Regulatory Affairs Specialist – Medical Devices – Part time.

About us:
Sontec Instruments, Inc. is a family owned & operated medical company, providing personalized service featuring the finest in surgical instrumentation for over half a century. Our office is located outside southeast Denver, in Centennial, Colorado.

Job description:
Responsible for developing and coordinating documentation of all aspects of an ISO 13485 and ISO 9001 certification process of medical devices. Provide industry GMP audit guidance according to ISO qualification requirements. Must have firm comprehension of medical device Design Control processes according to FDA regulation 21 CFR 820 regarding FDA 510(k) device submission.

Qualifications:
To be considered for this position the following qualifications of experience must be met:

- Thorough knowledge regarding ISO 13485 medical device certification process
- FDA Design Controls regulation for medical devices FDA 21 CFR 820.
- A basic understanding of handheld surgical instruments or previous medical device industry experience preferred.

Experience:
Must have experience in development of:

a) ISO 13485 and ISO 9001 certification process.
b) The structure of GMP in the medical device genre.
c) Design History files, Input and Output, Review, Verification and Validation, and Design Transfer
d) Excellent attention to detail and proven organizational skills, able to prioritize and multi-task and manage projects/assignments to completion.
e) Proficiency in MS Office, Outlook, PowerPoint and proprietary databases.
f) Proven leadership and negotiation skills, able to successfully manage cross-departmental expectations.
g) Excellent written and verbal communication skills.

Education requirements:

- Bachelor's degree
- Certification in Quality Assurance Regulatory Affairs, life science or related technical field is preferred.

Compensation

- The pay rate is $38-$48/hour, depending on experience.

How to apply: Please email Julian Ospina – julian.ospina@sontecinstruments.com with the resume and mention the Rocky Mountain Regulatory Affairs Society when you apply.