

FROM EVIDENCE TO EVALUATION. BUILD REGULATORY CONFIDENCE.

End-to-end Clinical Evaluation (MD) & Performance Evaluation (IVD), from strategy to Notified Body support.

Build and maintain credible clinical and performance evidence demonstrating device safety, performance and regulatory compliance throughout the product lifecycle.

YOUR CHALLENGES



CLINICAL & PERFORMANCE EVIDENCE How to determine the clinical or performance evidence required for your device under EU MDR 2017/745 or EU IVDR 2017/746?



POST-MARKET CONTINUITY How to keep CER/PER conclusions aligned with PMCF/PMPF findings and evolving post-market evidence?



DATA & LITERATURE RIGOR How to build robust State of the Art (SOTA) analyses, literature reviews and clinical data appraisals that satisfy EU MDR 2017/745, EU IVDR 2017/746 and MEDDEV 2.7/1 Rev.4.?

OUR APPROACH

01 ASSESS

- Comprehensive clinical & performance evaluation gap analysis
- Strategy definition (Article 61(10), direct clinical data, well-established technology, equivalence)
- Systematic literature search protocol and SOTA benchmarking



02 IMPLEMENT

- End-to-end authoring of CEP/CER, SSCP, and PMCF plans & reports (EU MDR 2017/745)
- Drafting of PEP/PER, analytical/clinical performance reports, SSP and PMPF files (EU IVDR 2017/746)
- Independent critical review, medical writing, and external expert sign-off



03 ASSURE

- Non-conformity remediation and formal agency response drafting
- Dedicated CER/PER & PMCF/PMPF report writing training according to EU MDR 2017/745 and EU IVDR 2014/746
- Direct scientific defense and ongoing support during Notified Body audits

YOUR BENEFITS



ROBUST EVIDENCE STRATEGY

Clinical or performance evidence aligned with your device, intended purpose and applicable requirements to support regulatory review.



INTEGRATED POST-MARKET EVIDENCE

Clinical evaluation and post-market data kept consistent.



DEFENSIBLE CLINICAL DOCUMENTATION

Systematic literature and clinical data appraisal aligned with EU MDR 2017/745, EU IVDR 2017/746 and MEDDEV 2.7/1 Rev.4 expectations and ready for regulatory scrutiny.

READY TO STRENGTHEN YOUR CLINICAL & PERFORMANCE EVALUATION?

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Committed to **Excellence**