

Beyond Documentation. We Build Compliance Systems.

End-to-end regulatory, quality, and compliance solutions for medical device companies designed to scale with your product and business.



Introduction

End-to-end regulatory and quality consulting designed for medical device startups and growing companies.

Unlike traditional consulting firms that deliver static documentation, we design and implement fully integrated compliance systems aligned with your product, team, and regulatory pathway.

Key Value Proposition

From Documentation to Deployable Systems

- Build audit-ready QMS, not just templates
- Align compliance with real operational workflows
- Enable faster approvals and smoother audits
- Reduce long-term compliance risk and rework

How We Work

1. Assess

Product, regulatory pathway, and current gaps

2. Architect

Custom compliance framework aligned to your business

3. Build

Implement systems, processes, and documentation

4. Enable

Train teams and support audits & lifecycle compliance

Key Benefits

- Faster time-to-market through structured compliance
- Reduced audit risk and remediation costs
- Systems that scale with product and organization growth
- Clear alignment between engineering, quality, and regulatory

Core Capabilities

Design Quality & Development

- Design Controls & DHF structuring
- Risk Management (ISO 14971)
- Verification & Validation planning
- Usability & system level documentation

Quality Systems (QMS)

- ISO 13485-compliant QMS design & implementation
- Process definition & workflow integration
- CAPA, deviation, change control systems
- QMS remediation & upgrades

Regulatory Strategy & Submissions

- FDA QMSR & EU MDR strategy
- Technical Documentation
- Global product registration support
- SaMD & software compliance

Post Market & Lifecycle Compliance

- Post Market Surveillance (PMS) systems
- Complaint handling & vigilance

Lifecycle compliance management

- Audit & Remediation Support
- FDA / ISO audit readiness
- Gap assessments & mock audits
- FDA Form 483 findings remediation
- End-to-end compliance recovery

Who We Support

- MedTech startups (0 → 1 journey)
- Companies preparing for FDA / CE marking
- Organizations undergoing audit findings or remediation
- Teams transitioning from ad-hoc docs to structured QMS



Book a Compliance Exploration Call

- A focused 30-minute session to:
- Evaluate your current compliance maturity
 - Identify critical gaps
 - Define a practical roadmap forward



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