

Volodymyr Hirnyj

Engineering Leader | Systems Architect | Product Development
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Summary

Engineering leader with over a decade of experience partnering with founders, executives, and cross-functional teams to transform innovative ideas into reliable, manufacturable products. Proven track record leading systems architecture, product development, and technical execution across regulated medical devices, robotics, industrial automation, and defense.

Career Highlights

- Delivered 5+ products from concept through production across startups and regulated industries
- Architected an autonomous robotic platform supporting SBIR funding exceeding \$2 million
- Established modern engineering practices including CI/CD, automated testing, static analysis, and IEC 62304-compliant software development processes for FDA-regulated medical devices
- Designed scalable and manufacturable embedded platforms for long-term product evolution
- Improved product quality, manufacturing efficiency, and customer satisfaction through production test systems, root cause investigations, and cross-functional product improvements

Experience

Cooler Heads

Lead Electronics Engineer

Jan 2024 - Present

Lead development of electronics and embedded systems for an FDA Class II medical device, providing technical leadership spanning product strategy, systems architecture, and engineering execution.

- Led cross-functional product improvements that reduced customer complaints, lowered costs, expanded functionality, and enabled scaling of annual production volume by 400%
- Defined product strategy and architected the next-generation electronics platform for scalability and long-term product evolution, shortening iteration cycle time by 50%
- Modernized embedded software development by introducing CI/CD, automated testing, static analysis, MISRA alignment, and an IEC 62304-compliant software development process
- Improved manufacturing efficiency and product reliability through production test systems, root cause investigations, NCRs, and CAPAs
- Coordinated external engineering partners and mentored engineers through technical leadership and design reviews

Q Harmonics

Founder & Principal Engineer

Mar 2016 - Jul 2024

Founded and operated an engineering consulting practice delivering product development services while serving as principal engineer across multiple concurrent client engagements.

- Partnered with founders and executive teams to reduce technical risk and accelerate product development
- Directed multiple concurrent engineering programs from concept through production
- Developed engineering standards, reusable frameworks, and lightweight quality systems

NuVasive	Lead Embedded Systems Engineer	May 2017 - Jun 2024
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Developed embedded and manufacturing solutions for an FDA Class III neuromonitoring system.

- Led development of an automated production test system reducing test time by 98%
- Developed embedded platforms for FDA Class III neuromonitoring systems
- Directed system, hardware, and software V&V activities for the PULSE neuromonitoring platform
- Resolved dozens of complex hardware, firmware, and manufacturing issues with supply partners
- Mentored 4 engineers and technicians

AXIUS	Lead Product Engineer	Jul 2020 - Jun 2024
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Led development of a wireless fitness product from proof of concept through commercial launch.

- Redesigned hardware through multiple iterations to achieve a manufacturable design
- Directed manufacturing transfer, testing, and issue resolution with overseas suppliers
- Guided hardware, firmware, and companion app integration
- Launched the product into commercial production, scaling annual production from 0 to 250 units

Pure Biomass	Lead Systems Architect	Oct 2017 - Jul 2021
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Partnered directly with the founder as technical lead and systems architect for an underwater algae-harvesting robotic platform.

- Led a team of three engineers to develop an autonomous underwater robotic platform
- Enabled \$2M+ NSF SBIR funding through proof-of-concept prototyping
- Hired and mentored two engineering interns
- Developed embedded electronics, controls, firmware, and communications infrastructure
- Devised a novel underwater localization technique

Citadel Defense	Systems Engineer	Aug 2016 - Sep 2017
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Advanced an early-stage counter-drone platform from prototype toward production.

- Re-architected the platform around SDR technology, improving scalability
- Developed production processes supporting rapid company growth
- Supported customer demonstrations, deployments, and engineering partner coordination

Education

Bachelor of Science, Electrical Engineering | Milwaukee School of Engineering

Diplom Ingenieur, Elektrotechnik (= M.S. Electrical Engineering) | Technische Hochschule Lübeck

Core Competencies

Leadership & Strategy: Engineering Leadership • Product Strategy • Systems Architecture • Cross-Functional Leadership • Talent Development • Engineering Process Development

Product Development: Embedded Systems • Electronics Design • Hardware–Firmware Integration • Systems Integration • Manufacturing Transfer • Verification & Validation

Regulatory: Medical Devices • Risk Management • IEC 62304 • FDA Design Controls • CAPA / NCR

Technologies: Embedded C/C++ • Python • RTOS & Bare Metal • Azure DevOps • Git • CI/CD • ARM Cortex-M • Altium Designer • OrCAD Allegro