

Job Descriptions
US Openings

QA/QC Medical Device Consultant

Openings: 1 (Los Altos, CA)

Experience: 10+ years

Employment Type: Consultant

Job Description:

Looking for a consultant with experience in QA/QC processes, SOP creation, and process development for a medical device design services company. This is a unique opportunity to help create processes and document SOPs around these processes, for ISO and FDA certification purposes. Candidate must have gone through at least one full design cycle for a medical device and successfully submitted design history file to the FDA. Development of SOPs that are compliant for certification by FDA and EU CE Mark.

Should have expertise in:

- IEC62304
- ISO14971
- IEC60601
- ISO13485

Good to have expertise in:

- FDA Ultrasound Clearance
- FDA Guidances for Software Validation
- FDA Guidances for Software Submissions