

**Job Title :** Director, Clinical Affairs  
**Department :** Clinical Affairs  
**Reports To :** CEO/President  
**FLSA Status :** Exempt

**Position Summary:**

The Director of Clinical Affairs (DCA) serves as the primary point of contact for Clinical Affairs to internal and external contacts influencing business leaders and driving SANUWAVE business goals by developing integrated clinical programs that reflect evidence based medicine.

The DCA ensures the execution of clinical strategies that provide the clinical evidence necessary to successfully market new products in an increasingly competitive environment; evaluate potential licensing and acquisition opportunities; meet regulatory requirements for market entry; and provide guidance for first-in-human use studies.

The DCA orchestrates the design, integration, and execution of their portfolio of clinical studies, adhering to the highest standards of regulatory and ethically-based clinical research. The DCA stays current with the therapeutic areas of focus and applies their knowledge of the scientific literature and health economics issues to the development of clinical strategy and study design. The DCA sustains awareness of the breadth of SANUWAVE clinical work globally, looking for opportunities to leverage it across the product portfolio of SANUWAVE. The DCA builds relationships in the medical community to cultivate study partners and resources. The DCA maximizes corporate performance and minimize risk through the application of their scientific discipline and expert influence to the business needs of SANUWAVE.

**Essential Functions:**

- Enabling business strategy by designing, planning and executing clinical strategies aligned with SANUWAVE's business needs.
- Professionally defining clinical study parameters, deliverables and direction, and providing guidance, expertise and oversight support to Clinical Affairs personnel.
- Building relationships and representing SANUWAVE in the medical and scientific community, cultivating outside partners and resources for clinical studies.
- Demonstrating leadership to enhance team processes and work across functions to accomplish the goals of Clinical Affairs, and SANUWAVE.

**Key Accountabilities:**

Enabling business strategy by designing, planning and executing clinical strategies aligned with SANUWAVE's business needs by:

- Demonstrating an understanding of the business, marketing, L&A, regulatory and healthcare economics strategies of SANUWAVE.
- Influencing good business decisions by articulating and positioning evidence based clinical data as a competitive tool, and driving the appropriate clinical strategy.
- Proactively contributing clinical input into cost/benefit analysis and resource management to support project prioritization as part of existing and new product development process.
- Translating business needs into responsive cost effective clinical strategies that are designed to provide competitive advantage and meet product innovation, regulatory submission and commercialization needs.

- Constructively challenging issues and influencing strategy based on a comprehensive clinical knowledge base, effectively applied to the business context.

Professionally defining clinical study parameters, deliverables and direction, and providing guidance, expertise, and oversight support to Clinical Affairs personnel by:

- Skillfully designing clinical studies aligned to business needs and outside regulatory agencies, including protocol development, investigative site selection criteria, and publication of results.
- Establishing and managing therapeutic portfolio priorities, milestones and time frames for clinical studies, consistent with SANUWAVE business needs.
- Overseeing and/or being actively involved during clinical studies, providing general direction, supporting problem identification and resolution.
- Analyzing and interpreting clinical study results, utilizing appropriate tools and methods, and culminating in the clinical evidence needs of the business.
- Ensuring that the highest scientific, medical, and ethical standards are adhered to in all clinical studies.
- Building relationships and representing SANUWAVE in the medical and scientific community, cultivating outside partners and resources for clinical studies by:
- Professionally representing SANUWAVE through active participation in the corporation and medical community.
- Developing, sustaining and providing value to relationships with physicians respected in their field.
- Making professional presentations both internally and externally pertaining to clinical research.
- Actively participating in and providing leadership to pertinent professional organizations.

Demonstrating leadership to enhance team processes and work across functions to accomplish the goals of Clinical Affairs, and SANUWAVE by:

- Effectively participating in appropriate SANUWAVE new technology assessment and development activities in support of SANUWAVE business goals.
- Skillfully mentoring and collaborating to assure appropriate training of staff to comply with federal agency regulations and develop biomedical skills/knowledge, new technologies and medical procedures.
- Professionally working with multiple levels and across functional areas to attain SANUWAVE goals and objectives.
- Actively modeling positive team behaviors in order to influence relationships to effect constructive change and align recommendations with departmental and SANUWAVE business strategies.
- Effectively enforcing Clinical Affairs policies/procedures, escalating as appropriate.
- Successfully identifying and working to resolve conflict through effective communications and negotiation.
- Actively promoting process and procedure improvement within Clinical Affairs and SANUWAVE as appropriate.

- Taking initiative to maintain relevant certifications and to respond to needs identified in individual development plans through continuing education.

## **Position Requirements**

### **Skill Sets**

- Comprehensive knowledge of ISO, GCP, ICH, FDA, and other applicable regulations governing the conduct of clinical trials
- Anticipates issues and organizes and leads other members of the team to resolve problems
- Desire to mentor others
- Medical aptitude
- Technical aptitude
- Good command of English language
- Technical writing skills
- Oral presentation/public speaking
- Must be extremely flexible and able to rapidly change priorities
- Ability to interact effectively with others

### **COMPUTER SKILLS**

Must be computer literate

- Windows, Word, Power Point, Excel
- Ability to learn new database systems (e.g., EndNote, etc.)

### **JOB EXPERIENCE**

- A minimum of 10 years with in a science or related technical field to include clinical trial program management and management of clinical trial personnel, preferably as a Manager, Clinical Trials for a minimum of 7 years. Medical Device experience is required.

### **EDUCATION**

- BS in a Biological science or related scientific/technical discipline
- Masters, Ph.D. or Pharm D. preferred

### **PHYSICAL DEMANDS**

- Normal physical activity only
- Must be able to travel globally approximately 30% of the time, per year (on average).