SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

SHERMAN EAGLES

Experience

- Over forty-five years of experience in the software field, including 18 years at Medtronic.
- Ten years as a Medtronic Technical Fellow, providing consulting and mentoring to Medtronic software development and software quality organizations.
- Experience developing software for operating systems, communications systems and medical devices, as well as developing software processes, tools and metrics.
- Led the establishment of corporate-wide life cycle software processes
- Introduced formal technical inspections and trained software engineers in their use
- Implemented predictive software quality metrics in software development
- Conducted software assessments, including SEI CMM experience and IEC 62304 assessments
- Led software risk analysis activities including software fault tree analysis
- Three years as a member of the technical advisory board of the Software Productivity Consortium.
- Former Chair of the AdvaMed medical device working group
- Provided training for IEC 60601-1 PEMS requirements in Frankfurt, Paris, Amsterdam and Washington.
- Provided assistance to companies creating safety assurance cases for FDA submission

Credentials

- Convener of the IEC working group that developed the Programmable Electrical Medical Systems (PEMS) requirements in IEC 60601-1
- Convener of IEC/ISO joint working group that developed IEC 62304 Medical device software life cycle processes and IEC 80002-1 Guidance on the application of ISO 14971 to software
- Co-Convener of the IEC/ISO joint working group that developed IEC 80001-1 Application of risk management for IT-networks incorporating medical devices
- Convener of the IEC TC 62 Software and Network Advisory Group and member of the IEC 62A Chairman's Advisory Group
- Co-chair of the Association for the Advancement of Medical Instrumentation (AAMI) software committee.
- Co-chair and editor for ANSI/AAMI SW87:2012 – Application of quality management system concepts to medical device data systems
- Member of the working group for AAMI TIR38, *Infusion devices – Assurance report case guidance*
- Lead developer and lead instructor for AAMI Safety Assurance Case course
- Presenter at numerous industry conferences on medical device software development, software safety and software standards
- Author or co-author of papers on software development, software risk management, software standards
- 2008 AAMI Technical Committee Award for work on IEC 62304
- 2012 AAMI Technical Committee Award for work on AAMI SW 87
- 2012 American College of Clinical Engineering Challenge Award for work on IEC 80001-1 and AAMI SW 87