TATA ELXSI

SAS FRAMEWORK FOR EU MDR/IVDR COMPLIANCE

Smart | Agile | Scalable

Trending

The new EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) may have significant business implications on all the global medical device OEMs and OBMs conducting business in European Union Nations unless they meticulously plan and execute the transition.

The industry is bound to witness an increased cost of quality (~3-5% of revenue) due to the high and unpredictability and volume of work.

OEMs are rationalizing their product portfolio to reduce their transition efforts. However, at the same time, tight transition timeline and a limited number of accredited notified bodies are further adding to the pressure of compliance.

Opportunities & Challenges

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

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

OEMs 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 OEMs

- Reduced turnaround per technical file
- Robust deliveries as per the latest requirements
- Centralized program management to foster collaboration between all the functions
- Cross-functional team for comprehensive remediation coverage
- Methods to minimize the cost of compliance and effect on R&D investment

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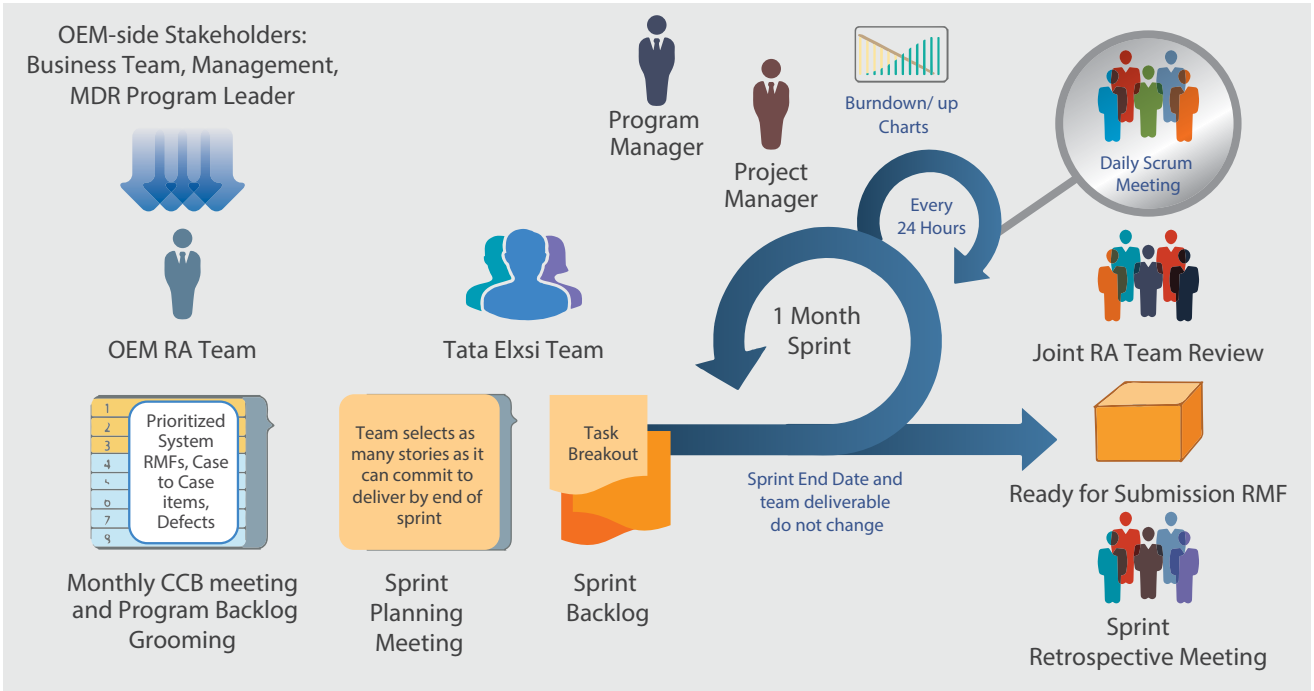
Agile-based Remediation



Tata Elxsi MDR Assets

Methodology to assess OEMs' preparedness for strategizing implementation approach

Reusable checklists for accelerated gap-analysis

Repository of templates for technical file remediation

Comprehensive training modules ensuring on-demand scalability

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Differentiators

- Agile-based gap analysis and implementation for fast deliverable throughput
- End-to-end DHF remediation
- Proprietary MDR assets for quicker turnaround, reduced cost of quality, and robust compliance
- One of the biggest teams of cross-functional engineers in the service industry
- Mature & flexible operating models to support customers through the unpredictable variability and volume of activities

Cases

EU MDR transition partner for global OEMs

- Remediation of 8,000-30,000 products
- Remediation of over 7000 reusable Class I articles in a span of 11 months for a German OEM
- Supporting organization-wide, site-wise, and function-wise transitions