



Cheryl Fisher

Senior Consultant, Quality Assurance

EXPERIENCE:

- Senior Business Analyst, Boston Scientific / Guidant Corporation
- Senior Regulatory Compliance Auditor, Guidant Corporation
- Independent Consultant
- Writer/Accountant, Redcreek Communications Technical
- Controller, Silicon Gear Corporation
- Manager, StellarTech

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Sleep Apnea
- Software
- Electrosurgical
- Minimally invasive surgical
- IVDD
- Blood
- Diagnostic

Disciplines:

- FDA Quality System Regulation (21 CFR Part 820) and ISO 13485:2003
- Procedure development for a QMS compliant with FDA QSR and ISO 13485:2003
- 510k Submissions
- ISO 13485 Internal Auditor and Awareness Training
- Audits to FDA QSR (21 CFR Part 820)
- Audits to ISO 13485 and MDD
- Regulatory-Market Position/Adoption Strategy

EDUCATION:

- Bachelor of Arts in Liberal Studies, San Jose State University
- Graduate work toward MBA, Pepperdine University

TRAINING and CERTIFICATIONS:

- RAB/QSA Principal QMS Auditor
- Certificate Technical Communications