

# DEVIN I. McELROY, M.B.A.

## Quality Professional Global SQM & Medical Devices

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### PROFESSIONAL SUMMARY

Quality and Regulatory professional with extensive experience in medical device, diagnostics, and SaMD industries. Proven expertise in QMS design, implementation, and compliance with ISO 13485, ISO 9001, ISO 14971, 21 CFR Part 11/820, and GMP requirements. Skilled in supplier quality management, audits, CAPA, risk assessment, and change control across global organizations. Certified Quality Manager/Organizational Excellence (CQM/OE), Certified Six Sigma Green Belt (DMAIC), and Certified IBM AI Developer, integrating process improvement and emerging technologies into quality strategies. Strong track record leading cross-functional initiatives that balance regulatory rigor with business needs to advance patient safety and product quality.

### CORE COMPETENCIES

- Quality Management Systems (QMS) Implementation & Optimization
- Supplier Quality Engineering & Supplier Audits
- Risk Management (ISO 14971, FMEA)
- Corrective and Preventive Actions (CAPA)
- Regulatory Compliance (ISO 13485, 21 CFR Part 11/820, GxP)
- Change Control & Document Management
- Combination Products & SaMD Compliance
- Data-Driven Process Improvement (Six Sigma DMAIC)
- Cross-Functional Team Leadership
- AI/Automation in Quality Systems

### PROFESSIONAL EXPERIENCE

**Quality System Modelers, LLC** – Fresno, CA | Remote  
**Managing Member/Principal Consultant**

May 2023 – Present  
[www.qualitysystemmodelers.com](http://www.qualitysystemmodelers.com)

- Designed and implemented phase-appropriate QMS frameworks for early-stage medical device and biotech companies.
- Supported supplier qualification, audits, and corrective actions across global supply chains.
- Led CAPA programs, risk assessments, and process improvement initiatives to strengthen compliance.
- Partnered with cross-functional teams to align product development with regulatory expectations for devices, diagnostics, and SaMD.
- Advised clients on electronic quality system (eQMS) implementation, including MasterControl and TrackWise.

**Sunrise Medical (US) LLC** – Fresno, CA | Hybrid/Remote  
**Sr. Director, Quality Assurance and Regulatory Affairs**

Jan 2018 – Apr 2023  
[www.sunrisemedical.com](http://www.sunrisemedical.com)

- Built and scaled QMS infrastructure to meet ISO 13485, EU, and FDA compliance requirements.
- Directed quality engineering teams responsible for audits, supplier management, and change control.
- Developed and implemented SOPs, training programs, and risk-based approaches to regulatory compliance.
- Supported successful FDA inspections and ISO certification and recertification audits.

**Neozene, Inc.** – Oakland, CA | Remote Consulting Focus  
**Sr. Director, Technical Engagements and Quality**

May 2015 – Aug 2017  
[www.neozene.com](http://www.neozene.com)

- Led quality assurance functions for combination products, medical devices, and pharmaceutical manufacturing.
- Drove continuous improvement programs, supplier partnerships, and cross-site quality harmonization.
- Managed documentation systems and compliance programs in global organizations.

### EDUCATION & CERTIFICATIONS

Certified AI Developer	IBM	2025
Certified Manager Quality/Organizational Excellence	ASQ	2023
ISO 13485 & ISO 9001 Lead Auditor (TPECS)	BSI Group America	2023
Six Sigma Green Belt (CSSGB)	The Juran Institute	2006
MBA, Technology Management	University of Phoenix	2005
BS, Business/Information Systems	University of Phoenix	2001