TATA ELXSI

SAS FRAMEWORK FOR EU MDR/ IVDR COMPLIANCE

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 bound to witness an increased cost of quality (~3-5% of revenue) due to the high unpredictability and volume of work. This can be attributed to the ambiguous nature of the regulations and the need to implement changes across the product portfolio.

Companies are rationalizing their product portfolio to reduce their transition efforts amidst the crunched timelines and limited number of accredited notified bodies.

Furthermore, this massive change in the regulations may have significant business implications on all the global medical device companies operating in EU nations unless they meticulously plan and execute the transition.

Opportunities & Challenges

Timely compliance with the new requirements may help companies to retain and gain additional market share in the region.

The high cost of quality along with a limited number of notified bodies for reviews may negatively affect companies' top-line and bottom-line.

Companies are required to have in-depth understanding of the new requirements, optimized process to minimize efforts, active program oversight, function-wise collaboration, and a cross-functional team, capable of handling unpredictability and high volume work associated with the transition.

Benefits sought by the companies

- Reduced turnaround time per technical file
- Centralized program management to foster collaboration between all the functions (Quality, Regulatory, R&D, etc.)
- Cross-functional team for comprehensive remediation coverage and robust technical file creation
- Rationalized product portfolio and standardized regulatory documentation & practices
- Methods to minimize the cost of compliance and its impact on R&D investments

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Tata Elxsi MDR/ IVDR Assets

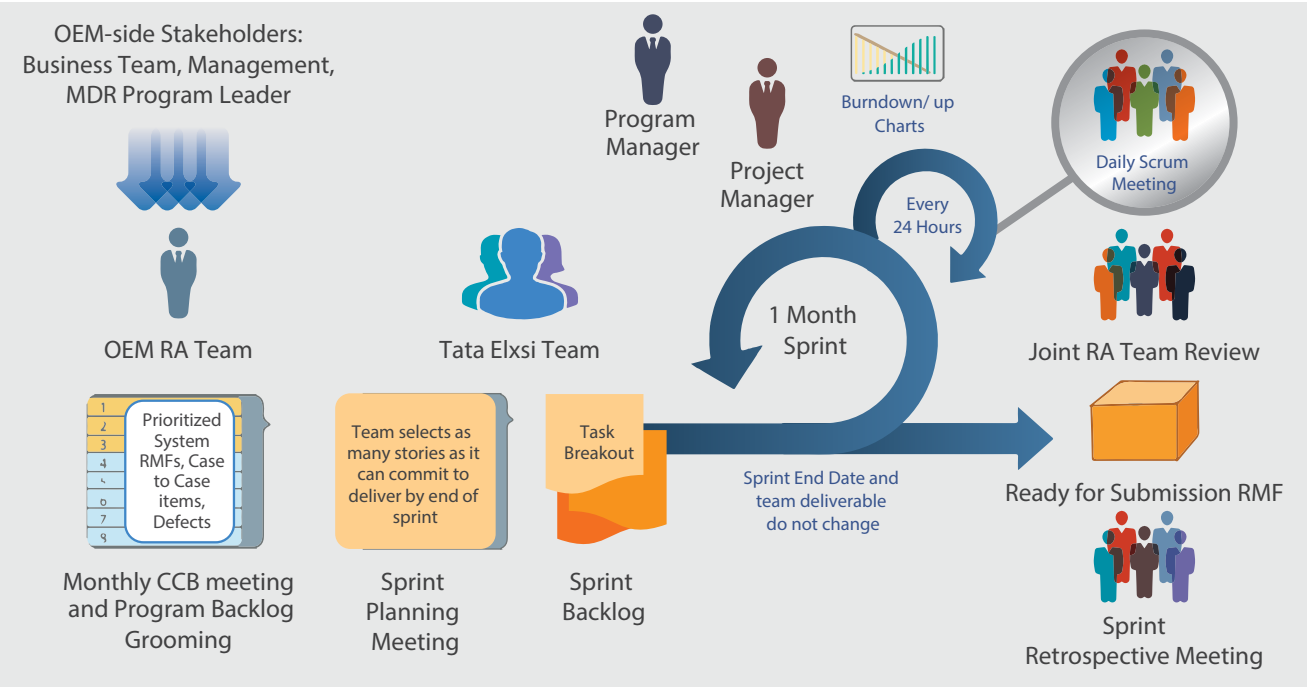
Cross-functional team of biomedical engineers, medical writers, regulatory and quality experts, etc.

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

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

Comprehensive training modules ensuring on-demand scalability

Agile-based Project Management



Differentiators

- Customized agile-based project management methodology with KPIs and pre-defined metrics
- 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
- Mature & flexible operating models to support customers through the unpredictable variability and volume of activities

Cases

Gap assessment & remediation of 330 + surgical product families in a span of 11 months

- Assessment followed by quick team ramp-up to remediate ~10,000 reusable class I articles and meet May 2020 deadline
- Optimized transition plan resulting in 30% reduction in lead time

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

- 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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