

QUALITY BY DESIGN. COMPLIANCE BY PRACTICE.

Turnkey ISO 13485:2016, MDR (EU) 2017/745, IVDR (EU) 2017/746 QMS for MedTech manufacturers.

Translate ISO 13485:2016 and EU MDR/IVDR requirements into practical, sustainable quality management.

YOUR CHALLENGES

-  **REGULATORY COMPLEXITY** Which ISO 13485:2016 and Article 10 (MDR/IVDR) requirements actually apply to your devices?
-  **QMS INTEGRATION** How to translate regulatory requirements into practical processes that work across the organization?
-  **AUDIT UNCERTAINTY** How to build a robust, defensible system that withstands auditor or Notified Body scrutiny?

OUR APPROACH



YOUR BENEFITS

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METHODOLOGICAL CLARITY & ALIGNMENT

Deploy a robust, right-first-time QMS using compliant templates and SOPs fully aligned with ISO 13485:2016 and Article 10.
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PRACTICAL & SUSTAINABLE QMS

Quality processes embedded into day-to-day operations for consistent, sustainable compliance.
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AUDIT & NOTIFIED BODY READINESS

Robust, well-documented QMS evidence designed to withstand audit and Notified Body scrutiny.

**READY TO ASSESS
YOUR QMS COMPLIANCE?**
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