BUSINESS CASE

Continuous maintenance of clinical documentation

CHALLENGE

A manufacturer of **Class IIb and III** medical devices under the MDR needed to keep its clinical **documentation continuously updated** and ensure readiness for Notified Body (NB) reviews and recertification.

Key Challenges included:

- Keeping Clinical Evaluation Reports (CERs) aligned with evolving clinical evidence.
- Ensuring **ongoing compliance** with the requirements of **MDR Annex XIV**
- Demonstrating alignment with the current State of the Art (SOTA).
- Integration of **PMS and PMCF** outputs into the clinical evaluation lifecycle.
- Managing multiple devices with varying levels of documentation maturity and distinct regulatory needs.

Without a structured approach, regulatory risk , documentation gaps and audit efforts increase.

SOLUTION

Asphalion assembled a multidisciplinary Clinical and Regulatory team to support the client's portfolio.

- Updating and maintaining Clinical Evaluation Plans (**CEPs**) and Clinical Evaluation Reports (**CERs**).
- Reviewing and **strengthening clinical evidence** through systematic literature activities.
- Developing and updating **Summary of Safety and Clinical Performance** (SSCP) documentation where required.
- Integrating post-market surveillance, vigilance, and clinical data into the clinical evaluation process.
- Ensuring traceability across clinical evaluation (CEP/CER), risk management (RMF), PMS/PMCF, IFU/labelling and GSPR evidence for consistency throughout the technical documentation.
- Assessing documentation against MDR expectations and regulatory best practices.

OUTCOME

MDR-compliant clinical documentation maintained across the portfolio.

Clinical evidence continuously supported by current literature and post-market information.

Increased readiness for surveillance audits and Notified Body assessments.

Reduced regulatory risk linked to outdated or incomplete documentation.

Greater consistency in clinical documentation across multiple product lines.

The focus was placed on creating a sustainable and scalable clinical evaluation framework.

www.asphalion.com
info@asphalion.com | +34 93 238 59 45