



Robert Seiple, RAC

Senior Consultant, Regulatory Affairs & Quality Assurance

EXPERIENCE:

- Director, Compliance and Regulatory Affairs, MedTrials, Inc.
- Quality Assurance Manager, NeoRx Pharmaceuticals
- President, QPM Consulting LLC
- Senior Quality Assurance Manager, Zila BioTech
- Senior Research Scientist, Steris Laboratories
- Lab Supervisor, Compliance Manager, Total Quality Group Leader, The NutraSweet Company

AREA OF EXPERTISE:

Device:

- Anesthesia/respiratory
- Cardiovascular
- Combination Devices
- Cosmetic/plastic surgery
- Dental equipment
- Implants active/inactive
- In vitro diagnostics
- Neurological
- Ob/gyn
- Sleep Apnea

Disciplines:

- Audits to: FDA QSR (21 CFR Part 820), CGMP (21CFR 210/211). GCP (21CFR 312/812, ICH E-6)
- Clinical Trials - USA (IND, IDE and pre-IDE)
- Quality System Implementation: FDA QSR (21 CFR Part 820) & CGMP (21CFR 211).
- FDA QSR Internal Auditor Training
- FDA 510k/513g submissions
- Training: FDA QSR (21CFR 820, CGMP (21CFR 210/2111 & GCP (21CFR 312/812, ICH E-6)
- FDA QSR 21 CFR Part 210/211, 312 & 314
- Project Management: Drug & Device development, Compliance Improvement
- ISO 14971 Risk Management Training
- CE Marking
- Canada device registration/submission
- Audits for Japan PAL/169 Compliance
- Electromedical Testing (601- EMC, etc.)
- *Pharmaceutical*
 - Radiological
 - Topical
 - Sterile Injectables
 - Oncology



EDUCATION:

- Masters – Project Management, Keller Graduate School of Business
- MS, Human Nutrition, Ohio State University, Columbus, OH USA
- BS Microbiology, Ohio State University, Columbus, OH USA

PROFESSIONAL AFFILIATIONS:

- Regulatory Affairs Professional Society (RAPS) – RAC certified 2005
- American Society for Quality
- Toastmasters International (DTM)