# QUALITY ENGINEER

**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 Engineer will actively monitor and improve the quality of our operational process and outputs. Using excellent troubleshooting skills, the Quality Engineer will ensure that the Cytrellis process and products consistently meet or exceed established quality regulations and standards. The Quality Engineer will report to the Quality Systems Manager and may be required to perform all, or a combination of the following essential responsibilities as determined by necessity. This role will be located in the Company's Woburn, MA office.

**Essential Responsibilities and Authorities**

- Develop, implement and maintain quality standards
- Develop, implement and maintain quality control systems
- Monitor and analyze quality performance, including developing and maintaining metrics for key quality indicators
- Inspection and testing of processes and products to ensure quality specifications are met
- Collaborate with Operations personnel and Contract Manufacturing Organization personnel to develop controls and improvements
- Responsible for IQ/OQ/PQ protocol/report review
- Investigate and troubleshoot product and production issues
- Develop corrective actions, solutions and improvements
- Participate in Design Control process to ensure compliance to regulations and standards are met and maintained
- Responsible for ensuring risk documentation is compliant to regulations and standards
- Responsible for NCR, SCAR, CAPA systems
- Perform internal and/or external (supplier audits)
- Promote and advance a Quality Culture

- Participate in regulatory inspections, as necessary

**Experience & Training:**

- Bachelor's degree in Engineering or Scientific discipline (required)
- 2+ years Quality Engineer 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
- Risk management processes
- Possess experience/knowledge of contract manufacturers, distribution, supply chain and logistics
- Possess effective written and verbal communication, presentation, facilitation and project management skills
- 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 computer skills and familiarity with Microsoft Office and other related software.
- Ability to handle time constrained projects simultaneously.
- Available to travel up to ~10%, when necessary

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