

Quality Engineers

Summary: Our client, a manufacturer of best-in-class visual fiber optics medical technology, is looking for Quality Engineers to lead Corporate and Value Stream Quality efforts. They need experienced Medical Device Quality Engineers to support the development and introduction of new products consistent with FDA requirements for medical devices.

Responsibilities: The corporately focused Quality Engineers will manage Complaint and warranty data capture and administration, CAPA's, Quality System oversight, Supplier Audits and other responsibilities. The Value Stream focused QE's will work on day to day Quality issues, new product intro and qualification, root cause analysis on issues, and other responsibilities. Quality Engineers other responsibilities will include defining and/or executing test and inspection protocols, supporting validation activities, establishing product acceptance standards and metrology and integrating new products into data collection systems to facilitate process control and continuous improvement efforts. They will also demonstrate expertise in using the "tools of quality" including statistical techniques, support continuous product improvement efforts including performance of root cause analysis/ corrective action implementation for customer complaints, manufacturing issues, cost reduction and in new product development, and participate in the definition, standardization and implementation of best practices associated with the quality system and business processes.

Qualifications: Qualified candidates will have a minimum of 5 years experience in a medical device Quality Engineering role with a demonstrated record of success in the competencies outlined above. They must have a minimum of a Bachelors degree in engineering, statistics, or a related discipline and expertise in FDA/QSR cGMPs, and ISO9001/13485. They must also have expertise in MS Office especially Excel and Quality Database experience. Some experience with endoscopy, video/visualization systems and fiber optics is a plus; as is, experience with soldering, wiring, clean room/clean manufacturing protocol, and hybrid/semiconductor microelectronics assembly techniques. The company would also strongly prefer ASQ Quality Engineer, Six Sigma Black Belt and/or Reliability Engineer certifications. The QE's must have excellent communication skills and the ability to drive and support efforts to achieve world class quality with a hands-on collaborative approach.

[Click here to apply online](#)

Or respond by phone to:

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