



Keith Lowrey

Senior Consultant, Regulatory Affairs

EXPERIENCE:

- Managing Director, Lowrey RA/QA Solutions
- RA/QA Vice President & Consultant, Xtract Solutions
- RA/CA Director, Computer Motion, Inc. and Consultant for Intuitive Surgical
- RA/QA Director, BioEnterics Corporation/Inamed Development Co
- Microbiology/Biomaterials Manager, Mentor Corporation

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Class III implantable – ventricular assist pumps, obesity, plastic reconstructive, and urological devices
- Class II software assisted robotic minimal invasive instruments and endoscopic devices
- Tissue reconstructive biomaterial and biological devices
- Urological, respiratory and general surgery devices, Surgical and dental laser devices
- In Vitro diagnostic devices and clinical laboratory devices

Disciplines:

- FDA Quality System Regulations – 21 CFR Part 820 and ISO 13485:2003 Quality Management Systems
- US FDA PMA submissions, 510(k) premarket notifications and Investigational Device Exemptions
- Medical Device Directive 92/43/EEC, CE Marking - Technical Files and Design Dossiers
- Microbiology, packaging and sterilization validations
- Material Biocompatibility Testing and Qualifications
- Design Control and Verification; Process Control – Installation, Operation and Process Validations

EDUCATION:

- MScellular Biology, University of Southern California at Santa Barbara, Santa Barbara, CA USA
- BS Medical and Industrial Microbiology, Brigham Young University, Provo, UT USA
- BS Clinical Laboratory Technology, Brigham Young University, Provo, UT USA

PROFESSIONAL AFFILIATIONS:

- American Society for Quality (ASQ)
- Regulatory Affairs Society (RAPS)
- American Society of Microbiology (ASM)
- American Society of Clinical Pathologists (ASCP)

TRAINING AND CERTIFICATIONS:

- Technical writing, document control, Quality Manual and SOP development
- Staff trainer for Quality Systems (21 CFR 820) and Quality Manage Systems (13485:2003)