TATA ELXSI

Case Study

Successfully delivered more than 55 CERs for Cardiovascular specialty

Reduction in turnaround time by 20%-25% for CER creation of legacy products/ class I devices/ newly classified medical devices

Scope

- Gap analysis w.r.t EU MDR and MEDDEV 2.7.1/Rev 4
- Creation of clinical evaluation plan | PMCF plan & report | Literature review plan, strategy & report
- Clinical Evaluation Report (CER) creation/ update
- Data gathering, analysis & interpretation
- MAUDE data analysis
- State of the Art (SOTA)
- Risk-benefit assessment
- Re-assessment of claims

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