SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

LUCILLE FERUS

EXPERIENCE

- Over thirty years experience in the design, risk assessment, validation and regulatory clearance of medical instrumentation
- Perform assessments and audits for overall quality systems, design controls and IEC 62304.
- Creation of quality system Standard Operating Procedures, compliant with FDA, ISO 9001 and 13485 including department
- Creation of Standard Operating Procedures for complete lifecycle of software based devices compliant with IEC 62304 and product and software risk management compliant with ISO 14971.
- Perform product and software failure and risk analysis for class II and class III devices.
- Constructed complete set of prospective and retrospective product life cycle documentation following design controls and IEC 62304 for wide array of software based medical instruments.
- Write technical sections of for domestic and international regulatory submissions
- Represented software development process during technical and regulatory reviews and independent audits.
- Organized and managed inter-discipline project teams of developers, test and quality assurance engineers involved in risk assessment and risk based verification and validation.

CREDENTIALS

- Formerly Vice President of Engineering for Natus Medical; manufacturer of newborn screeners.
- Formerly Engineering Manager, Software Compliance for Ventritex; manufacturer of implantable defibrillators.
- Responsible for establishing software development lifecycle and liaison for all regulatory submissions and audits.
- Responsible for product development including design, development, validation and regulatory clearance .for broad range of software based devices including Implantable Defibrillator, EEG Brainstem Response, Respiratory Gas Monitors, and Electrocardiographs.
- Instructor for in-house classes in ISO 14971, Software Risk Management, and design controls.
- Working group member of AAMI:TIR32 Medical Device Software Hazard Management, basis for IEC/TR 80002-1 2009 Medical Device Software Guidance on the application of ISO 14971 to medical device software.
- Master of Science in Bioengineering, Concentration: Computer Science
  Fairleigh Dickinson University, Teaneck, NJ, December 1982
- Bachelor of Science in Electrical Engineering, Concentration: Bioengineering
  Fairleigh Dickinson University, Teaneck, NJ, Magna Cum Laude, December 1978