



CLINICAL FIELD SPECIALIST/ SENIOR CLINICAL FIELD SPECIALIST

ABOUT US:

Cytrellis Biosystems, Inc. is a clinical stage medical technology company developing a new, proprietary class of aesthetic devices. Our devices are designed to remove sagging skin associated with aging without surgery or scarring, enabling aesthetic practitioners an unprecedented ability to improve age related changes in skin and restore youthful beauty. Cytrellis is dedicated to working with leading dermatologists, plastic surgeons and partners to develop unique product solutions which emphasize safety, clinical results and improved quality of life. We are a Boston-based venture capital backed company.

Cytrellis has a broad IP portfolio and has demonstrated proof-of concept in clinical studies. The company has raised a Series A financing led by ARCH Venture Partners. Merz Pharma has also made a strategic investment in the company

SUMMARY:

CFS's primary responsibility will be to execute Cytrellis Clinical Studies – coordinate, implement and provide on-site clinical and technical support for Cytrellis products during clinical trial participation. The CFS will be required to train physicians and allied professionals to use Cytrellis products as outlined in the Instructions for Use (IFU) and advise them on the clinical applications during clinical trial use. In addition, assist the site's clinical research coordinator to document specific data points during the clinical cases, and provide site guidance by interfacing with both physicians and allied professionals.

ESSENTIAL FUNCTIONS:

As a member of the Clinical Affairs Team, this highly motivated individual will train staff at the participating clinical site on the proper techniques and use of the Cytrellis system. This candidate will also be responsible for updating training materials, as needed, as well as developing and maintaining clinical communications to support, document and drive appropriate product utilization.

The CFS may be required to perform all or a combination of the following essential responsibilities as determined by necessity.

Essential Responsibilities

- Represent the Cytrellis device use in procedures and provide technical assistance
- Assess training needs and conduct training of investigators, study co-coordinators and other allied professionals in all clinical and technical aspects of the system
- Provide essential clinical and technical support at investigational sites by attendance at the treatment procedures
- Maintain contact with clinical sites
- Support clinical monitoring procedures from inception to end of clinical studies
- Assure clinical studies are in compliance with Domestic and International Good Clinical Practices
- Provide support with field clinical investigations. Assure accurate, complete and current records are maintained in accordance with the clinical study protocol and investigational plan
- Perform periodic site visits to assess study progress. Report and document site audit findings and corrective actions
- Support clinical evaluation data collection and review and summarize case report forms
- Identify, develop and document methods and processes to improve device performance and features in the field
- Provide feedback to engineering and marketing teams on system performance and opportunities for improvement
- Provide leadership and support in designing clinical protocols to improve and enhance clinical and productivity claims for the device
- Attend industry conferences, and cover pertinent clinical presentations
- Perform other related duties as assigned.

Experience & Training:

- A bachelor's degree in Health Science Related field, Biomedical Engineering, Scientific/medical background or professional health services licensure (i.e., LPN, RN, etc.)
- +7 years of prior medical device industry experience is required (aesthetic field experience with strong knowledge of its operations and competitive technologies is preferred).
- Familiarity with clinical trial monitoring process, prior experience and certification are preferred. Past experience in working with and monitoring CROs is preferred.
- Familiarity with research methodology and previous experience in coordinated clinical research.

- Strong interpersonal, analytical, organizational and leadership skills, training, and the ability to stay abreast of the current technology, company products and generally accepted medical practices related to products and procedural area.
- Strong written and verbal communication and presentation skills. Ability to present and effectively communicate complex clinical and technical data to the audiences of various backgrounds and knowledge levels.
- Strong computer skills and familiarity with Microsoft Office and other related software
- Ability to handle time constrained projects simultaneously.
- Availability to travel up to ~50%, when necessary