Quality and Regulatory Manager

Insight Medical Systems Austin, Texas Metropolitan Area

About the job

Insight Medical Systems is a medical device company that develops wearable augmented reality-based tools to help surgeons perform orthopedic procedures. We're upending the market by replacing large, expensive capital equipment with our miniaturized system. This fast-paced company provides an opportunity to take a leading role in shaping the quality system and culture of the organization.

Job Responsibilities:

- Build out and maintain an efficient ISO 13485-compliant quality management system
- Work with the team to develop Insight's navigation systems for joint replacement while ensuring product quality and adherence to company procedures and external regulations
- Support product commercialization by developing and executing inspection plans
- Support the preparation and execution of verification and validation plans
- Lead effort for FDA and international regulatory clearances for Class II medical devices
- Manage quality system audits
- Assist in preparation of project and design control documentation

Job Requirements:

Required:

- Bachelor's degree in an engineering or technical field
  Equivalent experience may be considered in lieu of a degree for exceptional candidates.
- Minimum 5 years of quality assurance experience
- Experience with software-controlled medical devices
- Experience leading or closely supporting 510(k) submissions through to FDA clearance
- Strong communication and interpersonal skills
- Excellent writing skills

Preferred:

- Familiarity with ISO 62304 standard and FDA guidance for medical device software lifecycle management and submissions

Insight offers a competitive benefits package including health insurance, dental and 401(k). If you're ambitious and want to develop exciting products that have a positive impact on people's lives, we want to hear from you.

To apply, please email a cover letter and resume to info@insightmedsys.com