

Contact

rblopeziv@gmail.com

www.linkedin.com/in/ramón-b-lopez-40b93b (LinkedIn)

Top Skills

Computer Software Assurance

Computer System Validation

AI for Quality

ramón b. lopez

Digital Quality & QMS Transformation Leader | Medical Device | AI-Ready Manufacturing Architecture | FDA · ISO 13485 · EU MDR | Open to VP / Fractional CQO

San Jose, California, United States

Summary

I build quality systems that keep medical devices safe — and I've spent the last several years turning that foundation into a platform for digital transformation and AI. As Sr. Sector Director of Global Digital Manufacturing Architecture at Jabil (100+ sites, all sectors), I own the strategy for modernizing the enterprise PLM/QMS/LMS ecosystem. My current work centers on a \$61.4M platform decision targeting 69–84% five-year cost savings by replacing fragmented legacy systems with a unified digital thread that connects design, change, quality, supplier, and training data in real time. Before that, I spent five years as Sr. Director of Global Quality Systems for Jabil Healthcare — launching a QMS across 37 manufacturing sites, on time, under budget, through a global pandemic — for the medical device industry's first large-scale CMO partnership. Multiple FDA, MDSAP, TÜV, and customer audits closed with zero findings. What makes my background unusual is the combination: 25+ years of deep regulatory compliance (FDA, ISO 13485, EU MDR/IVDR, MDSAP) paired with enterprise-scale digital architecture. Most quality leaders have one or the other. I've spent the last several years building both — and positioning regulated manufacturers for what comes next: AI-driven change impact assessment, autonomous deviation detection, and semantic data governance that makes AI agents actually viable in a 21 CFR Part 11 environment. Where I create the most value: ▶ Digital QMS / PLM Transformation — ETQ, Veeva, PTC Windchill, Siemens Teamcenter, SAP PLM, Propel ▶ AI-Readiness for Quality — data architecture, e-records/e-signatures, autonomous manufacturing ▶ QMS at Scale — global harmonization across 37–100+ sites, M&A integration, CMO partnerships ▶ Regulatory Excellence — FDA, MDSAP, EU MDR/IVDR, zero-finding inspection track record. I'm exploring my next chapter — VP/Sr. Director of Digital Quality or Digital Transformation in regulated industries, and select fractional CQO or consulting engagements where I

can accelerate a company's quality modernization. If you're building the future of digital quality in medtech or life sciences, let's connect. rblopeziv@gmail.com

Experience

Jabil

6 years 5 months

Sr. Director, Digital Manufacturing Architecture

July 2025 - Present (11 months)

Global Sr. Sector Director, Quality Systems @ Jabil Healthcare

January 2020 - January 2026 (6 years 1 month)

San Francisco Bay Area

Medical Device Manufacturing/Strategic Collaborator

BD

Global Director, Quality Systems @ BD Biosciences

May 2016 - January 2020 (3 years 9 months)

San Jose, California

Medical Device Manufacturing

Boston Scientific

10 years 5 months

Sr. Manager, Quality Systems

December 2010 - May 2016 (5 years 6 months)

San Francisco Bay Area

Medical Device Manufacturing

Analyst Principal, Quality Business Process Leader

January 2006 - November 2010 (4 years 11 months)

San Francisco Bay Area

Medical Device Manufacturing

Novellus Systems acquired by Lam Research Corporation

Analyst, SAP Functional Business

February 1996 - January 2006 (10 years)

San Jose, California

Semiconductor Capital Equipment Manufacturing