Terence Musoni

Quality Management Systems & Regulatory Affairs

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Summary

Highly accomplished Quality Management Systems (QMS) professional with over 15 years of experience in the medical device and healthcare industries. Expertise spans post-market surveillance, design controls, risk management, regulatory compliance, and quality assurance. Proven track record in implementing robust QMS frameworks, driving continuous improvement, and ensuring product reliability across multiple global organizations. Proficient in global standards including ISO 13485, EU MDR 2017/745, EU IVDR 2017/746, FDA QSR, and 21 CFR Part 820. Skilled in cross-functional collaboration, process optimization, and leveraging technology to enhance regulatory compliance.

Key Qualifications

- Bachelor's Degree in Evolution, Ecology & Organism Biology from The Ohio State University
- 15+ years of experience in quality management and regulatory compliance in the medical device industry
- Extensive experience in post-market surveillance, with leadership roles in PMS activities
- Strong understanding of engineering principles and their application in medical device design
- Proven track record in risk management, health hazard evaluation, and CAPA implementation
- Excellent verbal and written communication skills, demonstrated through cross-functional team leadership and training program development
- Expertise in auditing, both internal and external, including FDA, ISO, and EU MDR/IVDR requirements

Professional Experience

CooperSurgical | Technical Writer | January 2022 - Present

- Manage team responsible for PMS compliance across all sites
- Develop and monitor PMS reports, plans, and documentation
- Coordinate cross-functional teams for EU MDR regulation compliance
- Manage Health Hazard Evaluation Process and applicable Field Actions
- Ensure compliance with FDA QSR, ISO 13485, ISO 14971, and EU MDR

Beckman-Coulter | IVDR Technical Writer (Contract) | Oct 2021 – March 2021

- Updated PMS reporting procedures to align with EU IVDR 2017/746
- Prepared IVDR Class A, B & C Technical Documentation for Notified Body Submission
- Created PMS Plans for transitioning and in-development devices

Terumo BCT Corporation | EU MDR Consultant (Part-Time) | September 2019 – Nov 2020

- Reviewed Clinical Evaluation Reports for EU MDR 2017/745 alignment
- Created matrix for tracking and updating technical documentation
- Prepared design dossiers and PSURs in accordance with EU MDR requirements

Stryker Corporation | Supplier Auditor | April 2019 – February 2020

- Conducted risk-based audits of suppliers
- Managed supplier corrective actions and drove timely closure of non-conformances

Philips Corporation | Post-Market Surveillance (Complaint Specialist) | April 2019 – October 2019

- Evaluated and investigated complaints through established handling process
- Initiated CAPAs and performed impact and risk assessments
- Collaborated with cross-functional teams for root cause analysis and solution implementation

Diversified Inc. | Medical Device Product Engineer (Contract) | May 2018 – May 2019

- Led design activities for product development from concept to production
- Established PMS program and complaint handling procedures
- Developed Risk Management Files and FMEA documentation

Oxford Global Inc | Quality Systems Consultant (Contract) | January 2018 – May 2018

- Conducted quality audits for ISO 13485:2016 and MDSAP compliance
- Reviewed Technical Documents for EU MDR alignment
- Created SOPs and reviewed Design Dossiers

Allergan Inc. | Senior Quality Engineer (Projects) | April 2016 – Jan 2018

- Managed product integration projects and complaint investigations
- Served as Audit Program Manager, hosting notified bodies and regulators
- Trained personnel on MDSAP and ISO 13485:2016

Earlier Career Highlights (2008-2016)

- Held roles of increasing responsibility at companies including Philips Healthcare, Alcon/Novartis, Hospira, Grifols-Talecris
- Managed quality and regulatory compliance across multiple regions (LACAN, EMEA, ASIA)
- Developed and implemented quality systems, CAPAs, and audit responses
- Led validation projects and standardized processes across diverse platforms

Key Skills

- Post-Market Surveillance: Comprehensive management of PMS activities
- Design Controls: Implementation of rigorous design control processes
- Risk Management: Development of risk management files, FMEAs, and hazard analyses
- Regulatory Compliance: Expertise in EU MDR/IVDR, ISO 13485, FDA QSR, 21 CFR Part 820
- Quality Systems: Implementation and improvement of QMS systems
- Auditing: Internal and external audit management, including notified body and regulatory inspections
- Cross-functional Collaboration: Proven ability to work with diverse teams
- Leadership: Experience in managing and developing teams in quality assurance roles

Certifications

- EU MDR 2017/745 Auditor
- American Society of Quality (ASQ) Member
- Microsoft AI Solutions Architect Certification