

BRIAN PATE

EXPERIENCE

- 32 years of medical device industry experience including all facets of medical device engineering design including software development, electrical design, verification, validation, hazards analysis, risk management, and overall engineering management.
- Created software quality processes and methodologies including planning, configuration management, defect tracking, hazard analysis, code inspection and review methods.
- Document and documentation management systems and approaches for engineering productivity and quality management.
- Champion for Lean Product Development and project management expertise including IEC62304 compliant Agile methods.
- Detailed code inspection and review for embedded and clinical IT systems.
- Various engineering and management positions with Johnson & Johnson, Baxter Healthcare, and GE Healthcare Technologies.
- Management consulting for medical device companies including onsite coaching/mentoring, training, and leadership development.
- Expert analysis support for accident investigation.

CREDENTIALS

- Member of UL Standards Technical Panel for Remote Software Updates.
- Lead Faculty for AAMI/FDA Regulatory Requirements for Software Validation course.
- Faculty for AAMI/FDA Compliant Use of Agile Methods course.
- Lead Instructor for the SoftwareCPR® IEC 62304 and Emerging Medical Device Software and HealthIT Standards course.
- Member of AAMI TIR45 Task Group, Software Hazard Management, Guidance on the use of AGILE practices in the development of medical device software.
- Member of AAMI TIR32 Task Group, Software Hazard Management, basis for IEC/TR 80002-1, Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software.
- Co-authored numerous papers including Clinical Palatometer for Speech Evaluation and Therapy. Biomedical Engineering V: Recent Developments, Subrata Saha, ed., Pergamon Press, 1986, and Continuous Monitoring of Oxygen Uptake by Replenishment Compared to Oxygen Uptake Calculated by the Fick Equation. Anes Rev 15(1):49-51, 1988.
- Holds two patents: Method and System for Remotely Monitoring Multiple Medical Parameters, 5,855,550. Reconfigurable User Interface for Modular Patient Monitor, 6,188,407.
- MS, Honors graduate, Biomedical Engineering, UAB, Birmingham, AL, 1990.
- BS, Engineering, Mississippi State University, 1984.