

Micah Forstein

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SUMMARY

Medical-device program and project leader with nearly 30 years delivering complex, cross-functional technology programs in FDA/ISO 13485-regulated **orthopedic**, surgical-robotics, and imaging environments. Proven leading large cross-functional teams and multi-vendor efforts from planning through cutover and validation — including a 35-person, **\$11M** program delivered on schedule. Pairs hands-on modern cloud and software delivery (AWS-hosted serverless platforms, APIs, cross-platform release management) with the regulatory, risk, and change-control discipline required to move regulated systems, data, and applications safely between environments. Comfortable partnering with cloud/architecture leads to translate target-state AWS/Azure designs into actionable project plans, RAID logs, milestones, and cutover runbooks.

CORE STRENGTHS FOR THIS ROLE

Program / Project Management: Cross-functional team leadership • End-to-end program delivery • Project plans, timelines & milestones • RAID logs (risk, assumption, issue & dependency management) • Cutover / rollback planning • Readiness reviews & post-release validation • Executive & stakeholder reporting

Regulated & Compliance: Medical device (orthopedic, robotics, imaging) • FDA & ISO 13485 • Design controls & validation • QMS selection & Quality Manual • Structured change control

Migration & Coordination: Multi-workstream sequencing (data, applications, services) • Cross-organization & partner dependency management • Vendor / third-party coordination • Production cutover & release management

Cloud & Technical Fluency: AWS-hosted serverless & cloud services (Netlify Functions/Edge, Supabase) • APIs & back-end services • Cross-platform delivery (web, iOS, Android) • C++, Python, Java, TypeScript, SQL

EXPERIENCE

Senior Development Engineer / Project Lead, **Zimmer Biomet**

2003 – 2007

Cross-functional program leadership for a major orthopedic (trauma / ORIF) product platform.

- Led a **35-person cross-functional program** (engineering, manufacturing, quality, and external vendors) delivering a 250+ component orthopedic trauma / ORIF (Open Reduction & Internal Fixation) system on schedule to **\$11M first-year revenue**.
- Owned the full program lifecycle from concept to production — planning, workstream sequencing, milestone tracking, and risk/dependency management — within an FDA/ISO 13485 design-control framework.
- Coordinated internal teams and outside vendors across mechanism design, prototyping, and gauging, driving multi-workstream execution and escalations to leadership.
- Authored research and patent applications cited 400+ times (USPTO), establishing foundational IP for the platform.

Manager, Accessories Engineering, **Think Surgical**

2013 – 2024

Managed regulated software delivery and external-partner coordination for robotic surgical systems.

- Managed cross-functional software delivery across the full lifecycle of the TMINI and TPLAN robotic surgical systems, coordinating with **major external partners** and internal teams to align dependencies and timelines.
- Owned regulated release readiness — design files, validations, and FDA-ready documentation — with structured change control and controlled cutover to production.
- Integrated advanced surgical-planning algorithms and implant support, translating partner requirements into scheduled, validated deliverables.

Head of Engineering Assurance, **Redefine Surgery**

2025 – 2026

- Led QMS selection and Quality Manual development; stood up quality-system processes and automated documentation workflows for a regulated medical-device environment.
- Partnered with internal and external teams on prototype designs for a cutting-edge osteotomy device, managing governance and compliance deliverables.

Founder & Lead Software Engineer, **Chainmail Studio (Woven Rainbows by Erin)**

2025 – Present

- Delivered a cloud-backed application end to end — serverless APIs (Netlify Functions/Edge, AWS-hosted), cloud auth/data (Supabase), and billing (Stripe Connect) — coordinating multiple third-party platforms and app-store release processes.
- Managed the full release lifecycle to the App Store and Google Play, including build pipelines, staged rollout, and production cutover across three platforms.

Senior Systems Developer, **Fujifilm Medical**

2007 – 2012

- Built MRI/CT image-analysis software, 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.
- Led the effort that placed the company's first surgical-robot prototype into the Smithsonian Institution.

EDUCATION

Rensselaer Polytechnic Institute — M.S., Biomedical Engineering

University of Minnesota — B.S., Mechanical Engineering