FDA QSR to QMSR: Regulatory, Legal, and Risk Implications for Industry

Presenter: Denise Holliday, MS, RAC-DEVICE, ASQ CQE, CQA | Capwell Consulting

This webinar, recorded live on July 30, 2026 and presented by Denise Holliday with Capwell Consulting, focused on the FDA's transition from the Quality System Regulation (QSR) to the new Quality Management System Regulation (QMSR). Denise explained the reasons for the change, which include harmonization with the international standard ISO 13485-2016 to reduce duplication for manufacturers. She detailed the significant changes, such as the incorporation of risk-based thinking throughout the quality system and the FDA's expanded access to certain quality records. Denise also discussed the new risk-based inspection approach under the QMSR and shared insights from recent FDA inspection observations. The presentation emphasized that an effective QMS extends beyond compliance to manage organizational risk and improve inspection readiness.

Full On-demand Recording

On-demand Chapters:

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Denise Holliday is a proven strategic innovator and tactical leader in highly regulated environments, including medical device quality management systems, international regulatory compliance, and medical device risk management. As a leading medical device regulatory consultant, she provides strategic support to medical technology businesses, healthcare organizations, and startups. Spanning more than two decades, Ms. Holliday's career in medical device regulatory compliance and quality assurance showcases her extensive leadership experience. She conducts ISO 13485 Medical Device and ISO 9001 Quality Management certification audits, spearheads quality management system implementations, and manages regulatory assessments and submissions. She delivers expert testimony for medical device litigation, guiding attorneys and organizations through the complexities of the global medical device industry.