



TATA ELXSI

Unfolding the EU MDR through
the Lens of a Remediation Partner

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Abstract

The entire medical device community has been dealing with the new European Union Medical Device Regulations (EU MDR) for the last few years. The journey has been a struggle for many. Unexpected challenges have emerged in the fields of project management, cross-functional team harmonization, supplier coordination, CER, PMS, and non-EU regulatory submission space. These challenges have come forth as the bi-product of remediating large volumes of documents within a finite duration. Strong project management, communication and collaboration protocols, and gap assessment strategies would form the pillars of a successful EU MDR transition.

This whitepaper provides an insight into all the unexpected challenges faced during EU MDR compliance and presents possible solutions and best practices to overcome these challenges. It will utilize real-life scenarios and examples wherever possible to highlight the advantages these solutions bring to the table.



Introduction

The transition from EU MDD to EU MDR has been the most significant development in the medical device industry in the last few years. This transition has become important to maintain quality goods, accurate documentation and evidence, the safety of the end-users, and most importantly continuous monitoring and course correction during the lifetime of a device pre and post-marketing.

A sudden change in expectations from the manufacturers, vendors, retailers, notified bodies, etc. had taken its toll on the entire medical device industry and all the stakeholders. Manufacturers have been grappling with remediation of all their technical files, providing test evidence for all their products, changing their quality management systems to align with the new regulations, re-looking at the supplier collaborations, etc. Trying to maneuver their entire cross-functional teams together on such a large scale to achieve EU MDR compliance has been a huge challenge.

Apart from the documentation-related challenges like creating all the EU MDR-aligned templates, re-writing most of the existing documents, synchronizing the contents of all these documents, going through a huge review and approval cycle and management-related challenges have also come to the fore. To complete the transition program within a mid or large-sized organization, one needs to manage the following:

- Reams of documentation
- Verification and validation activities
- Synchronization between all cross-functional teams
- Large technical and regulatory workforce working towards a single goal
- Supplier inputs
- New setups for post-market surveillance or clinical follow-ups
- Collaboration with the clinical and patient community
- Global regulatory teams for submission updates across all markets (EU and non-EU)

The challenges and bottlenecks do not end with internal changes and EU MDR compliance. Dependencies on notified bodies for submissions should also be addressed.

This white paper would aim to address some of the management, collaboration-related challenges that were unanticipated when manufacturers started their transition planning and preparation. Each challenge will be followed by possible solutions and best practices that might resolve the issues to a great extent. The next section provides a brief glimpse of the structure of a technical file required as per EU MDR and all the corresponding stakeholders associated with it. It will help in understanding the overall scale of documentation, communication, and collaboration required.

Technical Documentation

According to Article 10 of EU MDR, 'technical documentation shall be such as to allow the conformity of the device with the requirements of this regulation to be assessed'. Annex II and III of EU MDR specifically highlight the content requirements for each document. As per the Annex II of the EU MDR, 'the technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex'. EU MDR has significantly raised the requirements (quantity and quality) for technical documentation and it emphasizes strict and vigilant scrutiny by the Competent Authorities (CAs) and Notified Bodies (NBs) as appropriate.

As technical documentation is often extensive, various sections of it may be stored in different locations, which are usually controlled by the manufacturer's QMS. Moreover, technical documentation must be updated promptly and as needed during the lifetime of the device, to make sure it accurately reflects the status, specifications, and configuration of the device.

Technical Documentation Content

Annexes II and III of the EU MDR outline some of the essential elements to be included as well as define an appropriate structure for creating technical documentation.

Manufacturers should refer to these annexes of the EU MDR to ensure their technical documentation complies with the new legislation.

Manufacturers while creating and maintaining the technical documentation should also provide conspicuous and unambiguous evidence to show that their device(s) satisfy the requirements detailed in Annex I of the EU MDR General Safety and Performance Requirements (GSPR).


Required Content of Technical Documentation as per EU MDR

a. Annex II – Technical Documentation:	b. Annex III – Technical Documentation on Post-Market Surveillance:
1. Device description and specification, including variants and accessories <ol style="list-style-type: none"> Device description and specification Reference to previous and similar generations of the device 	1. The Post-market surveillance plan drawn up in accordance with Article 84
2. Information to be supplied by the manufacturer	2. The PSUR (Periodic Safety Update Report) referred to in Article 86
3. Design and manufacturing information	3. PMS report referred to in Article 85
4. General safety and performance requirements	
5. Benefit-risk analysis and risk management	
6. Product verification and validation <ol style="list-style-type: none"> Pre-clinical and clinical data Additional information required in specific cases 	

Table 1 – Content of technical documentation as outlined in Annexes II(a) and III(b) of the EU MDR

Technical Documentation Stakeholders

Various stakeholders participate in creating multiple sections of the technical file. Internal and external stakeholders are as shown below:



Internal		External
<ul style="list-style-type: none"> Clinical Legal Management Manufacturing Marketing/Sales Quality Regulatory 	<ul style="list-style-type: none"> Research & Development Post Market Surveillance (PMS) Technical communication (website, manuals, IFUs) Labeling 	<ul style="list-style-type: none"> Competent authorities EU legislator Notified body Sub-contractor/ Suppliers

Figure 1 – Stakeholders participation in preparing a technical file

Stringent EU MDR requirements, the involvement of multiple stakeholders in creating the technical file, non-availability of inputs, decreased number of NBs, and extensive scrutinizing processes add up to challenges faced during the transition period.



EU MDR Transition: Challenges and Solutions

PROJECT MANAGEMENT

While working on new product development or design changes or remediation activities, a small to medium-sized team with a mixed skillset comes together and works on the product. In these cases, project management and product management go hand in hand. Contrarily, EU MDR remediation requires that the entire organization i.e. all departments and business units, work together in tandem on the complete range of product portfolio. The breadth and depth of project management required during this period are unprecedented. It brings in many more complex requirements such as:

- Planning and tracking of the entire volume of technical files. It implies tracking multiple activities performed by various cross-functional teams.
- EU MDR transition is a short period activity and working on compliance with the entire product range within this period requires a large influx of technical and regulatory resources. Manufacturers need to estimate and fulfil resource requirements without hampering existing R&D, maintenance, and other regular activities.
- As an extension of finding, utilizing, and managing a large team, communication, collaboration, and dependencies need to be handled efficiently.

Solutions

- 1. Adopting agile practices:** To manage a large program deftly while being flexible enough to accommodate all kinds of changes requires discipline and an ability to retrospect and change every once in a while. Adopting some of the agile practices and breaking down the large program into smaller workable units not only helps to manage the program better but also assists in estimating efforts and schedules. Stitching the Individual statuses will enable us to forecast timelines and provide a visualization of accomplishments. Running sprints of work packages gives a chance for periodic retrospection and course correction.

- 2. Building communication platforms:** Collaboration amongst all stakeholders is a strong requirement for the success of the transition program and requires looking into building platforms and processes for communication and collaboration with both internal and external stakeholders like notified bodies.
- 3. Collaboration with service providers:** As EU MDR transition is a time-bound activity, it acts as a strong motivator to look into collaboration with 3rd party service providers. Service providers bring in the ability to ramp up and ramp down skilled teams as and when required. Their forte is to bring cross-functional teams to the table and train them to quickly adapt to individual client requirements. This will fulfil the manufacturer's need for on boarding a large number of people just for a couple of years to work on the new compliance. It also provides them the freedom to continue their existing R&D activities thus maintaining their position in the market. Service providers come up with the experience of handling large projects. Customers can then manage large programs by utilizing only a handful of their experienced leaders by utilizing such collaborations.

DHF HARMONIZATION

In an organization, multiple stakeholders and teams are involved in the planning, creation, or remediation of product technical files. The complexity of maintaining harmonization amongst all these cross-functional teams is apparent. To meet EU MDR deadlines, multiple teams work in parallel and any communication gap between the respective stakeholders creates a lot of rework and significant delays.

For example, if the R&D team updates the product description and does not inform other dependent document owners about the update and modified content in time, they will end up with an inconsistent documentation set, significant rework, and probably delays in submission. Multiplying this scenario across all products, the small issue turns into a huge problem.

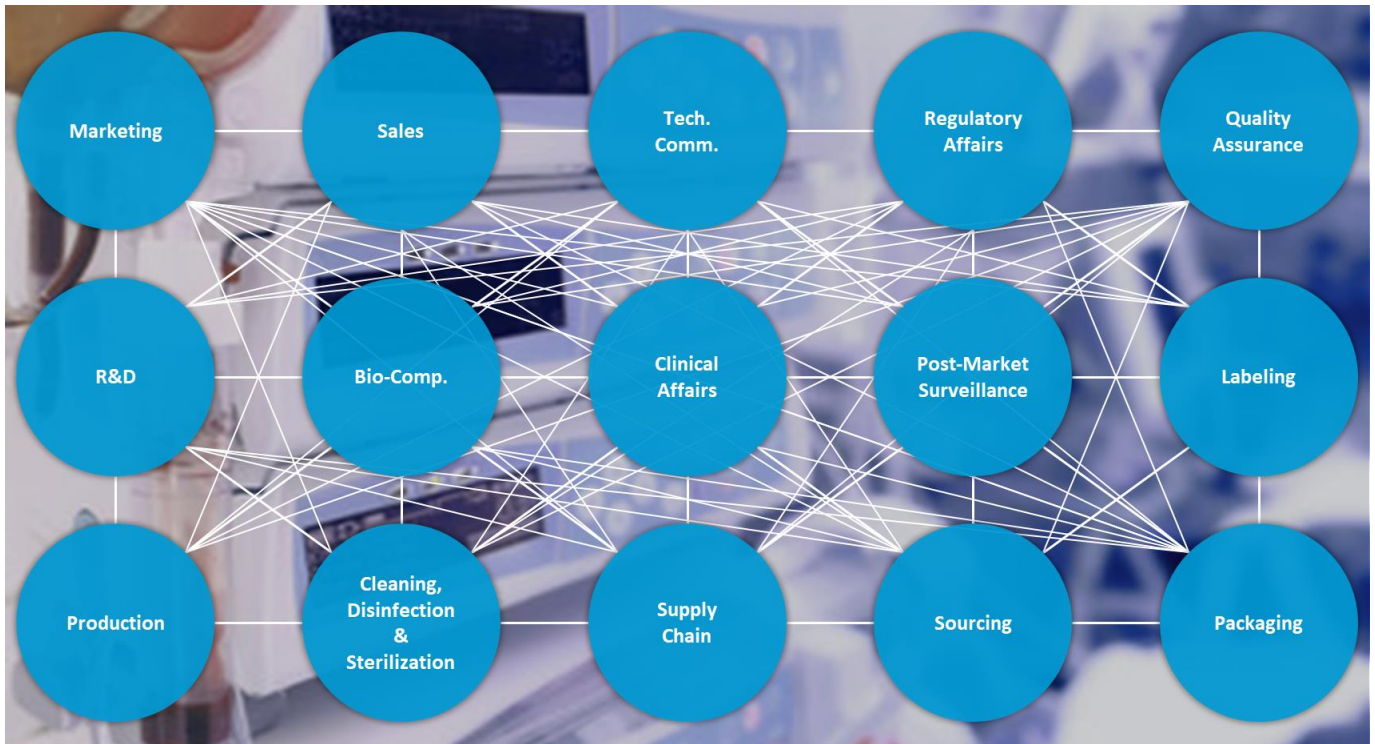


Figure 2 – The Inherent Complexity

The lack of harmonization between various cross-functional teams will create challenges in:

- Product-specific content synchronization affecting the consistency of the documentation
- Department wise planning due to insufficient and delayed information flow like - current status and notifications regarding any relevant changes

Solutions

To resolve these interlinked pieces of the challenge, the subsequent three options will help:

1. The transition from document management to content management

As a medical device industry practice, document management should transition into content management. Content management involves splitting the documents into content units based on functional ownership and content reusability. Each content unit should be assigned to respective functional owners/departments which will act as a source of truth for all related documents.

Documents can then be built by assembling the correct content units. This method will reduce inconsistency among documents, improve document maintainability in the future, optimized review efforts, and reduce errors.

2. Project tracking tool for information flow

An organization-wide project management tool can achieve information management, where all the multi-departmental planning and status can be integrated into one place. It helps the manufacturer to extrapolate timelines to identify possible delays in submission. Overall such a tool will help the manufacturer to make quicker decisions, identify bottlenecks, and prioritize their actions.

3. Best practices in gap assessment planning

Following simple best practices in gap assessment planning will cover the major challenges in EU MDR DHF remediation. Two steps effective strategy for planning gap assessment and implementation are:

- i. Always assess gaps across cross-functional areas together to be able to see the bigger picture. For example, assess gaps holistically in clinical safety, packaging, manufacturing, supply chain, etc. apart from R&D documentation and testing which is the common practice.
- ii. Perform product portfolio rationalization & prioritization based on the probability of resolution of the gaps and corresponding efforts required for compliance. Use the gap assessment to foresee the possible delays and plan to mitigate them in advance.

To summarize, investing in a holistic gap assessment, will lead to better planning and eventual time & cost saving.

SUPPLIER COORDINATION

One of the unexpected but common challenges most manufacturers are facing currently is supplier data extraction. The responses from the suppliers are much slower than expected and most of the time the response received can be equated to "data is not available".

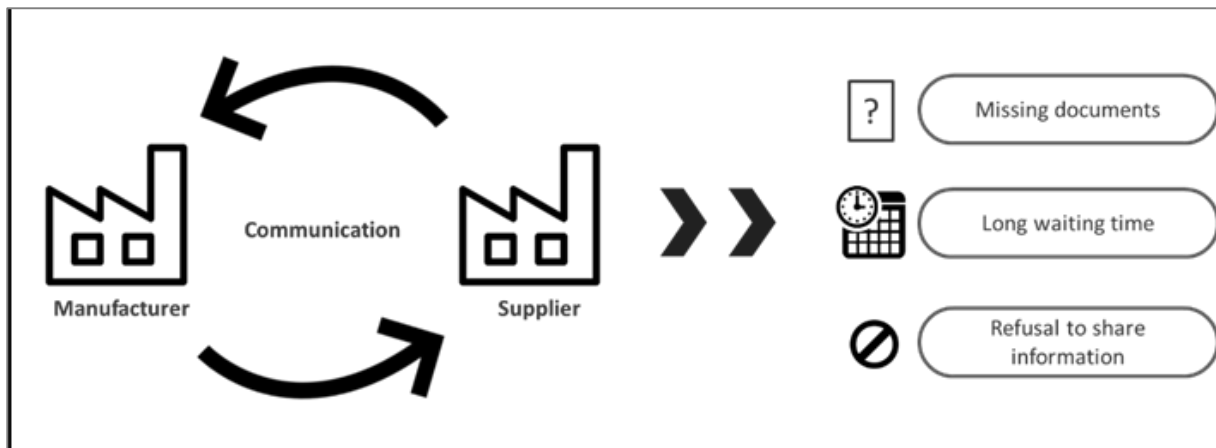


Figure 3 – Manufacturer and supplier coordination

History of contracts, previous communications significantly affected the outcomes. Suppliers who are competitors of the OEMs or suppliers with confidential technical information refuse to share the documents. The big question is - when do you stop requesting data or documents and start taking your actions?

Solution

This problem should be treated as a combination of technical knowledge and people coordination. Following processes can be utilized by manufacturers to ease the situation:

1. Create a dedicated team for periodic follow-ups utilizing different types of verbal and written communication. The communication protocols should be designed to be person-oriented. To support the coordination process flow, define the minimum artefact set for making the supplier request, and work on a plan to manage the rest using rationales and existing evidence.
2. OEMs can run a separate project with the suppliers for the creation of critical documents.
3. For confidential documents use supplier audits to provide evidence. In this case, observations or non-conformities (NCs) from NBs audit will ensure that the supplier creates the documents while maintaining confidentiality in the process.

Early supplier follow-up planning, well-defined communication protocols, and a dedicated team for proactive supplier coordination will help for document and data recovery.

EU MDR ORIENTED CLINICAL EVALUATION SETUP & EXPERTISE

One of the main challenges observed across OEMs is the lack of an adequate setup and expertise for clinical evaluation and PMS processes.

Challenge: Adequate Setup

The clinical evaluation processes follow EU MDD and are not updated to align with EU MDR, for instance, the best practices for equivalence do not take into account the additional constraints set by the new regulations. Similarly, for PMS processes, there is an increased emphasis on proactive data collection, rather than an exclusive dependency on reactive data analysis.

In addition, the CER and PMS documents need to be aligned with the rest of the EU MDR documentation to ensure consistency, and to avoid nonconformities being raised by the NBs.

Solution

1. Data retrieved from the vigilance system needs to be incorporated across different documents such as the CER, Post-Market Surveillance Report or PSUR, and Summary of Safety and Clinical Performance. For this reason, it is important to perform a gap assessment with existing processes and templates to ensure alignment with EU MDR.
2. To align CER and PMS with other EU MDR documents, there is a need to monitor and track the open/incomplete sections of the CER and EU MDR updates, such as ongoing bench testing, PMCF studies, Instruction for Use (IFU), and risk analysis updates, etc. This is possible only with adequate, efficient, and timely coordination between the teams developing the EU MDR documentation and the team performing the clinical evaluations. It is extremely important to develop pathways and work instructions to stimulate this coordination and crosstalk in order to have consistency across all documentation in a medical device technical file.

Challenge: Expertise for Clinical Evaluation and PMS processes

Developing clinical evaluations is not a solitary task, and coordination with other teams is essential. But what are the inherent requirements of a clinical evaluation team?

A technical expert is needed, especially for complex medical devices, who is capable of understanding and explaining the technical nuances of the device design, which may potentially affect device safety and performance. A scientific writer is required to perform comprehensive literature searches, appraise, and analyze the clinical data, while a clinician provides critical input on the clinical relevance of the data extracted on the medical device. Finally, a regulatory expert is essential to correctly interpret the various guidelines and regulations, and delineate a course of action based on the data available for the medical device under consideration.

Example: A scientific writer performs a systematic literature review and identifies several reports of kinking and unraveling of a particular percutaneous guidewire. The clinician determines that the kinking is a result of the guidewire itself and not due to excessive force applied with a tissue dilator inserted over the guidewire. The technical expert then determines that there was a design change in the material of this guidewire that allowed it to be more flexible for navigating tortuous anatomy but also potentially resulted in safety/performance issues due to kinking. The regulatory expert takes all this information under consideration and verifies that these risks are adequately addressed in the device risk documentation. In terms of the next steps, this expert determines whether or not a PMCF study is necessary, and also advises that the IFU/product documentation should perhaps specify the use of this guidewire for navigating specific anatomies and that the risk of kinking and unraveling should be included in the product documentation.

Solution

The collective skill set can foresee the expectations of the NBs, critically analyze the available data to determine sufficiency, update the product documentation, and accordingly plot the next steps for a PMCF study, if necessary.

Challenge: Critical Analysis in a Clinical Evaluation Report

With the introduction of MEDDEV 2.7.1/Rev 4 and later, EU MDR, an increasing emphasis is being given on critical analysis of the evidence presented in a CER. The proportion of boilerplate language in a CER has reduced and NBs are scrutinizing the content to determine how the OEM has discussed the overall relevance and significance of the data presented in the establishment of the device safety and performance.

Solution

Some core aspects of the CER where critical analysis is of the utmost importance: First, the clinical evaluation plan needs to identify specific and measurable safety and performance indicators for the subject device. These are based on the indication, intended use, claims, and hazard analysis documentation of the device. Next, the acceptability criteria for these indicators need to be determined based on the state of the art, using appropriate guidelines and clinical data on the state of the art. Every piece of clinical and nonclinical evidence, including pre-clinical/clinical testing, clinical investigations, clinical literature, and PMS data, is appraised and segregated into pivotal vs supporting data, based on its relevance to the subject device. For instance, if the subject device is a surgical suture utilized in different surgeries, the literature citing the subject device would not necessarily provide outcomes on the safety and performance of the suture. Hence, it is essential to segregate the outcomes related to the suture from the available data, rather than those related to other devices or the surgical procedure.

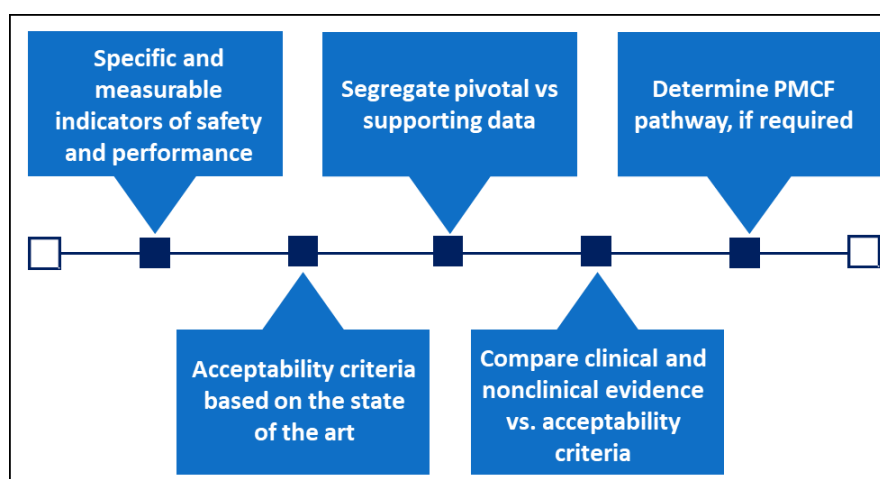


Figure 4 – CER Critical Analysis

The pivotal data on the subject device are then compared with the acceptability criteria from the state-of-the-art and the device risk documentation. This analysis may reveal gaps such as insufficient clinical data to support the device's safety and performance, or new risks, or risks with increased frequency. One of the significant gaps that need to be explained is the subject device safety and performance outcomes being out of range of the acceptability criteria. These gaps need to be clearly identified in the CER and discussed. If these gaps cannot be rationalized, a suitable PMCF pathway must be selected based on the gaps identified and the device class.

The clinical evaluation process will thus critically analyze and assess relevant clinical data and verify device safety and performance. Medical device manufacturers will have to ensure that they have processes in place to conduct a comprehensive assessment for product safety, performance and intended clinical benefits. Thus these steps are essential stepping stones for developing a comprehensive clinical evaluation that adheres to the current guidelines and regulations.

Challenge: Regulatory Submissions for Non-EU Geographies

Extending the EU MDR scenario to Non-EU geographies like Brazil, Mexico, Cuba, Russia, Australia, etc. which mostly rely on CE compliance, we will find that the EU MDR changes impact other global regulatory product submissions significantly.

Local regulatory submissions may or may not differ from the central documentation of technical files. A change in the central documentation i.e. technical documents, labels, IFUs, etc., will cause a mismatch between global and local submission repositories. Direct effects of such a mismatch can be seen in examples where local authorities like excise departments reject products during the import-export process because the labels in their system do not match the new globally updated labels.

OEMs who market in multiple countries will have a decent-sized problem on their hands. The challenge lies in assessing the impact and addressing it for all dependent geographies.

Solution

To analyze and optimally remediate, all local documentation to synchronize the EU MDR related changes following workflow can be utilized:

1. Assessment of regulatory impact in collaboration with regional/ country specific RA point of contact. Assess how the EU MDR changes will impact local regulations.
2. Creation of regulatory strategy and detailed action plan.
3. Prioritizing products and countries as per business needs, strategy, and forecasts.
4. Selection of the right submission pathway - Change submissions, notifications, no action or re-registration, etc.
5. Assess all the differences in MDR documentation and regionally submitted documentation. Make updates accordingly.
6. Perform regulatory submissions.
7. Once approvals are in place, update inventories and make relevant internal changes.
8. Launch the product.
9. Global Regulatory submission archival (registration/change submissions/renewals/notifications) should be created and systematically maintained as a best practice.

POINTS TO PONDER

The challenges listed above are a small sub-set of the entire picture. An exhaustive list of all EU MDR-related challenges would require a lot more scope than this paper. Having said that, there are a few more issues related to areas covered in the above sections, which are worth discussing briefly here.

Product Data Management - According to a report published by McKinsey Global Institute, most companies spend almost 20% of their time searching for and gathering internal information.

Management of huge amounts of product data, the safe handling of sensitive information, central content management, the protection of system interfaces, and complete documentation with inclusive transparency are the most important cornerstones for manufacturers that want to stay in the market in the future.

Product data management tools need to be developed and utilized for the efficient handling of internal data. This would be a central space where all the data for each product is collated and can be used by all stakeholders/functions. Such a system would be useful in production inventory & supply chain management. Once changes are made for reasons like EU MDR transition, they will reflect automatically in the central space thus allowing production to plan, manage inventory and make the other necessary changes in real-time thus resulting in cost saving.

Extensive scrutinizing procedures - Extensive scrutinizing procedures are to be performed within stringent timelines for class III implantable devices and class IIb products that have the potential to deliver drugs into the body (as per MDR Annex IX 5.1). The NBs evaluate the quality of clinical data supporting the CER generated by the manufacturer referred to in Article 61(12) of the EU MDR and prepare a clinical evaluation assessment report (CEAR) which bring conclusions concerning the clinical evidence provided by the manufacturer, particularly the benefit-risk determination, the consistency of the evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in MDR Article 10(3) and Part B of Annex XIV. This report is forwarded to a panel of experts Medical Device Coordination Group (MDCG) via the European Commission's (EC) to further determine if a scientific opinion will be presented within 21 days.

For this stringent review, manufacturers must take care of their documents (quality and supporting evidence) and processes should be reviewed and changed timely depending on the requirement. An intense and fast interaction between manufacturers, NBs, and EC panels must be established, maintained and, of course, improved.

Similarly, the decreased number of NBs from 80 to 59, especially troubling in the in-vitro diagnostics (IVD) sector, where approximately 80% of products - about 35,200 articles - will need an NB oversight for the first time.

Notified Body Feedback and Deficiency Response - As notified bodies are also facing tremendous pressure of stringent reviews/audits for multiple submissions, getting a quick and detailed review response from them will not be easy.

OEMs should consider creating a summary of entire technical files with a listing of evidence and conclusions, which will help notified bodies to perform faster and effective reviews and provide timely feedback. Apart from this, OEMs might try to plan for submitting an initial set of product documentation for early feedback and submitting it to multiple NBs for different opinions. Carefully strategizing submissions will help prevent major defects later and will help in gaining enough time for corrections. In addition to planning and strategy, a deficiency response repository (global) for efficient response drafting and utilizing standards response template across different NBs can also be implemented. Information flow will help correct the submissions that are still in progress thereby reducing the rejection percentage.

Conclusion

We keep unearthing challenges throughout our EU MDR journey. Some challenges were anticipated while some were surprising. It is a struggle to maintain a balance between what we usually do and what we should do.

We have seen the need for an extremely strong and robust project and people management in all the areas discussed above. The extent and magnitude of management require strong collaboration between everyone working on the transition program. Challenges like inter-department harmonization, supplier coordination, and global regulatory compliance show that we should move ahead as a group and not just as an individual technical or business team. Challenges in the DHF remediation, CER, and PMS space show that we still need to keep working on our infrastructure, technical expertise, process improvements, and technology support systems. Finally, to handle the massive amounts of work, we need to invest time and effort in analysis and planning before jumping into implementation.

With Class I remediation done, this is a good time to pause, learn, update, and start again. As the Class II submissions to the NBs start, we have lesser room for error and would also have to handle the time-bound feedback and closure of queries that come from the NBs. This would involve strong collaboration and commitment from all the departments needing an extension of the stronger project management practices for closure.

Similar to EU MDR, changes will soon be seen in many other medical device markets like Japan, China, and Canada, etc. Therefore, we should view the new regulations as an opportunity instead of a challenge and do it right to reap long-term benefits. By doing that, we work towards success namely good quality products, content authorities, satisfied customers, and improved human life.

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ABOUT TATA ELXSI

Tata Elxsi, a part of Tata Group, is among the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to medical device and healthcare companies, Tata Elxsi has built a comprehensive services and solutions portfolio that adds value at every stage of the customer's product development lifecycle. Tata Elxsi is an established name in technology consulting, new product design, development, verification and validation, and regulatory compliance services.

Apart from product engineering, Tata Elxsi has 1000+ person-years of experience in providing regulatory compliance services such as consulting, technical file remediation, compliance testing, clinical evaluation, post-market surveillance, packaging, and labeling services.

For more information, please visit www.tataelxsi.com click here



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