



MANUFACTURING 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 Manufacturing Engineer will work closely with manufacturing partners to ensure they are producing high quality and cost-effective products by driving manufacturing transfer and production activities. This individual will also provide R&D with design and supplier selection/evaluation feedback ensuring product manufacturability. This role will be supporting the scale-up of new manufacturing lines and the daily production for existing products. The Manufacturing Engineer may be required to perform all or a combination of the following essential responsibilities as determined by necessity. This position will report to the Director of Manufacturing. This role will be located in the Company's Woburn, MA office.

Essential Responsibilities

- Support of all internal manufacturing and process development activities.
- Support manufacturing process development and validation, either in-house or at contract manufacturers with focus on product quality.
- Troubleshoot manufacturing issues, providing engineering and quality input to manufacturing partners.
- Support of existing product transfers and new product startups with potential contract manufacturers.
- Develop processes that support scale up of manufacturing capacity.
- Support test planning, development, and execution. Work with R&D to define test requirements, as well as contract manufacturers and external test equipment development partners.
- Development of manufacturing process validation protocols and reports, both internally and at contract manufacturing partners.
- Support R&D to develop high quality products that are manufacturable, reliable, and sustainable.

Experience & Training:

- Minimum of a bachelor's degree in Mechanical or Manufacturing Engineering.
- Minimum of 5 years of medical device manufacturing experience required.
- Experience in developing manufacturing processes for electro-mechanical medical devices.
- Experience is designing and developing manufacturing and test fixtures.
- Experience in the use of vision and leak detection systems.
- Knowledge of electronics, plastics, and metal manufacturing in medical device new product introductions, manufacturing, technical transfers, and supply chain.
- Experience in sourcing materials to support product development initiatives, electronics based medical device finished products manufacturing, and assembly-oriented manufacturing environments.
- Experience with ISO 13485 compliant medical device projects and manufacturing environments.
- Working knowledge of Lean Manufacturing Principles.
- Working knowledge of Quality System elements including Design Controls, Design History File (DHF), Device Master Record (DMR), Device History Record (DHR), CAPA.
- Familiarity with SPC, Experimental Design and Statistical Sampling techniques.
- Excellent interpersonal, project management and presentation skills, with the ability to clearly present recommendations and ideas and to summarize complex issues.
- Strong written and verbal communication and presentation skills. Ability to present and effectively communicate complex technical data to audiences of various backgrounds and knowledge levels.
- Ability to work well under pressure in a fast-paced, time-sensitive environment with shifting priorities, and multiple deadlines.
- Working knowledge of statistics software packages such as Minitab, and standard Project Management tools such as MS Project/Smartsheets, Excel, Word, etc.
- The ability to collaborate with all levels of management in a matrix environment required.
- Availability to travel up to ~20%, when necessary.

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