



Kimberly McCoy

Senior Consultant, Quality Assurance & Regulatory Affairs

EXPERIENCE:

- Consultant, KJ Consulting
- Regulatory Specialist, Encore Medical, L.P.
- Quality Systems & RA Associate , Ethicon Endo-Surgery, Inc.
- Regulatory Specialist, Genzyme Biosurgery Fall River, MA USA
- International Regulatory Associate, Johnson & Johnson Medical, Inc.

AREA OF EXPERTISE:

Including, but not limited to

Products:

- Lasers
- Disposable
- Gastroenterology/urology
- Implants, non-active
- Mobility aids/equipment
- Orthopedic
- Reusable
- Surgical Instruments
- Therapeutic
- Wound Healing
- Cardiovascular

Disciplines:

- FDA QSR (21 CFR Part 820) Implementation
- FDA QSR Internal Auditor Training
- Audits to FDA QSR (21 CFR Part 820)
- ISO 13485 Awareness Training
- 510k/513g submissions
- Clinical Evaluation Reports
- Due Diligence Audits
- Electromedical Testing
- ISO 13485 Implementation
- ISO 13485 Internal Auditor Training
- Technical File/Design Dossier Preparation
- Auditing to ISO 13485 + CMDR
- Audits for Japan PAL/169 Compliance
- QMS Ordinance #169 in Japan



EDUCATION:

- Bachelor of Arts in Political Science/International Relations – Texas Christian University
- Pursuing MBA in Health Care Management – University of Phoenix

TRAINING and CERTIFICATIONS:

- US RAC Certification
- EU RAC Certification
- RAPS Cincy/Indy Chapter and presenter at RAPS 101
- Completed ISO 9001 and ISO 13485 Lead Auditor training