Micah Forstein

Topeka, KS | (785) 230-8782 | micahforstein@gmail.com | linkedin.com/in/micahforstein

SUMMARY

Hands-on software engineer with nearly 30 years developing FDA-regulated medical device software and systems that interface directly with diagnostic, imaging, and surgical hardware. Practical command of IEC 62304, FDA Design Controls, ISO 14971 risk management, and Software Verification & Validation — routinely incorporating V&V and user-testing findings into production releases. Strong coder in Python, Java, and C++ with a modern JavaScript/TypeScript (React/Node, Electron-adjacent) stack, and a track record of evolving established prototypes into compliant, commercialized products.

SKILLS

Regulated Medical Software: IEC 62304 • FDA Design Controls • ISO 14971 risk management • Software V&V • Requirements traceability • Lifecycle documentation • ISO 13485

Hardware Interfacing: Diagnostic / imaging / measurement hardware • MRI & CT image analysis • Surgical robotics • CAD/CAM toolpaths

Languages: Python • Java • C++ • TypeScript / JavaScript • SQL

Frameworks & Tools: React • Node.js • Electron-adjacent desktop (web/Capacitor) • Three.js / WebGL • Streamlit • Git • Visual Studio • Oracle

EXPERIENCE

Head of Engineering Assurance, Redefine Surgery — 2025 – 2026

- Drove Engineering Assurance for a cutting-edge osteotomy medical device, working alongside Quality and cross-functional teams under FDA Design Controls.
- Built internal applications to generate Quality System templates and streamline lifecycle documentation; oversaw QMS selection and Quality Manual development.
- Coordinated internal and external development teams to take prototype designs toward a compliant product.

Manager, Accessories Engineering, Think Surgical — 2013 – 2024

- Delivered FDA-regulated software across the full lifecycle of the TMINI and TPLAN robotic surgical systems — software interfacing directly with surgical robotic hardware and integrating advanced surgical-planning algorithms and implant support with major partners.
- Authored design files, validations, requirements traceability, and FDA-ready documentation, incorporating Verification & Validation results into successive software releases under design controls.

Founder & Lead Software Engineer, Chainmail Studio — 2025 – Present

Hands-on, sole developer — evolved an established prototype into a shipped commercial product.

- Owned the full software lifecycle of a cross-platform application (React/TypeScript/Node, Electron-adjacent desktop plus mobile), from prototype framework to release on the App Store and Google Play.
- Engineered real-time 3D rendering (Three.js/WebGL), computational-geometry and collision-detection algorithms, and a custom physics solver — plus billing, authentication, and serverless back-end services.

Senior Systems Developer, Fujifilm Medical — 2007 – 2012

- Built MRI/CT image-analysis software that interfaced with medical imaging hardware, developing back-end processing and imaging algorithms tuned for performance and clinical accuracy.

Implant Support Engineer, Integrated Surgical Systems — 1998 – 2003

- Wrote software and generated surgical toolpaths with CAD/CAM tools for one of the first FDA-cleared surgical robotics platforms — software driving diagnostic and cutting hardware.
- Led the effort that placed the company's first surgical-robot prototype into the Smithsonian Institution.

Senior Development Engineer / Project Lead, Zimmer Biomet — 2003 – 2007

- Led a 35-person cross-functional team delivering a 250+ item instrumentation and trauma ORIF system ($11M first-year revenue); authored research and patents cited 400+ times (USPTO).

EDUCATION

Rensselaer Polytechnic Institute — M.S., Biomedical Engineering

University of Minnesota — B.S., Mechanical Engineering