QMS Development

QMS Development & Implementation for Medical Devices Achieving Audit-Ready Compliance Through Structured, Risk-Based Transformation

The Challenge:

MedTech organizations face increasing complexity in aligning their Quality Management Systems with evolving regulatory expectations (ISO 13485), often resulting in:

- Fragmented processes and inconsistent documentation
- Limited audit readiness and inspection risks
- Inefficient resource utilization and reactive compliance

Our Solution: End-to-End QMS Gap Assessment

A structured, benchmark-driven evaluation of your current QMS against global regulatory standards to identify compliance gaps, operational inefficiencies, and improvement opportunities.

Deliverables:

- Comprehensive gap assessment report
- Risk-ranked findings and impact analysis
- Prioritized remediation roadmap aligned to regulatory expectations

Process Development & Documentation

We assist organizations in defining, documenting, and implementing robust, compliant processes across the product lifecycle. Process development areas include:

- Design & Development controls
- Risk Management (ISO 14971-aligned)
- Document & Record Control
- Change Management
- CAPA and Nonconformance Management
- Complaint Handling & Post-Market Surveillance
- Combination Product GMP interface (Drug–Device, Biologic–Device)

QMS Development

Structured QMS Gap Assessment & Remediation Framework

Establish the scope of the gap analysis:

Identification of applicable regulatory frameworks (e.g., ISO 13485), processes, and quality system elements to be evaluated.

Assessment of the Current QMS:

Systematic review of existing QMS documentation, processes, and controls to evaluate implementation and effectiveness against regulatory requirements.

Identification of Compliance Gaps

Determination of areas of nonconformity, partial compliance, or absence of controls where the current QMS does not meet applicable regulatory and standard requirements.

Prioritize Gaps (Risk-Based Approach)

Classify and prioritize identified gaps based on their potential impact on product quality, patient safety, and regulatory compliance.

Develop Remediation Plan:

Establish a structured and time-bound action plan to address identified gaps, including defined responsibilities, resources, and timelines.

Implement Corrective Actions

Execute the remediation plan through implementation of updated procedures, controls, and quality system improvements. (support in creation of Quality Manual, controlled procedures

Monitor Effectiveness & Progress

Track implementation progress using defined metrics and verify effectiveness of corrective actions through internal audits and performance indicators.

Continuous QMS Improvement:

Ensure ongoing improvement of the QMS through periodic review, CAPA integration, and alignment with evolving regulatory requirements and best practices

Why COD Research

- Deep MedTech domain and regulatory expertise
- Proven experience across ISO 13485, FDA QMSR frameworks
- Pragmatic, implementation-focused approach (beyond advisory)
- End-to-end partnership from assessment through execution

COD® RESEARCH

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