



Mike Begala

Senior Consultant, Quality Assurance and Regulatory Affairs

EXPERIENCE:

- QA/RA Consultant, Maximum Business Advantage
- Senior Consultant, International Services Associates
- Quality Assurance Engineer & RA Coordinator, Atrion Medical Products
- Chemist, North Water District Laboratories

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Cardiovascular
- Cosmetic surgery
- Dental
- Disposables
- Ear/nose/throat
- Gastroenterology
- Imaging equipment
- Implants (non-active)
- IVDs
- Mobility aids/equipment
- Orthopedics
- Patient monitoring
- Prostheses
- Ophthalmic
- Radiology
- Reusable instruments
- Surgical instruments
- Therapeutics
- Software-driven
- Urology

Disciplines:

- FDA Quality System Regulation (21 CFR Part 820) and ISO 13485:2003
- ISO 14971:2007
- Canadian Medical Device Regulations (CMDR)
- Gamma and EtO sterilization validations
- Internal auditing for QMS compliance
- Preparation of a Technical File and supporting documents to obtain the CE Mark



- Procedure development for a QMS compliant with FDA QSR and ISO 13485:2003

EDUCATION:

- Bachelor of Science in Physics, University of Texas at Austin
- Master of Science in Management, University of Alabama

PROFESSIONAL AFFILIATIONS:

- Member of the American Society for Quality and a Certified Quality Auditor (CQA)

TRAINING and CERTIFICATIONS:

- Training on US, Canadian and European medical device regulations
- Certified Quality Auditor (CQA)