MEDICAL DEVICE PLM®

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MDR and Medical Device PLM

How to prepare your clinical data for the EU MDR

Minerva

Here's why you should read this white paper:

This is yet another white paper on the upcoming EU MDR regulatory changes. But unlike the rest, this paper will focus on what medical device companies should do to improve the visibility and traceability of their product data, documents and technical files.

This is simply the most efficient way to ensure that the product data is ready for auditing and compliance with the EU MDR.

Because the truth is that... **medical device manufacturers are in risk of drowning in data**

A survey made by KPMG and RAPS reported that "58% of regulatory and quality leaders from more than 200 medical device companies responded that they had no strategy in place to remediate gaps in their clinical data or processes for collecting data".

Medical device companies are generating more data than ever before. But at the same time, the majority of regulatory and quality leaders inside medical device companies are struggling with both data visibility and traceability in their data.

From the increased level of data generation to the new demands placed on quality management systems, regulatory and quality leaders need to ensure that they have the right setup in place to handle the new requirements.

Without the right technology to manage the new and substantial requirements for product data, medical device manufacturers will drown and put their license to operate in Europe at risk.

To succeed and win against competitors, now is the time to restructure current processes to make them more efficient.

How the EU MDR will affect your product

One of the specific areas where the EU MDR will have a significant impact for all device manufacturers, is clinical data. The new regulations will impact current clinical data collection, management and retrieval processes and also how clinical data are prepared for submissions.

One thing is certain: Handling your data in a siloed way will not work. It is therefore highly recommended (and highly necessary) that manufacturers adopt a structured enterprise-wide cross-functional approach to the management of their data.

You also need to evaluate the current technology landscape to discover whether it is the right fit for the operational aspects of the new requirements.

Here is an overview of the most affected areas:

Eudamed:

A key aspect of the EU MDR is the creation of a European medical device database called Eudamed. The aim is to improve transparency and provide both healthcare professionals and patients with better access to detailed information about all medical devices sold in Europe. Options such as electronic templates may help to identify what is required and what may be missing from the submission.

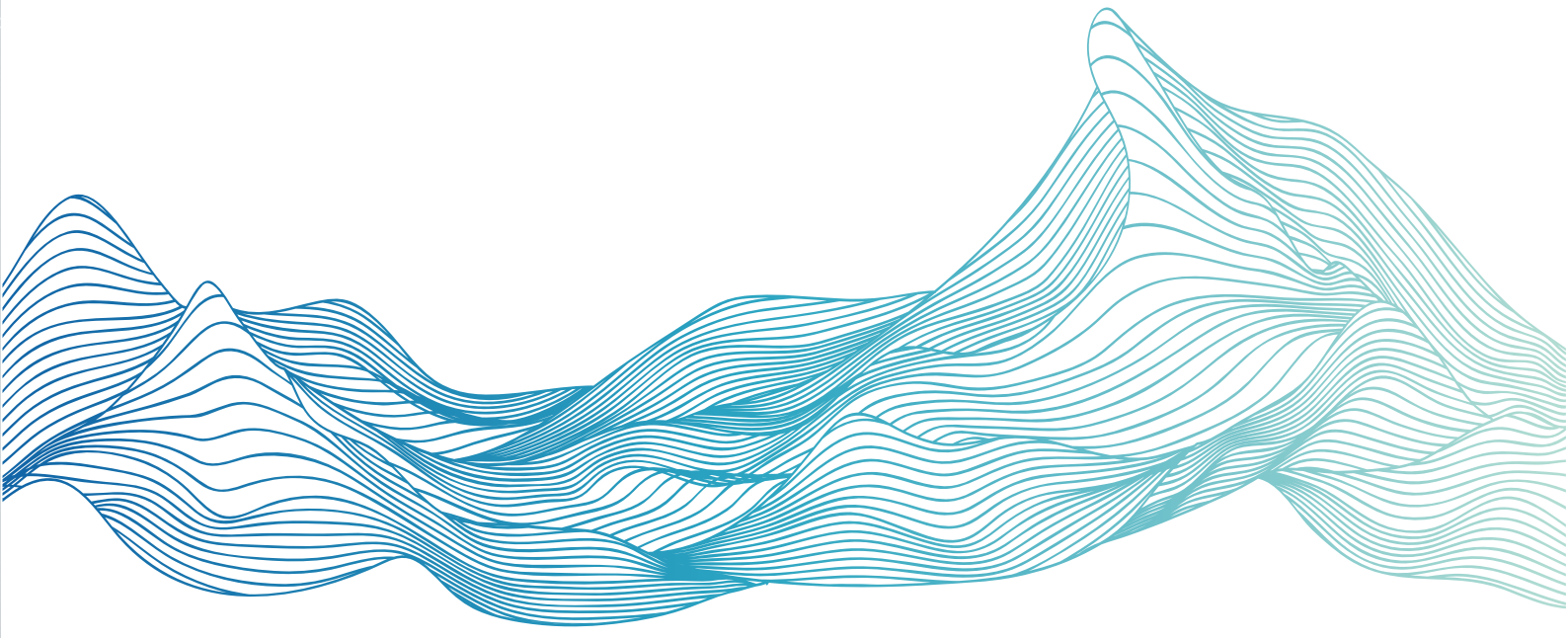
Recertification:

If you want to continue selling your products within the European market, you need to recertify all your medical devices under the new regulation. It will require new conformity assessments under the new rules for all devices currently circulating within the EU. No grandfathering is allowed. Clinical justifications based on device equivalence will be harder to make. You will need to identify all devices requiring recertification and collect all necessary data to build your technical files.

Bear in mind that Notified Bodies will also be recertified. That means you may have to deal with a new Notified Body as well.

IFU's:

Instructions for Use must be available to the public and be written in a way that a layperson can understand and apply them. Manufacturers that link the documentation to design source files may find it easier to keep documentation up to date.



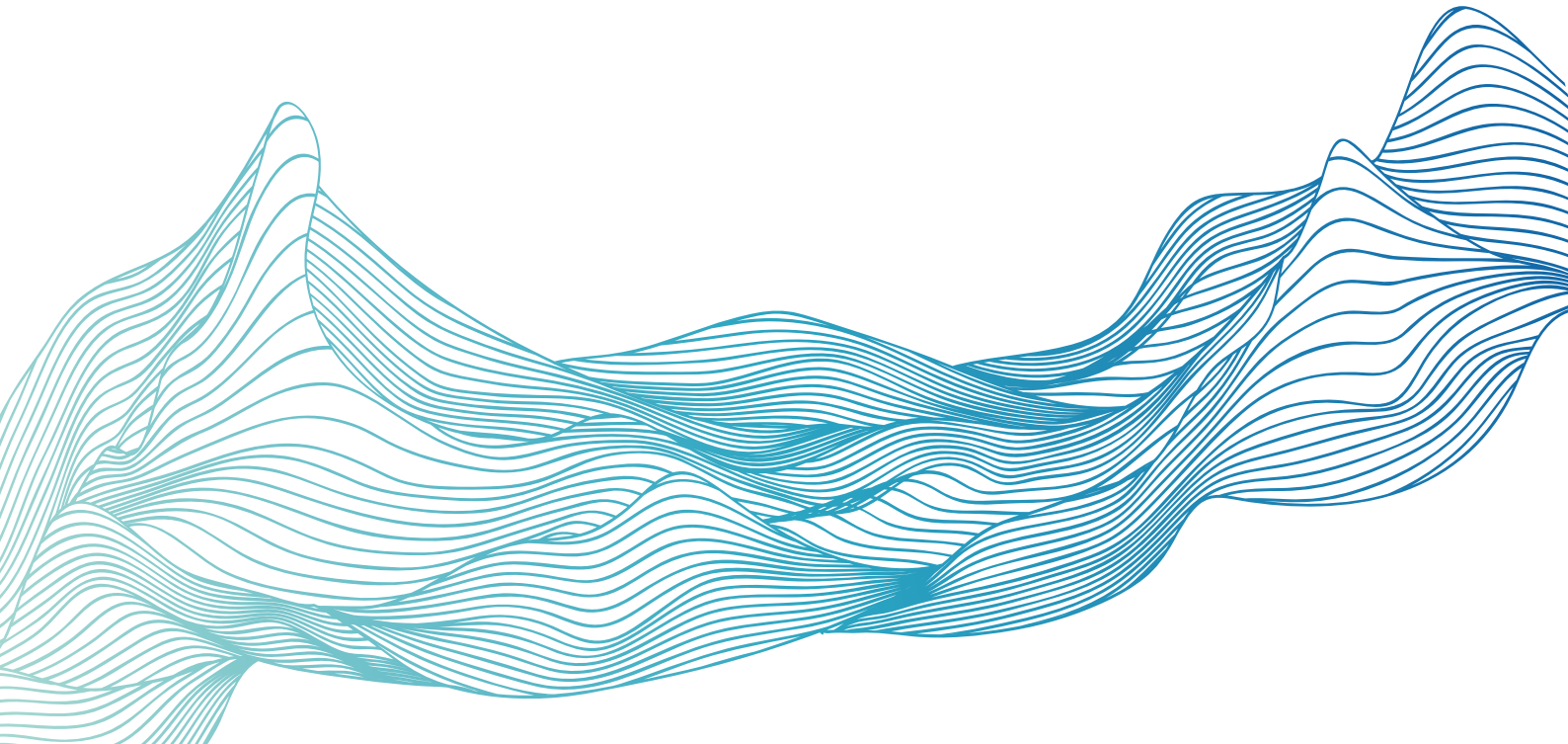
Post Market Surveillance:

The regulation requires device manufacturers to systematically conduct post-market surveillance on their devices. You must regularly update technical documentation with the newly collected data and lessons learned. If you can link your technical documentation to the results from post-market surveillance, it will be easier to maintain.

Quality Management System:

The EU MDR includes requirements for the QMS to be placed where the regulatory requirements come together to be implemented systematically throughout the life cycle of the device. The QMS should set high standards and support quality beyond simply satisfying compliance requirements for performance safety and outcomes. This will require additional planning and training on changes across the entire quality system with the addition of new SOPs, manuals and reporting functions.

Notified Bodies are also required to audit the QMS to ensure that "devices at every stage, from design through final quality control to ongoing surveillance" comply with the regulation.



Why you need to re-evaluate your current processes

Data silos

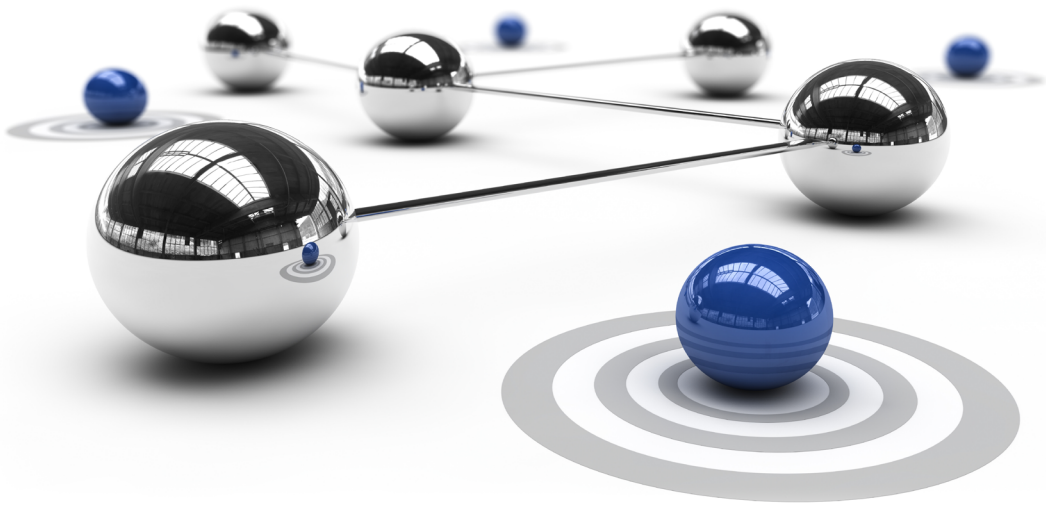
Data silos are a big issue in many manufacturing organizations, including medical device companies. Many companies have multiple systems in place, including ERP systems, document control systems as well as several quality management systems.

Having isolated islands of data not only hampers the flow of data but also makes it impossible to have any form of document traceability across the device life cycle.

Without traceability, employees are forced to manually identify and apply information to everything impacted by a change or update, putting themself in risk of inconsistency and quality issues. Updates become manual and resources focus more of their efforts on searching for documentation.

Digitize your document workflow

One of the first changes companies should focus on is digitize the way documents, datasheets and technical files are stored and managed. That will eliminate the silo between the data and documentation and create efficiencies that will make it easier to adhere to the EU MDR.



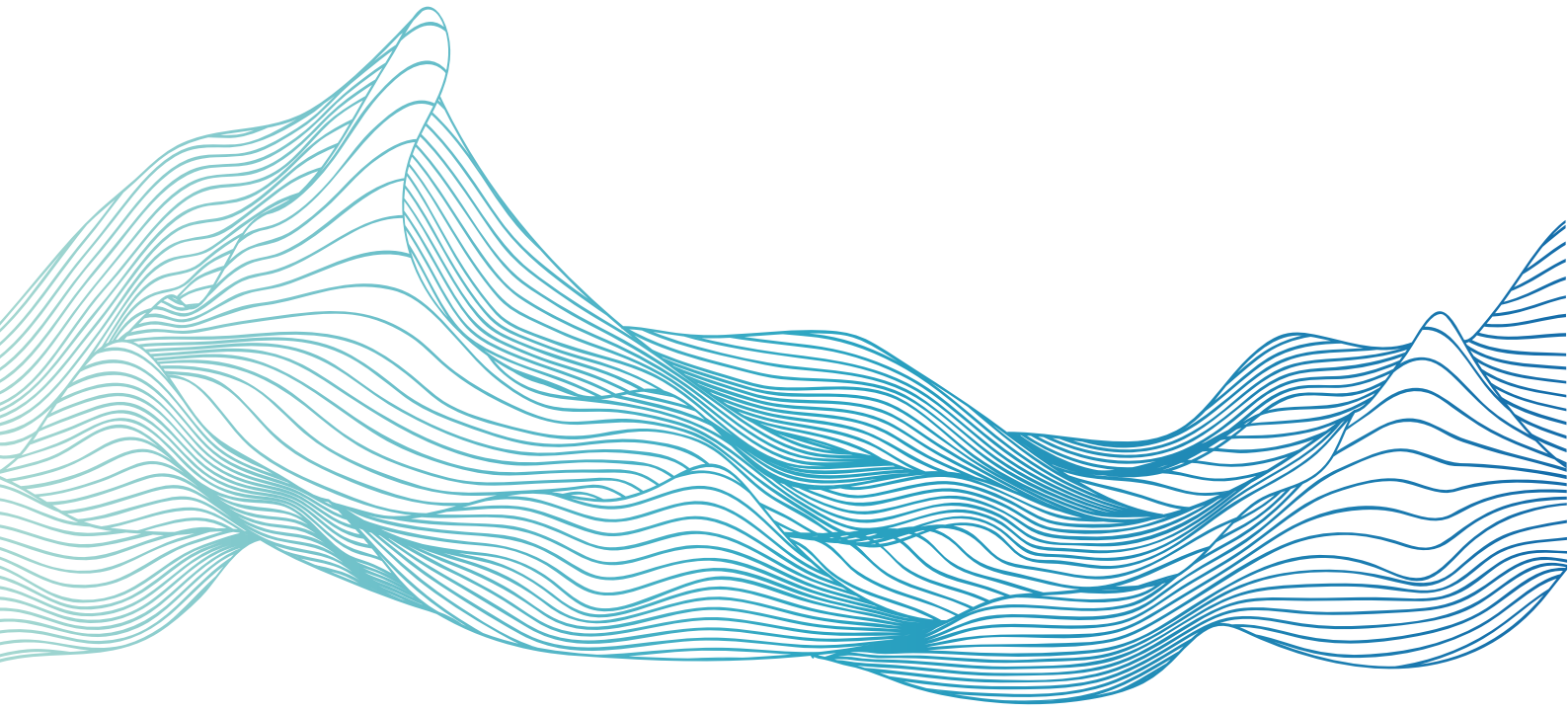
Create a single source of truth

Choosing the right solution architecture for your data is crucial. For some medical device manufacturers, having all their data in one single database may be the best solution. However, you can achieve the same goal by having platform that connects different sources of product data from a single hub.

A single point of access allows you to search across all of your data sources and export the elements that is required for regulatory submissions. A PLM system with a connectivity system is an example of such a system that would support that approach.

The key is to avoid manually collecting data and instead generate reports at the push of a button to get the data you need in a systematic and repeatable way that would make sense to an auditor.

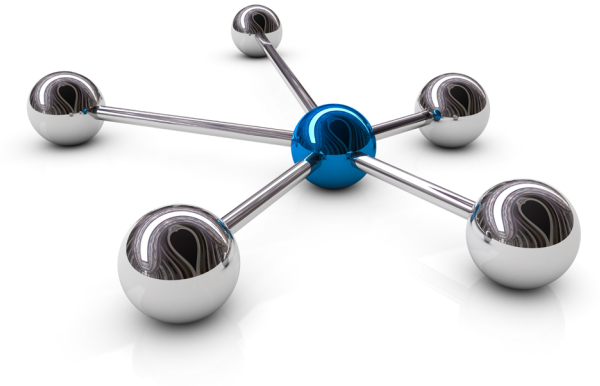
You also want to avoid making changes in multiple systems. Changes should be made once and apply everywhere.



Structure and manage your data

Searching for the required data to support regulatory submissions is a top challenge for manufacturers. To cope with that challenge, you should structure your product data so that there is a central access to it.

Since processes will be structured aroud the product life cycle, consider starting with the CAD data and the digital product definition. The CAD data can then be the foundation for your product, and then you can map your processes based on the product data.



Automate product life cycle processes

Now is an excellent time to review best practices and workflow templates available in a PLM solution, specifically made to the medical device industry. A solution that are based on working, time-tested implementations.

Remember, manual processes consume time, waste efforts, and take away from adding value to medical devices. The more you can automate processes, the more efficient they will be, and your data will be more reliable.

In particular, a design control process that manages change as a natural extension of an engineer's everyday work activities is much more likely to provide reliable, audit-worthy data than processes that rely on manual "to do" lists.

The power of a medical device-specific PLM system

A specific medical device-specific Product life cycle management system can manage product development processes with end-to-end traceability and provides a complete and accurate picture of a medical product at any point in time.

The PLM system ties product information, decisions, and history together in a structured, integrated way that captures product innovation and knowledge throughout the product life cycle. It establishes traceability from early in the front end of innovation through development, manufacturing, service, clinical surveillance, and end of life.

> When PLM processes span the enterprise, the entire team including engineering, manufacturing, quality assurance, regulatory, and service, has access to the same information, it will improve collaboration.

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The resulting efficiencies benefit the business with increased productivity, improved quality, and more opportunities to create new value.

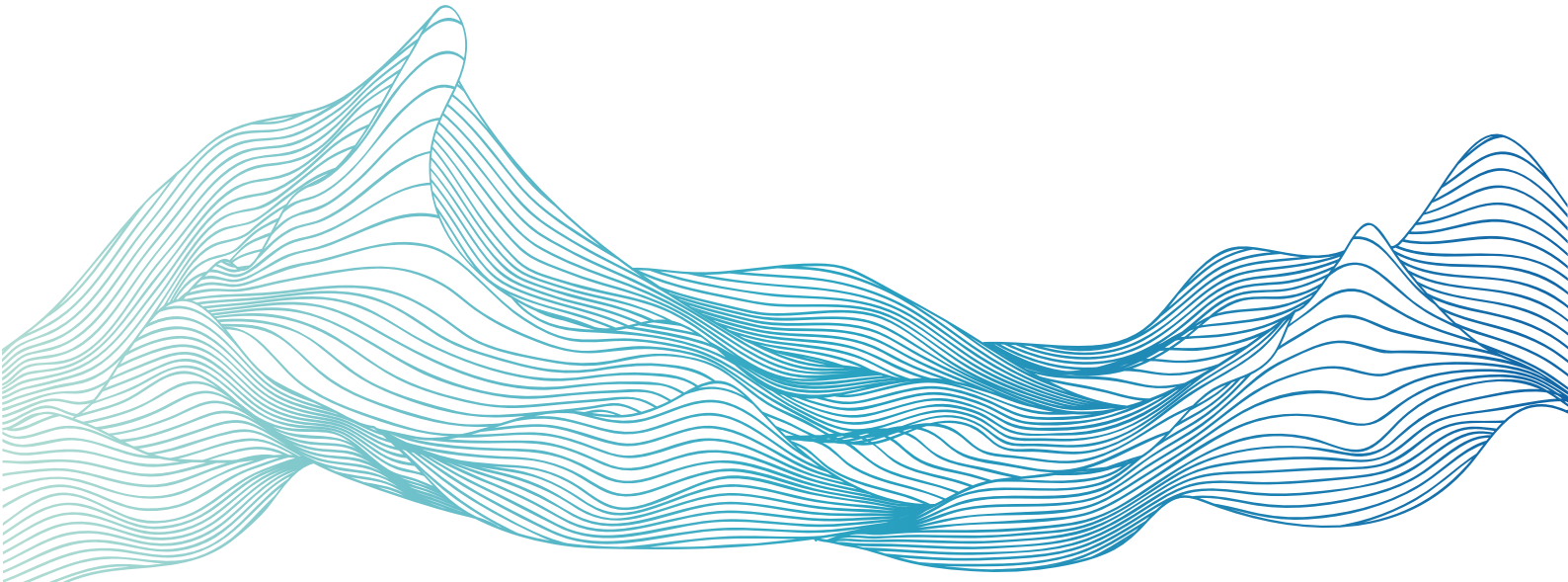
Conclusion:

The EU MDR includes many impacts on product data that cross the complete life cycle of the device. Traditional manual processes will make it challenging to comply with the EU MDR. By adopting a digitized approach, you can establish a foundation for compliance to the EU MDR as well as future regulatory changes and updates. Most importantly, you will be setting your company up to be more competitive now and into the future.

The level of time and effort needed to implement necessary changes in order to comply with the upcoming regulations is not to be underestimated. Medical device companies will need to dedicate significant resources to plan an effective implementation and overall compliance strategy to fulfill the appropriate requirements

In short:

- Use the EU MDR as an opportunity to digitize your document-related processes to improve efficiency, visibility and traceability of your clinical data.
- Consider a medical device-specific PLM system that supports the digitalization of your clinical data and serves as a foundation for EU MDR compliance.
- A PLM system ties product information, decisions, and history together in a structured, integrated way that captures product innovation and knowledge throughout the product life cycle.



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Disclaimer:

This white paper is primarily focused on the Medical Devices Regulation (EU MDR) and the requirements of the EU MDR apply in large to the medical device industry. Also, this paper reflects the information available to Minerva Group as of March 2019. This information is subject to changes and readers should not base their regulatory policies on this white paper alone.

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