QUALITY SYSTEMS MANAGER

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 Quality Systems Manager will be hands-on and drive the implementation and refinement of the quality management system in compliance with FDA 21 CFR 820 and the ISO 13485:2016 standard. This key individual will provide support involving product design and development, product testing and disposition, quality investigations and cGMP oversight to product manufacturing, evaluation, and release. The Quality Systems Manager may be required to perform all or a combination of the following essential responsibilities as determined by necessity.

Essential Responsibilities and Authorities

The Quality Systems Manager will report to the VP of Quality, Regulatory and Clinical Affairs. This role will be located in the Company's Woburn, MA office. The Quality Systems Manager may be required to perform all or a combination of the following essential responsibilities:

- Develop, establish and maintain phase appropriate quality systems, policies, procedures and controls ensuring that the quality of products conform to applicable regulatory requirements and company standards
- Provide guidance to external partners to ensure MFG activities are performed in a compliant manner with company and regulatory expectations
- Work with the R&D team to ensure compliance to design controls and establish key areas for QA oversight for new products and processes; routinely audit the design history file (DHF), device master record (DMR) and design history record (DHR) documentation.
- Responsible for managing operational QA systems: change control (Engineering Change Order and Inventory Change Order), non-conforming material, investigations and root cause analysis, CAPA and records maintenance
- Authority to review and approve executed device history records and all associated documentation
- Responsible and authority disposition of products

- Responsible for the complaint handling process, including receipt, investigation and closure and work closely with Regulatory Affairs relating to reporting.
- Plan and manage audit programs (internal and external) using risk-based assessments, reporting findings/compliance metrics and implementing appropriate risk escalation and mitigation strategies
- Implement and manage training program, including managing training plans, training files and records, company-wide cGMP and new hire QMS overview
- Work closely with Operations to support the supplier management program; qualify and routinely monitor supplier performance and institute Quality Agreements, as required
- Business Owner/Administrator for the PLM system (Arena)
- Manage the software validation program for design and manufacturing tools/applications (requirements management, ERP, CRM) and assure that software revisions are appropriately assessed for existing tools incompliance with Part 11/GAMP 5
- Manage and communicate quality data from multiple sources to assist in the risk management and risk-based decision processes
- Collect and report on quality metrics via Quality Management Reviews
- Perform product labeling review/approval
- Assist with compiling/review of company regulatory submissions
- Promote and advance a Quality Culture
- In conjunction with the VP of Quality, Regulatory and Clinical Affairs, host regulatory inspectors

Experience & Training:

- Bachelor's degree in Engineering or Scientific discipline (required)
- 5+ years Quality Management System experience required in medical device industry
- Certified Quality Auditor (CQA) or Certified Quality Engineer (CQE) preferred
- Working knowledge, understanding and experience implementing 21 CFR 820, ISO 13485:2016, and ISO 14971 processes, specifically proficient in:
    - design control
    - design verification/validation and process/software validations
    - manufacturing IQ/OQ/PQ of medical products, preferable with plastic consumables, and capital medical devices
- Possess experience/knowledge of contract manufacturers, distribution, supply chain and logistics
- Possess effective written and verbal communication, presentation, facilitation and project management skills
- Able to manage multiple priorities and execute on time
- Possess effective leadership skills; able to lead, motivate and inspire others
- Available to travel up to ~10%, when necessary

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