

CSA MEDICAL, INC.

Senior Quality Engineer

Position Description

The Sr. Quality Engineer supports design and development teams by applying best practices to ensure compliance to medical device regulations and standards for both commercial products and new product development, focusing on the requirements for design controls, risk management, and product and process validation. This position also provides support for the management of the Quality Management System (QMS) processes.

Areas of Primary Responsibility

- Lead design assurance activities for projects from concept to post-launch, including design history file and technical file development and maintenance.
- Support verification and validation activities, including advising engineers on: developing V&V plans and strategies, developing V&V protocols and reports, design of experiments, qualifying test fixtures, sampling plan selection, and conducting statistical analyses.
- Lead/Support risk management activities during design and development as well as post-launch.
- Perform activities to support IDE, 510(k) and PMA submissions.
- Lead/Support the management of QMS processes, which may include CAPA, complaint investigations, internal/supplier auditing, contract manufacturer management, etc.
- Some travel (1-2 day per month) and willingness to observe medical procedures required.

Qualifications

- Current in and demonstrated continuous learning in QMS best practices and requirements, including 21 CFR 820, ISO 13485, ISO 14971, IEC 60601, ISO 62304, and related medical device regulations and standards.
- B.S. degree in Sciences, Engineering or Medical field.
- 5+ Years of Quality experience in a Medical Device company.
- Experience with electrical medical devices and sterile medical devices
- Experience collaborating on cross-functional projects with Product Development, Marketing and Manufacturing.
- Critical reasoning and excellent data presentation skills.
- Background in statistics and design of experiments.
- Teamwork, flexibility and adaptability to change.
- Excellent written and oral communication and negotiation skills.
- Self-initiator with strong organization skills.
- Ability to lead through influence.

CSA Medical® is a privately-held, venture-funded company based in Lexington, Massachusetts. Our team consists of highly-skilled professionals who work together to enable customers to advance patient care through innovative spray cryotherapy devices. Our work environment is highly collaborative and our employees drive CSA Medical's friendly, fast-paced and energetic environment. We offer an excellent benefits package and an engaging, small, entrepreneurial environment, which allows individuals to contribute, learn, grow and develop. We are always looking for motivated individuals who are interested in growth opportunities to join our vibrant team.

CSA Medical, Inc. is an equal opportunity employer

How to Apply:

Submit your resume and cover letter to careers@csamedical.com