Quality Management System Regulation

The FDA's transition from the Quality System Regulation (QSR) to the new Quality Management System Regulation (QMSR) marks a pivotal shift for the medical device, in-vitro diagnostic, and combination product industry.

The migration to QMSR will have far-reaching impact on how medical device manufacturers approach quality management systems. The new streamlined regulation is harmonized with internationally recognized QMS standards and emphasizes a data driven risk-based approach that introduces updated processes for quality management and enhanced inspectional responsibilities for regulators. With key milestones approaching, a trusted regulatory partner is paramount to effectively navigate the changing landscape.

ELIQUENT Life Sciences is uniquely positioned to support organizations during this critical transformation. Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to provide tailored solutions that ensure a smooth and successful adaption to the new framework. Together, we unlock regulatory excellence.

Specialized Solutions

A strong quality program is a cornerstone of regulatory success. For medical device, in-vitro diagnostic, and combination product manufacturers, realignment to the FDA's new QMSR is critical to maintain compliance, ensure product quality, and remain competitive in an evolving regulatory landscape. As the industry leader in quality and compliance solutions, ELIQUENT partners with companies to ensure a seamless to the new regulation while maintaining regulatory compliance and product excellence.

Compliance (Gap) Assessments

Our industry-recognized team guides companies to sustainable success with comprehensive technical process audits that identify areas of non-compliance and provide a roadmap to achieve full alignment with the new QMSR.

Quality Systems Strategy

Clients count on ELIQUENT to develop customized, effective and efficient quality systems that transition organizations to the new QMSR framework with best-in-class direction on design, optimization, and implementation.

Inspectional Readiness

ELIQUENT applies extensive regulatory expertise to develop and implement custom strategies that prepare companies for the QMSR's enhanced FDA inspectional responsibilities, while aligning with global regulatory standards and expectations.

Post-Market Surveillance

With ELIQUENT's strategic direction and hands-on support, companies can confidently transition to the new QMSR with a robust post-market surveillance system that meets compliance requirements and enhances overall business performance.

Regulatory Engagement

ELIQUENT experts bring an unmatched level of credibility and trust when interacting with global regulators by providing valuable guidance on regulatory communications, meetings, and correspondence with regulatory authorities.

Compliance & Enforcement Actions

Our deep bench of former FDA officials and industry experts provide full-service engagement and objective advice to successfully guide companies as they encounter complex regulatory compliance and enforcement actions.

Consultation & Regulatory Guidance

ELIQUENT goes beyond traditional consulting to provide market leading insight and global solutions equip companies with solutions that reduce the risk of non-compliance while enhancing operational efficiency, product quality, and market access.

Expert Training

Built on the industry's largest portfolio of quality and regulatory training content, ELIQUENT experts create broad QMSR training solutions that empower teams to elevate regulatory compliance and optimize quality management practices.

Unmatched expertise

ELIQUENT brings the unmatched expertise that companies need when adapting to the evolving regulatory framework. With decades of experience, our team of professionals have directly influenced significant policy decisions and regulatory actions through their service at global regulatory authorities. The team's combined capabilities and experience building effective and sustainable Quality Management Systems enable a cross-functional, full-service engagement that unlocks regulatory excellence.

DAVID ELDER

23-year veteran of the FDA with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions.

BRIAN BURNS

Recognized industry expert with extensive experience leading large-scale enforcement-related remediation programs across the medical device industry.

KRISTEN GRUMET

25-year compliance career including nearly a decade as an FDA Field Investigator specializing in medical devices.

JOHN LOVE

20+ year background of driving operational excellence and regulatory compliance through robust instructional design, development, and delivery in the life sciences industry.

CAROLYN TOMLINSON

30+ years of Life Science industry experience in quality system development, management, auditing, training and consulting.

JANET WHIPPLE

35 years of experience in medical device, in-vitro diagnostic and combination product quality, regulatory compliance, design, and operations.

Full-Service Support

ELIQUENT's team of global experts work cross-functionally to provide a **full-service engagement**. Our unique platform goes beyond traditional consulting to **deliver end-to-end solutions**. No matter your pathway position, regulatory requirements, global market or therapeutic area – ELIQUENT's integrated solutions align with your regulatory goals to unlock success. ELIQUENT's comprehensive capabilities include:

Regulatory Affairs Solutions

From the earliest phases of innovation through regulatory submissions, to post-approval support, ELIQUENT's robust blend of technical skill and clinical expertise guide companies to approval and beyond.

PV+ Postmarket Surveillance

With an approach that includes both strategic direction and hands-on global support, ELIQUENT's customized pharmacovigilance services empower companies to operate with confidence.

Quality & Compliance

ELIQUENT's team of highly specialized compliance experts build customized solutions that equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions

Our team of respected quality experts and global specialists bring an unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Expert Training

ELIQUENT's customizable training programs equip teams and employees with the tools and skills to maintain global regulatory processes and build a common culture of accountability.