



POSITION TITLE Senior Quality Engineer/Manager
TYPE Full-Time
LOCATION Rocky Hill, CT
COMPENSATION Includes salary commensurate with experience, equity, health and retirement benefits.

Lumeda Inc. is an early-stage medical device company applying advanced photonics and artificial intelligence (AI) to automate and digitize Photo-Dynamic Therapy (PDT) light delivery to enable a breakthrough intraoperative procedure as an adjuvant therapy in lung cancer surgery. We are a multidisciplinary team of highly experienced individuals committed to pioneering the advancement and efficacy of PDT for improved patient outcomes in treating thoracic malignancies.

Lumeda Inc. is currently seeking a Senior Quality Engineer/Manager, with direct report to founder and VP of Engineering. This individual will possess deep regulatory experience to work closely with the Lumeda engineering team to assure design files meet regulatory standards and applicable regulations. In addition, the candidate will support design of product compliance test plans and act as point of contact with external testing services.

Requirements/Qualifications:

- BS degree required
- Minimum 5 years relevant experience, or advanced degree with minimum of 3 years relevant experience

Experience or familiarity with the following;

- Plan, coordinate and own quality subsystems such as design control, design verification, design validation, process validation, etc.
- Perform design review inspections, design control reviews, and other quality and regulatory associated activities, working closely with the Lumeda engineering team.
- Lead the documentation, technical writing and reporting of quality engineering functions for FDA forms, submissions, approvals and tracking.
- Familiarity with IEC 60601 and ISO 13485 Standards, CFR Title 21 Part 820.
- Strong written/oral communication skills and competence with MS Office software packages.
- Ability to work independently and within a team-oriented entrepreneurial environment.
- Work authorization for United States required.

Lumeda Inc. is an equal opportunity employer that is committed to diversity and inclusion in the workplace. We prohibit discrimination and harassment of any kind based on race, color, sex, religion, sexual orientation, national origin, disability, genetic information,



pregnancy, or any other protected characteristic as outlined by federal, state, or local laws.

This policy applies to all employment practices within our organization, including hiring, recruiting, promotion, termination, layoff, recall, leave of absence, compensation, benefits, training, and apprenticeship. Lumeda Inc. makes hiring decisions based solely on qualifications, merit, and business needs at the time.