

## EXPERIENCE

- Twenty-three years of experience in all facets of medical device software development including requirements analysis, architectural design, detailed design, construction, verification and validation, maintenance, and configuration management
- Sixteen years of experience as a Principal Software Engineer and Software Engineering Manager at Baxter Healthcare in software development for four hemodialysis machines and three peritoneal dialysis machines
- Developed software engineering processes and performed software process quality inspections
- Performed detailed code inspections and reviews for Class C software systems, including the integrated use of static code analysis tools
- Champion for the effective use of software engineering process tools as part of a software life cycle process that is not only high-quality and compliant but also lean and agile
- Designed and implemented user interfaces and control software for many medical devices
- Designed and implemented embedded software for many other commercial, industrial, and transportation applications
- Created tool for management and traceability of requirements, risk analysis, and design documentation used for FDA 510(k) submission
- Developed software for automated support of localization of software for medical and commercial embedded devices
- Created test automation software for verification and validation of medical device software

## CREDENTIALS

- IEC 62304 Training course – SoftwareCPR: Sherman Eagles (2008)
- Design Control and Software Validation course – CDRH directors Larry Kessler and Al Taylor, et al. (2006)
- Corrective and Preventive Action (CAPA) for Medical Devices course (2002)
- Software Verification and Validation course – University of Maryland University College (1997)
- Training by Baxter Healthcare:
  - Quality System Regulation for Design Control
  - Product Development
  - Design Controls
  - Product Requirements Management
  - Product Clinical Hazards
  - Risk/Hazard Management
  - Failure Mode and Effects Analysis
  - Design Review
  - Software Development
  - Software Configuration Management
  - Software Code Inspection
  - Software Validation
  - Commissioning Software Tools
  - Product Lifecycle Management
  - Product Complaint and Adverse Event Handling
  - Measurement, Analysis, and Statistical Techniques
  - Design History/Technical Files
  - Document Controls
  - Quality Audit
- Presenter at the Baxter Science and Technology Symposium
- Recipient of the Baxter Technical Award
- Patent: Distributed processing system and method for dialysis machines, 9,180,238
- Member of AAMI and IEEE
- B.S. Mathematics Focus, Excelsior College (University of the State of New York), Albany, NY