MARTIN QUALITY CONSULTING

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Regulatory Compliance

Guiding you through compliance complexities with expertise and precision.

Martin Quality Consulting specializes in navigating the intricate landscape of regulatory compliance, ensuring your medical devices meet FDA and international standards with confidence and clarity. Our comprehensive services include:

- **Regulatory Strategy Development:** Crafting tailored regulatory strategies to align with business goals, product roadmaps, and global markets.
- **Gap Analysis:** Identifying areas of non-compliance and providing actionable recommendations to reduce business risks.
- **Audit Preparation and Support:** Assisting with audit readiness and preparation for notified body and FDA inspections.
- **Training and Workshops:** Offering customized training programs on regulatory requirements and best practices.

Quality Management

Empowering excellence in quality management for enduring success.

We help organizations implement robust Quality Management Systems tailored to their unique needs, fostering a culture of quality, continuous improvement, and customer satisfaction. Our quality management services include:

- **QMS Implementation:** Developing and implementing customized Quality Management Systems.
- **Quality Audits:** Conducting internal and supplier audits to assess compliance and identify improvement opportunities.
- **CAPA Management:** Establishing and managing Corrective and Preventive Action programs.
- **Quality Metrics and Reporting:** Developing and analyzing key quality metrics to drive improvement initiatives.

Design Assurance

Ensuring design integrity from concept to market.

Our Design Assurance services ensure that your products are developed with rigorous design controls, risk management, and validation processes to meet regulatory requirements and exceed customer expectations. Our design assurance services include:

- **Design Control Implementation:** Implementing robust design control processes to manage product development.
- **Risk Management:** Conducting comprehensive risk assessments and developing risk management plans.
- **Verification and Validation:** Performing thorough verification and validation activities to ensure product performance and safety.
- **Design History File (DHF) Assessment:** Reviewing and assessing DHFs in compliance with regulatory requirements.

Continuous Improvement

Driving continuous improvement for sustainable growth.

We partner with organizations to identify opportunities for improvement, implement Lean practices, and drive continuous improvement initiatives that enhance efficiency, reduce costs, and drive innovation across the organization. Our continuous improvement services include:

- **Lean Process Improvement:** Implementing Lean methodologies to streamline processes and eliminate waste.
- **Kaizen Events:** Facilitating Kaizen events to identify and implement quick-win improvements.
- **Performance Metrics and KPIs:** Developing and tracking performance metrics and Key Performance Indicators (KPIs) to measure improvement.
- **Change Management:** Providing guidance and support for managing organizational change effectively.

Areas of Expertise

- **ISO 13485:** Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- **21 CFR Part 820:** FDA Quality System Regulation & Quality Management System Regulation (QMSR)
- **21 CFR Part 11:** Electronic Records and Electronic Signatures
- **EU Medical Device Regulation (MDR) 2017/745**
- **EU In Vitro Diagnostic Regulation (IVDR) 2017/746**
- **MDSAP:** Medical Device Single Audit Program
- **IEC 60601:** Medical Electrical Equipment
- **IEC 62304:** Medical Device Software - Software Life Cycle Processes
- **ISO 14971:** Medical Devices - Application of Risk Management to Medical Devices