company that has industry-leading approaches to planning and conducting real-world studies and clinical trials, combining knowledge and experience with data-driven insights to make valuable contributions throughout the trial lifecycle.

TO APPLY: Please send your resume to: employment@impedimed.com, subject line reading **Director, Clinical Trials**

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.*

POSITION SUMMARY
The Director, Clinical Trials will manage the clinical trials and clinical data management functions for ImpediMed under the direction of the Senior Vice President Medical Affairs. He/she will provide leadership and clinical expertise in

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support of new product development as well as marketed products. This roll will have responsibility for both strategic clinical activities, as well as hands-on operational clinical activities and will partner with regulatory affairs. They will drive best in class development of US clinical strategies and ensure the highest possible performance of clinical affairs deliverables to achieve the company's clinical initiatives.

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

- Develops and manages the budgeting, designing, planning, resource management, institutional review board, legal agreement with sites, purchasing, execution and management of clinical trials protocols, compliance, contracting and data management and analysis of clinical study data.
- Sets the direction, planning, execution and interpretation of clinical trials/ research and data collection activities.
- Establishes and approves scientific methods for design and implementation of clinical protocols, data collection systems and final reports.
- Provides clinical program management for study activities including statistical analysis for regulatory submissions.
- Responsible for managing full scope of study, protocol and scientific publications.
- Co-authors clinical section of FDA pre-submissions.
- Conducts site selection, qualification, feasibility assessments, including establishing a business development type relationship with clinical trial sites.
- Conducts or participates in research activities for new methods of measurement and analysis in pursuit of ImpediMed's marketing and clinical goals.
- Develops and manages budgets for clinical trials including contingency planning.
- Selects, develops and evaluates needed personnel to ensure the efficient operation of the clinical trials function.
- Works closely with business units to ensure a coordinated approach to statistical and data management activities.
- Collaborates cross-functionally with departments such as Marketing, Regulatory Affairs, R&D and Quality to determine development timelines, resources requirements, program costs etc.
- Uses statistical analysis systems, such as MATLAB, SAS, as appropriate, to assist with data analysis.
- Addresses data management issues by reviewing protocols for cross-project consistency and identifying standard case report form modules to meet objectives.
- Provides early strategic input into protocol design focused on data management issues.
- Reviews and resolves data discrepancies – both in-house and at sites for standardized data validation systems and procedures.
- Collaborates and coordinates with others to design and implement clinical protocols and data collection systems.
- Develops study related documents and provides direction for the clinical sites to establish protocol development.
- Ensures compliance with/and training for good clinical practices, good documentation practices, and regulatory guidelines, ensuring adherence to domestic and global regulations.

SUPERVISORY RESPONSIBILITIES

- As assigned

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) 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.
- Experience with CRO/CRA management and overall life-cycle clinical trials

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- Must possess strong leadership, influencing skills, having the ability to guide others with authority.
- Strong project management skills.
- Ability to management medical advisory boards and clinical studies.
- Excellent knowledge of the device development process, device laws, regulations and guidelines.
- Superb analytical skills and problem-solving ability.
- Excellent oral and written communication skills, with the ability to discuss scientific/technical data and regulatory requirements with senior management and agency personnel.
- Ability to read, analyze and interpret common scientific and technical journals and other related materials
- In depth understanding of bioimpedance and its applications in the medical market is desirable.
- Ability to be self-motivated, work independently and balance multiple priorities in a fast-paced FDA regulated environment.
- Strong organization and planning skills with an attention to detail and accuracy.
- Ability to effectively present information to top management and/or the scientific community.
- Established relationships with KOLs in the fluid monitoring space.

Must Be Proficient in the Following Software or Systems:

- Microsoft Office, including Word, Excel and Access
- Microsoft CRM
- Microsoft Office SharePoint Server (MOSS)
- Statistical analysis programs such as MATLAB or SAS

TYPICAL MINIMUM EDUCATION, EXPERIENCE or CERTIFICATIONS

- Bachelor's Degree in Science, (Life Science focus preferred)
- A minimum of seven (7) years of experience in clinical research, preferably for medical devices, with an emphasis in the cardiology or oncology space with demonstrated expertise in clinical trial study design, trial management, statistical method, statistical programming, clinical data management, database design and clinical programming, application validation.
- Minimum three (3) years management experience.
- Proven track record for innovation in clinical design and execution.

WORK ENVIRONMENT & PHYSICAL REQUIREMENTS

- Travel: Position requires some business travel (including overnight and international) up to 30% and valid driver's license and valid passport. Position may be based partially in an off-site healthcare facility.
- Physical Demand: Light physical effort
- Mental Demand: Moderate to high degree of concentration

WHAT WE OFFER:

- Competitive benefits, including 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, Employee Assistance Program (EAP)

ImpediMed is an Equal Opportunity/Affirmative Action Employer