

ONE AUDIT. MULTI-MARKET ACCESS.

Accelerate your MDSAP QMS compliance and unlock global MedTech markets.

Bring MDSAP requirements into one coherent QMS – strengthening cross-market compliance, audit evidence and organizational readiness.

YOUR CHALLENGES



REGULATORY FRAGMENTATION How to address Medical Device Single Audit Program (MDSAP) requirements across participating jurisdictions within one consistent QMS?



QMS HARMONIZATION How to integrate market-specific requirements without creating fragmented or duplicative quality processes?



AUDIT UNCERTAINTY How to ensure your single audit withstands Auditing Organization (AO) scrutiny?

OUR APPROACH

01 ASSESS

- Assessment of organizational & multi-country device needs
- Regulatory gap analysis across MDSAP jurisdictions
- Prioritized compliance roadmap & actionable project plan



02 IMPLEMENT

- Provision of a ready-to-use MDSAP Quality Management System (QMS) toolkit
- Hands-on implementation support with dedicated experts
- Mock audits & end-to-end AO support



03 ASSURE

- Focused MDSAP team training (on-site or virtual)
- Specialized Technical & Regulatory Management hotline
- Continuous maintenance & audit readiness support

YOUR BENEFITS



HARMONIZED MULTI-MARKET ACCESS

Consolidate divergent national regulations into a single, structured QMS covering target jurisdictions.



CONSISTENT & TRACEABLE QMS

Aligned processes, controls and documentation that support consistency and traceability across markets.



AUDITING ORGANIZATION CONFIDENCE

Robust, accessible evidence and well-prepared teams ready to demonstrate QMS effectiveness during the audit.

**READY TO ASSESS YOUR
MDSAP COMPLIANCE?**

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