TATA ELXSI

Case Study

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

Remediated PMS documentation for a US based medical technology company

Scope

- 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

info@tataelxsi.com