

Quality Engineer

EndoTheia is looking for a motivated and talented Quality Engineer that will be responsible for developing, implementing, and performing Quality Assurance and Quality Control related activities to support the products designed and manufactured by EndoTheia. The ideal candidate will have a passion for the development of innovative medical devices, and demonstrative experience in the creation and management of quality systems.

Key Activities:

- Assist in the continuous evaluation and improvement of the EndoTheia Quality System.
- Serve as an independent reviewer for design reviews.
- Perform supplier evaluation related activities.
- Develop metrics to evaluate and perform supplier performance evaluations.
- Maintain and update Supplier Performance Files.
- Participate in Risk Management, Design Verification, Transfer and Change activities.
- Provide direct quality support for CAPA/Deviations/Change Control, DFMEA, PFMEA, etc.
- Review product life-cycle documents and deliverables, e.g., reports, SOPs, studies, protocols, batch records, etc.
- Provide compliance and quality guidance for design verification, design validation, shelf-life stability studies, simulated distribution studies, feasibility studies, and test method validations.
- Other duties as determined by business needs.

Education:

- Bachelor's or Master's degree in Life Sciences, Engineering, or other relevant discipline.

Experience:

- 3 years of medical device, pharmaceutical or other highly regulated industry (e.g., automotive, nuclear, telecom, defense, etc.) experience
- 2 years of quality assurance and/or quality control experience in medical device development

Requirements

- Advanced knowledge of risk management, regulatory, quality and/or human factors engineering polices, principles and best practices
- Advanced knowledge of FDA/ISO applicable guidance, regulations and standards including: ISO 13485, ISO 14971, TIR 57, IEC 62366, 21 CFR 820.30
- The position requires 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:

- Medical Device product design experience
- ASQ CQE/CSQE/CQA certification preferred
- Familiarity with Greenlight Guru or comparable QMS software

About EndoTheia

At EndoTheia, we believe that surgeons 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 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 bringing our first product to market through the development and oversight of an ISO-13485-certified quality management system. The quality frameworks that you develop will facilitate future product development and growth into adjacent markets. 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 competitive 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>. Submit a resume or CV, along with a cover letter. Be sure to detail past quality management experience, problem-solving skills, and medical device product design experience (if any). Ideal start date is January 2021, but there is some flexibility.