

## EXPERIENCE

- 20+ years experience with medical devices doing systems engineering, software development, safety analysis, and regulatory engineering
- Critical and complex medical device failure analysis and risk management, especially software-focused analysis and usability engineering (ISO 14971, IEC 62366, FTA, FMEA, PFMEA, Corrective/Preventative Action)
- In-depth experience planning and executing software validation, including design of instrumentation and simulation
- Numerous validations related to production and quality system software and tools
- Performed detailed computer system validation and 21 CFR Part 11 planning for clinical research organizations
- Examples of projects:
  - numerous hemodialysis and peritoneal dialysis
  - insulin and infusion pumps
  - implantable devices
  - patient monitoring equipment
  - medical imaging equipment
  - large, critical pharmaceutical manufacturing processes
  - blood bank systems and critical diagnostic devices
  - In-Vitro Diagnostic Devices (IVDD)

## CREDENTIALS

- Safety-related usability engineering (IEC 62366): analysis of usability/safety and integration of usability engineering into 14971 risk management
- Held management positions at Johnson and Johnson Medical and Baxter Healthcare
- Avionics and software safety lead consultant to NASA for the ARES and Space Launch System launch vehicles (also commercial space systems safety engineering reviewer)
- Speaker at HIMA/FDA, ADVAMED, RAPS and AAMI conferences on various software and safety related topics. Member of AAMI TIR32 Software Risk Management working group
- Broad understanding of medical device compliance issues and regulatory submission requirements; submission preparation of many critical medical devices FDA 510k/PMA and CE marking; involvement in negotiations and recovery from FDA enforcement actions
- Have authored risk analysis/management plans and procedures, usability engineering processes, software quality assurance processes, software V&V plans, and have extensive experience with writing requirements and traceability
- B.Sc. University of Alabama College of Engineering 1984, electrical engineering