

Regulatory & Quality Solutions LLC



MARIA FAGAN, PRESIDENT
B.S. Mechanical Engineering. Maria has worked in regulated industries since 1988 including over 12 years at the Malcom Baldrige winning MEDRAD, Inc., in quality and regulatory leadership roles

LISA CASAVANT, VICE PRESIDENT
M.S. Mechanical Engineering. Lisa has 10 years of broad industry experience including regulatory leadership and worldwide submissions for new product development teams at MEDRAD, Inc.

ROBERT MARKLEY, VICE PRESIDENT
MBA. Bob has successfully founded and grown two prior consulting organizations in western-PA.

Regulatory & Quality Solutions LLC provides full-service regulatory affairs and quality assurance expertise to medical device organizations. Our mission is to navigate the complex regulatory landscape and determine the most efficient paths to a safe and effective product, cleared for U.S. and international marketing. This is accomplished through results-driven, experienced team members providing you with on-site leadership and support in all areas of regulatory affairs and quality assurance. Our services focus on the following:

Regulatory: Regulatory strategies, FDA 510(k)s, EU Technical Files/Design Dossiers and worldwide registration. Includes regulatory standards requirements assessment.

Regulatory Officer Retention: Regulatory Officer to provide guidance to management teams regarding day-to-day regulatory decisions and regulatory risks.

Quality System: ISO 13485:2003 and FDA QSR compliant quality system development and training, manufacturing registrations, device listings, and quality system auditing.

Clinical Trials: Clinical trial strategies including alignment with FDA and clinical trial management.

Product Quality: Predictable product quality through development of processes for supplier qualifications, supplier quality inspections, part and tool qualifications, and capability analyses.

Safety Risk Management: Risk management process development to ISO 14971 standard & implementation for new products. Early-stage safety risk assessment for new VC funded products.

Verification and Validation: Verification and Validation process and tools development, planning and test protocol generation.

Acquisition Integration Leadership: Acquisition assessments of regulatory and quality aspects as well as integration planning and completion of all regulatory and quality areas.

Post-Launch Regulatory Support: Development of post-market surveillance processes and ongoing support of associated activities including field safety risk assessments, field corrections, recalls, supplier assessments and FDA inspection preparation and guidance.

Venture Capitalist Due Diligence: Assessments of medical device companies from the perspective of regulatory, quality system, product safety, product quality, clinical strategy, reimbursement, and other industry-specific processes.

For more information, contact:

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