Joe Martin

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Profile

I'm a proven leader and change agent devoted to balancing business and customer needs by facilitating organizational learning and building highly effective teams using situational leadership techniques. With over 20 years of experience in the medical device industry, I have successfully deployed Quality Management Systems, maintained Regulatory Compliance, delivered products to market, and facilitated Continuous Improvement initiatives. My success has been built with a "go to GEMBA" approach, building cross-functional relationships and utilizing systems thinking techniques to solve complex problems. I'm a lifelong learner seeking to work for an organization that embraces innovation, operational excellence, and delivering value to customers.

Experience

PRESIDENT & FOUNDER, MARTIN QUALITY CONSULTING; PELHAM, NH - 2024-PRESENT

- Founded Martin Quality Consulting with a mission to empower medical device manufacturers with quality management and regulatory compliance solutions.
- Lead cross-functional teams to deliver customized consulting services tailored to each client's unique needs.
- Established Martin Quality Consulting as a trusted partner in the medical device industry through thought leadership, innovation, and exceptional service delivery.

DIRECTOR, QUALITY & COMPLIANCE, DRAEGER MEDICAL SYSTEMS; ANDOVER, MA - 2018-2024

- Lead Product Quality, Software Quality, and Post Market Surveillance teams in support of New Product Development, Sustaining Engineering, Complaint Handling, and Vigilance activities. Since 2019, I have led and supported the expansion of the quality team from 5 team members to 25 in support of the on-site quality system and product quality.
- Perform regular stakeholder analysis to ensure my team and I deliver on expectations, track progress, and identify further opportunities for improvement.
- Provide Monthly and Quarterly Product Quality Data Analysis to internal stakeholders and leadership to ensure visibility and alignment on Production Failure Rates, Field Failure Rates, Complaint Trends, quality-related sustaining projects, CAPAs, and Field Actions. This close monitoring and partnership resulted in a 75% reduction in Field Failure Rate over 3 years.
- Support cross-functional teams in developing products and processes to ensure compliance with FDA and MDR Pre/Post-Market Requirements including conformance to IEC60601, IEC62304 standards, and applicable guidances (Interoperability, Cybersecurity). Specifically, I lead a cross-functional team to establish a closed-loop escalation system to address software anomalies and cybersecurity vulnerabilities.
- As Management Representative, established and led the Audit/Inspection Readiness Program to successfully respond to announced and unannounced notified body audits, MDSAP audits, and FDA inspections. Activities included conducting mock surprise inspections to assess the readiness of sister sites.

- Led and supported FDA Warning Letter remediation by driving process improvements (including Design Controls, Defect Management, Field Action Management, CAPA, and Interoperability) and submitted 510(k)s to bring the product portfolio back into compliance. After the FDA inspection conducted in 2019 a follow-up inspection was conducted in 2022 that demonstrated significant improvements had been made.
- Establish and Lead the CAPA Review Board to assess and address quality issues in a cross-functional manner. This resulted in a significant reduction in aging CAPAs through improved collaboration and resource allocation.
- Lead Health Hazard Evaluation and Field Action activities ensuring timely notification to competent authorities and customers.
- As a Person Responsible for Regulatory Compliance, review technical files, sign declarations of conformity, and perform independent reviews of 510(k) submissions resulting in a reduction of follow-up questions. 510(k) submissions included OS updates, cybersecurity improvements, and feature releases.
- As Software Validation Officer I performed review and release activities for several development tools and a new electronic PLM system. Additionally, I provided training and key-user support for cross-functional teams on the new PLM system.

MANAGER, QUALITY ENGINEERING, SCIEX INC; FRAMINGHAM, MA - 2015- 2018

- Provide leadership for quality engineering teams and provide direct support for a skunk-works development team tasked with releasing a system solution for Vitamin D3 analysis combining mass spectrometry, HPLC, automated pipetting, reagents, and software. In this capacity, my team and I worked within a matrix development team to ensure that design controls were effectively considered, executed, and documented.
- Worked closely with cross-functional stakeholders to improve development processes to ensure compliance with regulations and improve planning across the product roadmap.
- Support the maintenance and support of clinical trials by reviewing and maintaining trial folders.
- Led cross-functional Audit Readiness Program that resulted in the successful expansion of scope to ISO 13485:2016 & ISO 9001:2015. During my time leading this program, I was also the front room lead for all notified body and customer audits.
- Developed and established of IVDR transition strategy and roadmap to ensure compliance with stated deadlines.
- Establish Quality Assurance Agreements with contract manufacturers.
- Manage product recall operations and closure.
- Led and supported several Kaizen events to improve internal processes to improve efficiency, effectiveness, and compliance. These events resulted in the improvement of regulatory shipping controls, implementation of visual management for product development and CAPA, improved customer needs analysis and establishment of UDI controls.
- Perform internal quality audits, DHF reviews, and supplier audits.

QUALITY ENGINEER, HOLOGIC INC; BEDFORD, MA-2002-2015

- Starting as an electro-mechanical assembler in 2002, I moved to the quality department to become a calibration administrator in 2006. Between 2006 and 2015, I held several escalating roles to calibration coordinator, quality assurance associate, and quality engineer.
- Lead internal and external quality audits.
- Manage Corrective and Preventive Action program.
- Manage high-volume Calibration and Preventive Maintenance program.
- Develop and implement corporate standard operating procedures.
- Develop and conduct group training throughout the organization.
- Develop, publish, and present quality management system metrics to the executive management team.
- Member of Continuous Improvement Steering Team.
- Work regularly with IT staff to implement and improve electronic quality management systems/databases.
- Support product development and risk management.
- Conduct complaint handling investigations.
- Lead software and hardware recalls.

SECTION CHIEF (SERGEANT), MASS ARMY NATIONAL GUARD; METHUEN, MA - 1997-2006

- Train, lead, and motivate soldiers in accordance with ARMY standards and regulations
- Conduct performance reviews and guide aspiring leaders
- Maintain 100% accountability of personnel and equipment

Education

- Cornell University - Ithaca, NY - Certificate Systems Thinking - 2020
- Northeastern University- MS Regulatory Affairs for Drugs, Biologics and Medical Devices - 2018
- American Society for Quality - Certified Quality Engineer - 2014 (Active)
- Northeastern University - BS Business Management - 2013
- Middlesex Community College - AS Business Administration - 2011
- American Society for Quality - Certified Quality Auditor - 2007 (Active)
- Additional Certifications: ISO9001, ISO13485, MDSAP, ISO14971, MDR, 21CFR820

Skills

Situational Leadership * Systems Thinking * Product Development * Project Management * Lean Continuous Improvement * Policy Deployment * Software Validation * Technologically Adept * Data Analysis * Regulatory Compliance