



## **Director Clinical Operations**

### **ABOUT US:**

Cytrellis, a venture-backed medical technology company, has developed a new, proprietary category of micro-coring devices designed to remove sagging skin associated with aging, without surgery or scarring. The devices have the potential to provide aesthetic practitioners with an unprecedented ability to improve age related changes in skin and restore youthful beauty. Cytrellis is dedicated to working with leading physicians to develop unique product solutions which emphasize safety, clinical results and improved quality of life

### **SUMMARY:**

The Director of Clinical Operations will have oversight and lead all clinical operations activities at Cytrellis for new and existing medical products. This position is responsible for promoting, executing, and establishing the Company's clinical strategies in-line with the Company's mission and vision. This position is expected to expand in scope over time and may include direct reports. The role may be required to perform all, or a combination of, the following essential responsibilities as determined by necessity This position will report to the President and CEO.

### **ESSENTIAL RESPONSIBILITIES:**

- Develop and successfully execute clinical strategies and implementation plans to ensure product approval and adoption while meeting corporate objectives within applicable regulations and guidelines.
- Provide direct supervision of any clinical team members and manage outsourced work with consultants, advisors, and vendors
- Partner with cross functional teams in marketing and R&D to develop overall Clinical strategy and plans including key deliverables, corporate goals and objectives, timelines, budget projections, milestones and key decision points
- Create and manage to clinical budget
- Define the clinical organizational structure and drive recruitment of new team members, define most effective manner to build team for faced paced growth and long term success of the company
- Direct the development of practices and processes to ensure efficient and effective clinical trials including clinical trial management, data analysis, final study report and publication while ensuring all clinical studies operate to the highest ethical and safety standards.

## Director Clinical Operations Job Description

- Ensure clinical studies involving non-significant risk (NSR) class II medical devices and products are completed. Develop clinical protocols, providing strategic and tactical input for design and execution
- Direct site selection, qualification and enrollment processes
- Communicate and work with Key Opinion Leaders (KOLs), Physician Investigators, Site Coordinators, Data Management Organizations, Institutional Review Boards (IRBs) or other relevant external organizations
- Lead the development, preparation and design of protocols, informed consent forms, photograph release forms, marketing testimonial release forms, subject questionnaires, case reports forms, source documents, instruction materials, and various study logs. Ensure documents are controlled according to quality and regulatory requirements, compliance with GCP.
- Provide operational oversight during trial period; complete site visits, report review, report preparation, payments to sites, compilation and completion of TMF
- Manage all vendor resources and activities to ensure study is being conducted according to protocol, timelines and budget
- Manage correspondence with IRBs including preparing and submitting initial submissions, amendments and required reports
- Ensure clinical investigators are properly trained and comply with protocols
- Lead preparation high quality presentation materials and abstracts in concert with physician KOLs for professional medical meetings
- Attend relevant scientific and/or medical meetings as needed
- Contribute to regulatory documents with the FDA and international regulatory agencies.
- Ensure effective ongoing review of any adverse events.
- Provide leadership and direction for significant clinical deviation events that may impact compliance status or significant business risk.
- Customer focused, ensures customer requirements are met
- Ability to develop meaningful metrics to track clinical operations performance
- Provide scope, status, and scheduling updates to leadership
- Member of Cytrellis' Leadership Team
- Effectively communicate the clinical operations strategy to Company stakeholders including potential partners and investors and the board of directors
- Build and drive a positive, passion-to-win culture

### EXPERIENCE AND TRAINING:

- BA/BS in life sciences or healthcare field
- 15 + years of experience in leading medical device clinical efforts (recent experience in a small/start-up company point-of-view is highly desirable)
- The ideal candidate for Cytrellis will have a successful track record of managing and leading clinical teams
- Ability to manage diverse and simultaneous projects of various complexity.

## Director Clinical Operations Job Description

- Experience in Class II NSR aesthetic medical devices is strongly preferred
- Strong sense of urgency and a desire to roll up his/her sleeves to do the work
- Experience in strategic planning and collaboration with executive teams.
- Proven record of leadership and managing organization's clinical operations
- High level of personal and professional integrity and trustworthiness with strong work ethic and the ability to work independently with minimal direction.
- Ability to develop and manage a high performance team focused on meeting and exceeding expectations.
- Ability to lead, influence, create and work within cross-functional team environments.
- Assertive, proven manager with a strong results orientation, positive "can do" attitude and a sense of urgency to get things done.
- Broad knowledge of medical device operations and quality guidelines and regulations and GCPs
- In depth knowledge of medical terminology, physiology and pathophysiology related to the relevant clinical trial
- Topnotch interpersonal, analytical, organizational and leadership skills, training, and the ability to stay abreast of the current clinical trial methods
- Outstanding written and verbal communication and presentation skills. Ability to present and effectively communicate complex concepts to the audiences of various backgrounds and knowledge levels
- Excellent computer skills and familiarity with Microsoft Office and other related software
- Availability to travel up to 25-30%