

MASTER RISK. STRENGTHEN DEVICE COMPLIANCE.

ISO 14971:2019 risk management for robust MDR 2017/745 and IVDR 2017/746 compliance.

Strengthen risk management compliance with robust risk analysis, control and benefit-risk determination.

YOUR CHALLENGES



RISK MANAGEMENT COMPLEXITY How do you ensure risk management activities, responsibilities and outputs are consistently applied across the device lifecycle?



BENEFIT-RISK JUSTIFICATION How do you justify residual risks and demonstrate an acceptable benefit-risk profile?



TRACEABILITY & REGULATORY EVIDENCE How do you maintain traceability from risks and controls to supporting evidence?

OUR APPROACH

01 ASSESS

- Comprehensive review of current risk management files, procedures, and reports
- Gap and impact analysis against ISO 14971:2019 and MDR/IVDR requirements
- Assess risk control, residual risk and benefit-risk practices
- Define priorities and action plan



02 IMPLEMENT

- Targeted update of risk management procedures, files, and matrices
- Benefit-risk ratio documentation and combined risk evaluations
- Consistent traceability across risk management activities
- Hands-on execution support and complete action plan tracking



03 ASSURE

- Dedicated team training on medical device risk management (MD/IVD)
- On-demand technical expert hotline for fast query resolution
- Full support during technical documentation review and Notified Body audits.

YOUR BENEFITS



ROBUST RISK MANAGEMENT

Deploy an operational, standard-compliant risk framework tailored to your devices and operational workflows.



DEFENSIBLE BENEFIT-RISK EVIDENCE

Deliver robust, defensible technical files aligned with applicable regulatory requirements and designed to support compliance readiness.



REGULATORY READY DOCUMENTATION

Consistent risk management evidence that integrates with technical documentation and supports regulatory review.

**READY TO STRENGTHEN YOUR
DEVICE RISK MANAGEMENT?**

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