



Adrienne Lenz

Senior Consultant, Quality Assurance & Regulatory Affairs

EXPERIENCE:

- Founder, Pathway Regulatory Consulting, LLC
- Regulatory Affairs Director, GE Healthcare
- Regulatory Engineer Smiths Medical PM, Inc
- Research Assistant, Medical College of Wisconsin

AREA OF EXPERTISE:

Including, but not limited to

Products:

- Diagnostics ECG
- Holter ECG
- Incubators/Infant Warmers, Maternal/Fetal monitors, Breast pumps
- Patient monitoring
- Sleep apnea monitoring and software
- Software
- Anesthesia Delivery
- Blood processing
- Software
- Ventilators
- Medical suction and vacuum pumps (thoracic, negative pressure wound therapy, general)

Disciplines:

- Clinical Trials - USA (IDE and pre-IDE)
- FDA QSR (21 CFR Part 820) Implementation
- FDA QSR Internal Auditor Training
- ISO 13485 Awareness Training
- 510k/513g submissions
- Clinical Evaluation Reports
- Due Diligence Audits
- Electromedical Testing (601- EMC, etc.)
- ISO 14971 Risk Management Training
- Validation (Process, Software)
- Audits to ISO 13485 and MDD
- CE Marking and CE Marking training
- Technical File/Design Dossier
- Auditing to ISO 13485 + CDMR



- Canada Device Registration/Submission

EDUCATION:

- MS Physiology, Medical College of Wisconsin Milwaukee, WI USA
- WI BS Biomedical Engineering, Milwaukee School of Engineering Milwaukee, WI USA

PROFESSIONAL AFFILIATIONS:

- Regulatory Affairs Professionals Society
- Biomedical Engineering Society: 1991 to 1998. Vice President, student chapter: 1994.
- ASTM International, member: 2000 to 2004.

TRAINING AND CERTIFICATIONS:

- GE Healthcare
- RxTrials Institute, GCP for Medical Device Clinical Trials: 2007
- Clinical Device Group, Good Monitoring Practices: 2007
- EduNeering, 18 online courses in FDA and ISO Quality System Regulations: 2007
- AAMI, Corrective and Preventive Action Requirements and Industry Practice: 2006.
- American Society for Quality
- MRA – The Management Association, Inc, Internal Auditing for ISO 9000 Systems: 2002
- Babson College of Executive Education
- US Regulatory Affairs Certified (RAC), Regulatory Affairs Professional Society: 2007 to present
- Six Sigma Green Belt Certified, GE: 2005. American Society for Quality Senior Member: 2004 to 2009
- GE Healthcare, Stock Option Grant Award: 2010, Landsteiner Award: 2008, 2010, Salk 3 Awards: two in 2008, QARA award: 2006, Management awards: 2005, 2006