

ANTICIPATE REGULATORY SHIFTS. STRENGTHEN COMPLIANCE WITH CONFIDENCE.

Tailored regulatory & standards monitoring for Medical Devices & IVDs across global markets.

Turn regulatory intelligence into informed decisions, controlled change and sustained compliance across your product portfolio.

YOUR CHALLENGES

- 
REGULATORY CHANGE COMPLEXITY How to identify which evolving regulations, standards and guidance are relevant to your products and markets?
- 
IMPACT ASSESSMENT How to determine the implications of regulatory changes for your QMS, technical documentation and product lifecycle?
- 
CONTROLLED IMPLEMENTATION How to translate regulatory intelligence into timely, traceable updates across affected processes and documentation?

OUR APPROACH

01 ASSESS

- Applicability and impact of identified regulatory and normative changes
- Gap analysis between current compliance status and newly identified standards
- Identification of relevant sources and monitoring priorities



02 IMPLEMENT

- Compliance-focused integration and practical application of identified frameworks
- Setup and update of dedicated QMS procedures, files, and monitoring records
- Hands-on impact assessments and prioritized implementation roadmaps



03 ASSURE

- Expert hotline for ad-hoc regulatory queries
- Dedicated QMS audit support relative to regulatory surveillance processes
- Periodic regulatory briefings across Europe, UK, Switzerland, and the USA

YOUR BENEFITS



RELEVANT REGULATORY INTELLIGENCE

Focused monitoring of the regulatory and standards developments that matter to your products and markets.



CLEAR COMPLIANCE IMPACT

Structured assessment of how regulatory changes affect your QMS, products and technical documentation.



ONGOING REGULATORY ALIGNMENT

Controlled, traceable implementation of required changes to support ongoing compliance.

**READY TO STRENGTHEN YOUR
REGULATORY INTELLIGENCE?**

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Committed to **Excellence**