

## Manufacturing/Product Development Engineer

EndoTheia is looking for a motivated and talented Manufacturing and Product Development Engineer that will be responsible for translating medical device prototypes into viable commercial products that can be manufactured at scale. The ideal candidate will have a passion for the development of innovative medical devices, and demonstrative experience in the design and engineering of medical devices from concept all the way through to production.

### Key Activities:

- Develop and engineer medical devices from concept to production, while ensuring that designs meet performance, regulatory, manufacturing, and budget requirements.
- Use software (SolidWorks or Autodesk Inventor) to develop 3D CAD models and drawings of medical instruments, catheters, user interfaces, and/or packaging. Includes component, subassembly, and top-level drawings.
- Use in-house prototyping equipment to generate conceptual and functional prototypes.
- Incorporate user feedback and contribute creatively to the industrial design of medical devices.
- Collaborate with outside suppliers and OEMs on the sourcing of critical components.
- Prepare documentation release packages, including detailed drawings, bills of material, and/or assembly procedures.
- Identify and liaise with external contract manufacturers to translate in-house prototyped devices into commercial products that can be manufactured at scale.
- Work with test engineers to verify that designs meet functional requirements through performance of engineering analyses and testing.
- Identify and implement design/process improvements to maximize performance/yield and minimize manufacturing/assembly cost.
- Perform tolerance analyses on mating components and sub-assemblies.
- Contribute to the Design History File (DHF).
- Participate in design control efforts related to risk analysis (FMEA) and design reviews.
- Participate in project planning and scheduling.
- Provide direct quality support for CAPA/Deviations/Change Control, DFMEA, PFMEA, etc.
- Other duties as determined by business needs.

### Education:

- Bachelor's or Master's degree in Mechanical, Industrial, Biomedical, or Manufacturing Engineering.

### Experience:

- 2+ years of product/design/industrial/manufacturing engineering experience, preferably in medical devices or another highly-regulated manufacturing environment.

### Requirements

- Demonstrated ability to bring products from concept to market.
- Familiarity with FDA, QSO, and ISO 13485 medical device regulations and standards.
- Demonstrable knowledge in DFMA, GD&T.
- Extensive experience in CAD (SolidWorks preferred), and willingness to provide examples of previous work.
- Experience with industrial/human-factors design (knowledge of ANSI/AAMI HE75 a plus).



- Experience with office productivity software (Microsoft Excel, PowerPoint, Word, Etc.).
- Strong oral and written communication and organizational skills, technical problem solving, the ability to work in teams, critical thinking, the ability to adapt to a rapidly changing environment, and desire to contribute to meaningful and innovative products.
- Proven ability to work cross-functionally to achieve business outcomes.
- Self-motivated, with ability to keep track of and prioritize multiple projects and timelines
- Must be able to multi-task, meet tight deadlines, and prioritize changing demands in a fast-paced environment.

#### Additional Desired Skills/Qualifications/Competencies:

- Familiarity with plastics design and manufacturing methods (injection molding, thermoforming).
- Familiarity with laser-cut hypodermic tubing and requisite assembly processes.
- Knowledge of catheter molding design and assembly processes (extrusion, braiding, coiling, reflow, etc.)
- Experience with organic/free-form/mesh modeling.

#### About EndoTheia

At EndoTheia, we believe that clinicians can do amazing things when empowered with the right tools, and we are developing technology that can unlock the full potential of their skill and experience to improve outcomes for their patients. EndoTheia was founded in 2018 to commercialize University-developed flexible medical device technology, and opened its doors full-time in September of 2020. Currently, EndoTheia has 3 full time employees and several consultants. EndoTheia is currently accelerating its development and rapidly growing its team.

Our first product is an innovative disposable device that enables endoscopic surgeons to treat biliary disease more effectively, with better patient outcomes. As a member of the EndoTheia team, you will play a crucial role in designing our first product and pushing it to market. For more information about EndoTheia's team and mission, visit <https://www.endotheia.com/>.

EndoTheia is an equal opportunity employer and committed to a diverse workplace. All applicants will be considered equally without regard to race, color, ethnicity, veteran status, religion, national origin, marital status, political affiliation, age, sex, sexual orientation, membership in an organization or any other non-merit factors. Employees at EndoTheia enjoy a full range of benefits including premium coverage for medical/dental insurance, retirement matching, flexible work-from-home options, and generous PTO and sick leave.

#### To apply

Apply online at <https://www.endotheia.com/careers> or by sending an e-mail to [careers@endotheia.com](mailto:careers@endotheia.com). Please include a resume or CV, along with a cover letter. Be sure to detail past medical device product design experience (if any). Ideal start date is January 2021, but there is some flexibility.