CYTRELLIS
BIOSYSTEMS

Director or VP of Clinical, Regulatory and Quality Affairs

ABOUT US:

Cytrellis, a venture-backed medical technology company, is developing 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 or Vice President (VP), Clinical, Regulatory and Quality Affairs will be the pivotal leadership role in promoting, executing, and establishing the Clinical, Quality and Regulatory strategies in-line with the Company's mission and vision. The Director or VP will implement and monitor all company quality systems to demonstrate compliance with the FDA requirements and will oversee process of preparing new or modified products for submission to FDA and global regulatory bodies for clearance. This position is responsible for providing quality guidance for design, development and manufacturing strategies for electro mechanical capital systems and consumables and must have a demonstrated working knowledge of quality systems and compliance to support both systems, software, service and consumables. This position will have oversight of all clinical operations activities. This position has direct reports and will report to the President & CEO. This role will be located in the Company's Woburn, MA office.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Member of the Leadership Team; ensure business objectives are aligned with all clinical, quality and regulatory initiatives and the company meets all operational objectives.
- Provide supervision of the clinical, quality and regulatory team and outsourced work with consultants, advisors, and vendors.
- Partner with cross functional teams in sales, marketing, service, R&D and operations to develop overall quality, clinical and regulatory strategy including key deliverables, corporate objectives, timelines, budget projections, milestones and key decision points.
- Develop and manage budget for quality, clinical and regulatory efforts.
- Define the quality, clinical and regulatory 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.
- Develop and successfully execute quality, clinical and regulatory strategies and implementation plans to ensure product approval and adoption while meeting corporate objectives within applicable regulations and guidelines.

- Direct the development of systems, 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.
- Communicate and work with Key Opinion Leaders (KOLs), Physician Investigators, Site Coordinators, Data Management Organizations, Institutional Review Boards (IRBs), Clinical Research Organizations (CROs) and various US and OUS regulatory bodies.
- Manage the development, preparation and design of clinical protocols including gaining any relevant regulatory approvals, selection and management of clinical study sites, data management and creation of reports.
- Lead development of FDA and global regulatory submissions, amendments, and required reports to the FDA.
- Develop a right-sized quality organization and system that provides flexibility but assures compliance for a competitive advantage through policies, standards and audit systems.
- Develop short and long-term quality plans and strategies that support company investigational products and commercial readiness.
- Provide leadership and guidance to the organization regarding quality, training and inspection readiness, ensure effective ongoing review of product design and/or manufacturing changes and adverse events.
- Work with senior leaders to establish a culture to ensure that there is a quality focus in all activities of the business.
- Provide leadership and direction for significant deviation events that may impact compliance status or significant business risk.
- Responsible for company's compliance with regulatory agencies and all applicable standards.
- Attend any relevant scientific and/or medical meetings.

QUALIFICATIONS:

- BA/BS in life sciences or healthcare related field, masters degree a plus.
- 15 + years of experience in leading medical device quality, clinical and regulatory effort. Experience in a small company is a must.
- Experience in Class II NSR dermatology and/or medical aesthetic devices is preferred or experience with a medical device cash-pay company.
- The ideal candidate for Cytrellis will have a successful track record of managing and leading high performance quality, clinical and regulatory teams, focused on meeting and exceeding expectations.
- Ability to manage diverse and simultaneous projects of various complexity.
- Self-starter, strong sense of urgency, assertive, proven manager with a strong results orientation, positive "can do" attitude.
- Experience in strategic planning and collaboration with executive and key operational groups.
- Extensive experience in regulatory compliance relevant to medical devices.
- Experienced in regulatory filings for US (510(k)) and other key countries/regions.
- High level of personal and professional integrity and trustworthiness with strong work ethic and the ability to work independently with minimal direction.

- Ability to lead, influence, create and work within cross-functional team environments.
- Broad knowledge of medical device operations and quality guidelines, regulations and GCPs
- 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%.

Interested candidates should send their resume to careers@cytrellis.com for consideration.