***Devin I. McElroy, M.B.A./TM****https://www.linkedin.com/in/devinmcelroymba/*

**About Me**

I have 20+ years hands-on experience in the medical device industry working as a Quality Management System expert for all device classifications. I have earned numerous professional certifications in QMS, Process Improvement, and Management areas. I have built Quality Management Systems from the ground-up for start-ups and have implemented Quality Improvement Programs for Fortune 500 companies with multinational footprints.

Quality Management Systems | Process Improvements

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I will add significant breadth and depth of expertise in improving Quality Systems to more effectively comply with worldwide regulations and standards. I can significantly reduce your risk for receiving nonconformances from regulatory agencies and streamline remediation processes to eliminate repeat findings.

**Core Competencies**

- Technical Expertise: Integrating functional expertise with business knowledge to develop optimal solutions for the enterprise.

- Building and Leading Teams: Designing and implementing workforce planning strategies to ensure a pipeline of talent over the long term and leveraging understanding of strengths and weaknesses of team members in positioning them in the team.

- Maintaining a Customer Focus: Establishing monitoring systems and practices to systematically gauge customer satisfaction.

- Collaboration and Teamwork: Advancing positions that support the long-term strategic interests of all stakeholders.

- Decision Making: Establishing decision-making processes that are appropriate given the complexity, risks, and impact of decisions and their urgency and/or importance.

**Greatest Achievements**

- Initiated error proofing initiative that resulted in a 80% reduction in manufacturing rejects and saved ~$150,000 annually.

- Initiated a change control initiative that reduced engineering changes from 1203 minutes to 672 minutes (a 56% improvement in turn-around-time) while maintaining resource levels. I also earned my Six Sigma Green Belt from this initiative.

Contact me at 925-353-0042 or devin@dmcelroy.com if you are looking for a QMS expert specializing in medical device manufacturing.

**Education & Certifications**

* **Master of Business Administration** (MBA), Technology Management – University of Phoenix 2005
* **Bachelor of Science** (BS), Business/Information Systems – University of Phoenix 2000
* **Six Sigma Green Belt** (CSSGB) – The Juran Institute 2006
* **ISO 13485:2016 Lead Auditor** (TPECS) – BSI Group America 2023
* **ISO 9001:2015 Lead Auditor** (TPECS) – BSI Group America 2023
* **Certified Manager of Quality / Organizational Excellence** (CMQ/OE) – American Society of Quality 2023
* **Process Improvement Auditor** (PIA) – BSI Group America 2024

**Work Experience**

Quality System Modelers, LLC – Fresno, CA *www.qualitysystemmodelers.com* May 2023 – Present

*Quality System Modelers, LLC provides Quality Management System expertise and guidance for medical device manufacturers.*

***Managing Member / Lead Consultant***

* Lead expert for all consulting services including QMS creation, management, improvement, remediation, monitoring, and tool creation compliant with worldwide regulations and standards.

Sunrise Medical (US) LLC – Fresno, CA *www.SunriseMedical.com* Jan 2018 – Apr 2024

*Sunrise Medical develops, designs, manufactures and distributes manual and powered wheelchairs, mobility scooters and both standard and customized seating and positioning systems.*

***Sr. Director, Quality Assurance and Regulatory Affairs***

* Served in capacity of North American Management Representative and Person Responsible for Regulatory Compliance (PRRC).
* Provided oversight on QMS processes including deviations, investigations, CAPAs, complaints, risk management, and design controls.
* Implemented North American processes for hosting regulatory inspections and served as primary liaison.
* Implemented processes to ensure compliance with all applicable FDA, EU, and Rest of World regulations, standards, and guidance documents.

Neozene, Inc. – Oakland, CA *www.Neozene.com* May 2015 – Aug 2017

*Neozene is a high-performance CRO and professional services organization focused on providing solutions for life science manufacturers.*

***Sr. Director, Technical Engagements and Quality***

* Established new and remediated existing Quality Management Systems for clients
* Created and implemented formal training programs for organizations on Quality and Regulatory Requirements including QSRs, CAPAs, Risk Management, Design Controls, inspection techniques, audit readiness, etc.
* Led quality audits assessing compliance with 21 CFR 820, ISO 13485, MDD 93/42/EEC, CMDR SOR/98-282, MDR EU/2017/745, IVDR EU/2017/746, MHLW MO No. 169 (Japan), TGA (Australia), etc.
* Provided direct oversight of all inhouse Quality and Regulatory subject matter experts as well as project leadership and oversite for client projects. Managed budgets and resource allocations.

Self Employed – San Jose, CA May 2008 – May 2015

*Served clients in the capacity of a QMS leader or Subject Matter Expert.*

***Quality System Consultant – Independent***

* Created new or enhanced complaint investigation, CAPA (including root cause analysis), NCMR, compliance readiness, and process enhancement programs. Led associated implementation activities and provided professional training and certification.
* Provided Quality expertise for new product development projects for all classifications of devices.
* Lead Auditor for quality audits assessing compliance with 21 CFR 820, ISO 13485, MDD 93/42/EEC, CMDR SOR/98-282, MDR EU/2017/745, IVDR EU/2017/746, MHLW MO No. 169 (Japan), TGA (Australia), etc.

Genentech, Inc. – South San Francisco, CA *www.genentech.com* July 2002 to September 2007

*Innovative* [*biotechnology*](http://en.wikipedia.org/wiki/Biotechnology)[*corporation*](http://en.wikipedia.org/wiki/Corporation) *widely considered to have founded the* [*biotechnology*](http://en.wikipedia.org/wiki/Biotechnology) *industry.*

***Technical Manager/Project Manager (FTE)***

* Led an enterprise-level process improvement project team that resulted in an 80% reduction in manufacturing rejects and saved ~$150,000 annually.
* Led a production process improvement project team that resulted a 56% improvement in turn-around-time while maintaining resource levels.
* Developed and performed professional in-house training courses for risk management, root cause analysis, compliance practices and regulations, etc.