Reduced turnaround time by 25% by ensuring quality deliverables for PMS documentation as per EU MDR

Background: Leading US based global provider of medical technologies company needed services in post-market surveillance documentation to comply with the EU MDR regulation

Successful delivery of PMS documentation in multiple therapeutic segments:

- Gap analysis w.r.t EU MDR and MEDDEV 2.7.1/Rev 4
- Preparation of PMS Plan | PMSR | PSUR | PMCF plan
- Data collection, detection, assessment, monitoring, analysis and interpretation
- Database search and summarize findings (DAEN, BfArM, MAUDE, MedWatch, MHRA, Eudamed, Med Effect Canada)
- Complaints analysis (serious, non-serious, side effects, FCA, recall, CAPA, EU Trend reporting) and benefit-risk assessment.
- Specialist or technical literature
- Similar devices on the market

Team Size	Model	Performance	Business Impact	Risk Classes
5	Outcome based/Fixed price	Standardization across multiple manufacturing sites + PMS updates as per MDR compliance	Submissions initiated to Notified Body	Class I and Class II

Reference mockup image