TATA ELXSI

EU MDR/ IVDR COMPLIANCE SERVICES

Smart | Agile | Scalable

Trending

With the new European Union Medical Device Regulation (EU MDR) and In Vitro Diagnostic Devices Regulation (EU IVDR), the industry is witnessing an increased cost of quality (~3-5% of revenue) due to the high unpredictability and volume of work as a result of ambiguous nature of the regulations and the need to implement changes across the product portfolio.

The massive change in the regulations has significant implications for all the global medical device companies operating in the EU nations. Companies are optimizing their transition efforts by rationalizing product portfolio, hiring consultants for guidance, and ramping-up implementation teams to meet the timelines. Despite these efforts, businesses may still need to tackle the high volume of work within the stipulated timeframe.

Although the EU parliament approved a one-year delay that pushed the MDR DOA to May 26, 2021, companies need to continue meeting their internal transition deadlines based on expiry to mitigate any business implication arising out of implementation delays.

Opportunities & Challenges

The Healthcare industry continues to grapple with stringent regulation, pressures to retain profit, increase customer loyalty, and maintain brand value.

The pressing demand to focus resources on EU MDR has resulted in reprioritization and deferment of internal R&D investment. To reduce the cost of compliance and minimize associated risks, organizations need to adopt best practices and configure processes that ensure certainty and maximize confidence in transition. Given the ambiguous nature of the requirements, lack of legacy data, and the limited number of notified bodies, organizations need to implement measures at the operational level to minimize stress on the bottom-line and have greater visibility into the overall transition expenditure. Centralizing agile-based project management can foster functional collaboration, ensure SLAs-driven high documentation throughput, and swiftly address any rework or uncertainty associated with implementation.

Moreover, organizations must build transition assets that focus on content reusability and the first-time-right concept to improve operational efficiency.

Benefits Sought by the Companies

- Optimized compliance costs and greater visibility into overall transition spend
- Centralized program management to foster cross functional collaboration
- Comprehensive remediation coverage and robust technical file creation with reduced turnaround time
- Improved agility to swiftly address any additional rework

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TATA ELXSI COMPLIANCE ASSURANCE

Industry first catalog pricing & outcome-based model

Tata Elxsi MDR/ IVDR Assets

Complexity-based Categorization
Technical file complexity scorecard across class I, IIa, IIb, and III

Catalog Pricing
Upfront per technical file/product family pricing

Cross-functional team of biomedical engineers, medical writers, regulatory and quality experts, etc.

Reusable checklists for accelerated gap analysis of QMS, CERs, labeling and packaging processes, etc.

Outcome-based Commercial Model
Execution model based on business outcomes

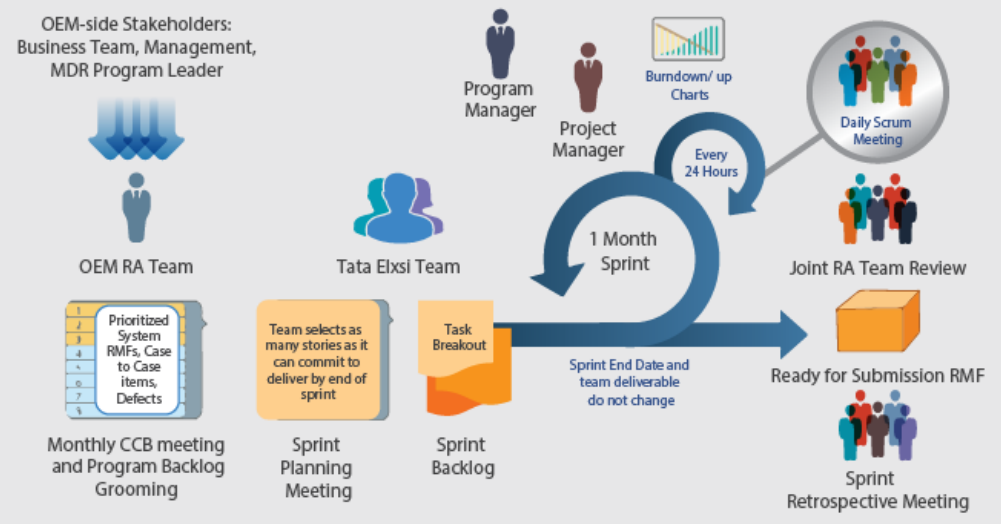
Service-level Agreement
Predictable remediation outputs owing to pre-defined SLAs

Repository of templates for technical file remediation (For e.g. IFU, UDI, etc.)

Comprehensive training modules ensuring on-demand scalability

ScrumDR

An agile-based project management



Differentiators

- Centralized agile-based project management methodology ensuring predictable outcomes with pre-defined SLAs
- Catalog pricing and outcome-based commercial model to support customers through the unpredictable variability and volume of activities
- End-to-end DHF remediation, including drawing creation, testing, process validation, translation etc., ensuring submission-ready dossier
- Proprietary MDR assets for quicker turnaround time, reduced cost of quality, and robust compliance

Cases

EU MDR remediation of 500+ surgical product families

- Assessment followed by quick team ramp-up to remediate ~10,000 class I articles: all DoCs signed by Oct, 2020
- Remediation of ~11,000 class IIa, class IIb, and class III surgical implant systems by Dec, 2022
- Optimized transition plan resulting in 30% reduction in lead time

EU MDR transition for packaging & labeling function of a leading cardiovascular product manufacturer

- Remediating 15,000+ labels in 7 different labelling systems and 300+ packaging configurations
- Developed a custom tool to standardize input documents for all manufacturing sites
- Reduced 40% MDR transition cost by employing flexible onsite-offshore delivery model

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