SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

# BRIAN PATE

## EXPERIENCE

- 40 years of medical device industry experience including all facets of medical device product and software development, regulatory classification and FDA interaction, design verification and design validation, safety and cyber risk management, and other quality management system processes.
- Lead instructor for SoftwareCPR® "IEC 62304 and other Emerging Standards" course publicly and privately since 2010 to hundreds of regulatory, quality, and engineering professionals each year. The course has been taught throughout North America, Europe, Asia, and Australia.
- 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.
- 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 member of the Technical Panel for UL1998 Software in Programmable Components Technical Panel for UL 5500 Remote Software Updates.
- Longtime lead Faculty for AAMI/FDA Regulatory Requirements for Software Validation course.
- Faculty for AAMI/FDA Compliant Use of Agile Methods 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.