



Medical Device Regulatory Affairs Associate

Responsibilities:

Successful candidate will possess the ability to interpret regulatory requirements for product introductions and develop Class I and Class II 510k submissions (preferably for software medical devices and medical device data systems).

In addition, this individual will have the ability to properly classify software medical devices in accordance with regulatory classifications, interpret new regulations and develop relevant procedures for implementation.

This position also requires that the candidate possess the ability to:

- initiate and close CAPA's and Continuous Improvement Reports
- interface with the FDA and other regulatory agencies to address and close any open issues concerning proper pre-market requirements
- facilitate closure for Medical Device Reportables and Class I (Critical) Complaints

Successful applicant will have at least 3 to 7 years of experience working as a Regulatory Specialist; preferably in a software medical device environment.

If interested, please email your resume to careers@isirona.com. Candidates selected for interviews will be notified by phone or email.