



## Jim Craig

*Senior Consultant, Quality Assurance and Regulatory Affairs*

### EXPERIENCE:

- ISO Consultant
- Spar Aviation, Service Quality Manager
- DND, Quality Manager

### AREAS OF EXPERTISE:

#### *Devices:*

- Orthopedic devices
- Injectable and Implantable devices
- Ophthalmologic devices
- IVDs
- Dental Equipment and Devices
- Specialized Thermal Devices
- Training

#### *Disciplines:*

- FDA Quality System Regulations – 21 CFR Part 820
- CE Marking –Medical Devices (MD) and Invitro Devices (IVD)
- Canadian Medical Device Requirements
- ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
- Electro Static Discharge (ESD) Program Requirements

### EDUCATION:

- B.Sc. Physics / Chemistry, University of Calgary, Calgary, Canada

### TRAINING AND CERTIFICATIONS:

- RAB/QSA former QMS Auditor Q085509

### PUBLICATIONS AND PRESENTATIONS:

- Development of multiple Quality Systems
- Presentations to various State Medical Device Manufacturer Associations