

Gerald T. Rigdon

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Experience Summary

I have over 35 years of experience in safety critical software driven real-time embedded systems spanning multiple diverse industries, Process Control Instrumentation, Burner Controls, Dynamically Stabilized Balancing Machines, and Medical Devices.

I spent 11 years leading the software development in a small private industrial instrumentation company, 2 years owning burner control projects, 6 years wearing numerous hats in a renowned startup company, and presently 17 years in a senior staff technical leadership position for a large publicly owned medical device corporation.

Hands-on in all stages of the software development process in dynamic safety/security critical environments with breakthrough technologies.

Core

- General Purpose Programming
 - C#, Perl, Python, Java, Kotlin, SQL, VB, Lab Windows CVI
- Web Development
 - JavaScript, HTML, CSS, Bootstrap
- Mobile Development
 - Xamarin X-Platform & Bluetooth Low Energy

Safety Critical

- Embedded Systems & Real-Time Programming
 - C, C++, Assembler for 8088/PIC/ST/HC11
- Software Design Patterns, Full SDLC, Agile, Systems Engineering Practices, Risk Management
- Software Unit, Integration, Verification, Validation Testing
- Static Analysis Tools/Custom Techniques, MISRA, Coding Standards, AI/ML
- Product Safety Recalls, Accident Investigations, Defect Analysis, CAPA, Post-Market Surveillance
- Class III Medical Devices, Regulatory, Business Acumen, Marketing Research and Specifications
- IEC 62304, ISO 14971, ISO 13485, TR 80002-1, FDA Design Controls

Security

- Embedded Systems & Enterprise
- Secure Coding Standards, TIR 57, IEC 81001-5-1, JSP, NIST SSDF, FDA Cybersecurity Guidance
- Cryptography, Secure Product Development Frameworks
- Kali Linux Toolchain, Nmap, Traceroute, Metasploit Netcat, WinSCP, Social-Engineering Toolkit (SET)
- Cyberwar Simulations – Denial of Service, Water Hole, Ransomware, Endpoint Detection, Honey pots

AI/ML

- Python, LangChain, Streamlit, Multiple LLMs, AWS, Azure

Blockchain

- Solidity, React, Node.js, Ethers.js, Web3.js, JSX
- Truffle, Hardhat, Redux, Mocha, Chai, Ganache, MetaMask, Remix, Open Zeppelin, Infura

Entrepreneurial Endeavors

- Created a Medical Device Software Process Training Course on Udemy – 2023
<https://www.udemy.com/course/medical-device-software-process-blackbelt/>
- Designed the e-Commerce Store <https://thinkairpurifiers.com/> – 2020
- Designed and engineered a commercially available product called “Tune Tutor & Tools”, a hardware/software integrated PID educational package. This taught me a lot about R&D from the ground up including first-hand experience in the sales and marketing of my very own product. – 1996

Work Experience

Boston Scientific, MN

Fellow, Implantable Firmware Engineering

2007-Present

- Member of the Firmware Design Advisory Board whose charter includes solving difficult technical issues across multiple projects, oversight of safety critical software design patterns, static analysis techniques, Cybersecurity, AI/ML
- Hands-on development for implantable Class III medical device firmware and external infrastructure
 - Pacemakers, Defibrillators, Diagnostic Recorders, Urology Research Controls
 - Mobile Device Apps, Device Programmers, Cloud Connectivity
- Other key responsibilities as a Technical Fellow per HR description:
 - Principle leadership role in functional area using technical expertise to support new technology
 - Conducting research, managing major projects, firmware design and implementation
 - Determining emerging technological trends by reviewing scientific data
 - Supporting documentation effort for regulatory submissions, spokesperson to customers
 - Maintaining substantial knowledge of state-of-the-art principles and theories in area of expertise

Segway, NH

Team Leader / Project Leader / Software Engineer V

2001-2007

- Original member of the product development team of a highly visible startup company that created the world’s first commercially available dynamically stabilized balancing machine, namely, the Segway Personal Transporter. At Segway I enjoyed a wide variety of work experiences from concept creation to product development and release, to manufacturing and serviceability tools, as well as leading investigations for issues in fielded products and subsequent software maintenance releases.
 - Led the early D3 prototype software team
 - Created requirements, design, implementation, and testing of the Segway PT firmware safety kernel
 - Developed the release test software fault handling validation suite
 - Delivered manufacturing line testers and designed service tool software
 - Analyzed root cause of field issues, provided reports for legal department, recall management

Invensys, CO
Software Project Leader
1999-2000

- Project Leader for the successful submission of a micro-controller-based gas ignition product line in compliance with the UL 1998 software safety requirements.

Electron Machine Corporation, FL
Lead Software Engineer
1988-1999

- Designed and implemented real-time software applications for use in embedded systems to provide feedback for process control instrumentation in safety critical areas of industrial environments.
 - Refractometers, X-Ray Gauges, CO2 Analyzers, Black Liquor Recovery Boiler Monitors

Education/Degrees

Doctorate Cybersecurity	Marymount University	Ongoing
Master of Science in Regulatory Affairs	Northeastern University	2014
Master of Business Administration	Regis University	2002
Bachelor of Science in Computer Systems	Regents College	1998
Electronics Diploma	Cleveland Institute of Electronics	1993
Associate of Science Computer Science	Lake Sumter State College	1984

Professional Certifications

Certified Computing Professional	ICCP
Certified Solidity Developer	Blockchain Council
Certified Ethereum Developer	Cadena
Certified Cybersecurity Expert	Global Tech Council

Specialized Training

- MISRA Standard from Perforce
- EKG Rhythm Interpretation Black Belt from Med Mastery
- Cardiac Rhythm Management Advanced Training
- Safety Critical Software by Nancy Leveson

Notable Medical Device Static Analysis Projects

- Requirements architect and project lead for two customized static analysis projects with an industry leading tool vendor to facilitate the domain specific analysis of Class III medical device firmware.
 - Reference <https://rigdonhouse.com/docs/GammaCaseStudy.pdf>

Organizations

- Health Services Coordinating Committee (HSCC) Cybersecurity Working Group

A Few Published Works

Security Papers & Presentations

- “FDA Cybersecurity Guidance for Medical Devices – A Brief on the Law, SPDF, JSP, and NIST SSDF”, Medical Device Summit, White Paper, 2024
- “Understanding the FDA Cybersecurity Final Guidance”, Presentation at Medical Device Summit, 2024

Other Technical Papers & Presentations

- “An Analytical Approach to Identifying Software Initialization Issues”, White Paper, 2012
- “Streamlining Analysis of Medical Device Software”, Case Study, 2010
- “Static Analysis Considerations for Medical Device Firmware”, White Paper, 2010
- “Static Analysis Considerations for Stack Usage”, White Paper, 2010

- “Static Analysis”, Presentation at Perforce Conference, 2018
- “Static Analysis”, Presentation at Embedded Systems Conference, 2010

PID and Closed Loop Control

- “Control Training with its Own Process”, Software Review, Control Engineering Magazine, 1996
- “Tune Tutor”, PID educational hardware and software toolkit, U.S. Copyright TXu 792-019, 1996

Fiction

- “High Striker” - Screenplay, 2019
- “High Striker” - Novel, 2012

Interests

- Physical Fitness, Billiards, Basketball, Football, SCUBA