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Clinical Trials Manager - Carlsbad, CA, USA

JOB OPENING:

We are looking for an experienced candidate to join our Clinical team at a Manager level. This position is responsible for the oversight and management of clinical trial activities, ensuring quality, on-time, and cost-effective execution of clinical trials in the areas of oncology and cardiology.

To be successful in this position, you will need to be highly organized and motivated with experience in the medical device / biotech industry. This position will collaborate with ImpediMed's Clinical/Regulatory Team and Finance Department, and cooperate at a high level with study site personnel, outside vendors, and data management.

At ImpediMed, you can expect to find a friendly, fun and supportive work environment. You will be joining an amazing Clinical Team and a company that is working to Change the Future of Healthcare!

About ImpediMed

ImpediMed is the world leader in the design and manufacture of medical devices employing bioimpedance spectroscopy (BIS) technology for use in the non-invasive clinical assessment and monitoring of tissue composition and fluid status. Our BIS technology is non-invasive, highly accurate and simple to operate. It is unique in that it scans 256 frequencies from 3 to 1000 kHz. Our devices are the instrument of choice by researchers around the globe, as a measurement system for non-invasive fluid measurement and tissue composition, used in both human and animal research.

ImpediMed's FDA cleared devices are 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 lymphedema. ImpediMed was the first company to receive FDA clearance in the U.S. to aid healthcare professionals to clinically assess unilateral lymphedema of the arm and leg in women and the leg in men, for its L-Dex® device.

Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, CA and Bloomington, MN, and a European office in Thessaloniki, Greece, 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. During all development and growth, ImpediMed strives to uphold its Company Vision: *Leave no patient untested who could benefit from our technology.*

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: **Clinical Trials Manager**

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POSITION SUMMARY

The Clinical Trials Manager, under the direction of the Senior Vice President of Medical Affairs, executes activities to ensure the adequacy and efficiency of the company's clinical initiatives.

PRIMARY DUTIES & RESPONSIBILITIES (Essential functions of the position to include, but are not limited to the below. Other duties may be assigned)

- Manages overall operation of the entire clinical study including project planning, budget negotiation, resource management, institutional review board, legal agreement with sites and purchasing.
- 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.
- Uses statistical analysis systems, such as SAS, as appropriate.
- Ensures compliance with/and training for good clinical practices, good documentation practices, and regulatory guidelines, ensuring adherence to domestic and global regulations.
- Recommends and implements innovative process ideas to impact clinical trials management.
- Manages clinical budget and develops contingency plans for clinical trials.
- Responsible for managing full scope of study, protocol and scientific publications.
- Acts as a cross functional liaison to ensure study plan aligns with business development and R&D strategies.
- Develops systems for organizing data to analyze, identify and report trends.
- Addresses data management issues by reviewing protocols for cross-project consistency and identifying standard case report form modules to meet objectives.
- Develop data quality plans.
- 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.
- Responsible for tracking and management of study materials, including devices, in conjunction with R&D.
- Conduct or participate in research activities for new methods of measurement and analysis in pursuit of ImpediMed's marketing and clinical goals.
- Write, or assist in writing as required, research papers for publication.
- Co-Authors Clinical section of FDA pre-submission

SUPERVISORY RESPONSIBILITIES

- As assigned

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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
- Ability to read, analyze and interpret common scientific and technical journals and other related materials
- Experience in management and co-ordination of clinical trials.
- In depth understanding of bioimpedance and its applications in the medical market is desirable.
- Ability to 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.
- Self-motivated.
- Excellent organizational and problem-solving skills.
- Ability to effectively present information to top management and/or the scientific community.
- Must Be Proficient in the Following Software or Systems:
- Microsoft Office, including Word, Excel and Access, Microsoft CRM, Microsoft Office SharePoint Server (MOSS)

TYPICAL MINIMUM EDUCATION and/or EXPERIENCE

- Bachelor's Degree in Science, preferable in (Life Science focus preferred)
- Five (5) years minimum working in clinical affairs, in a life sciences field (medical device preferred)

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.
- Physical Demand: Light physical effort.
- Mental Demand: Moderate to high degree of concentration.

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.
- Basic Life, AD&D, STD/LTD, Life Assistance Program (LAP)

ImpediMed is an Equal Opportunity/Affirmative Action Employer