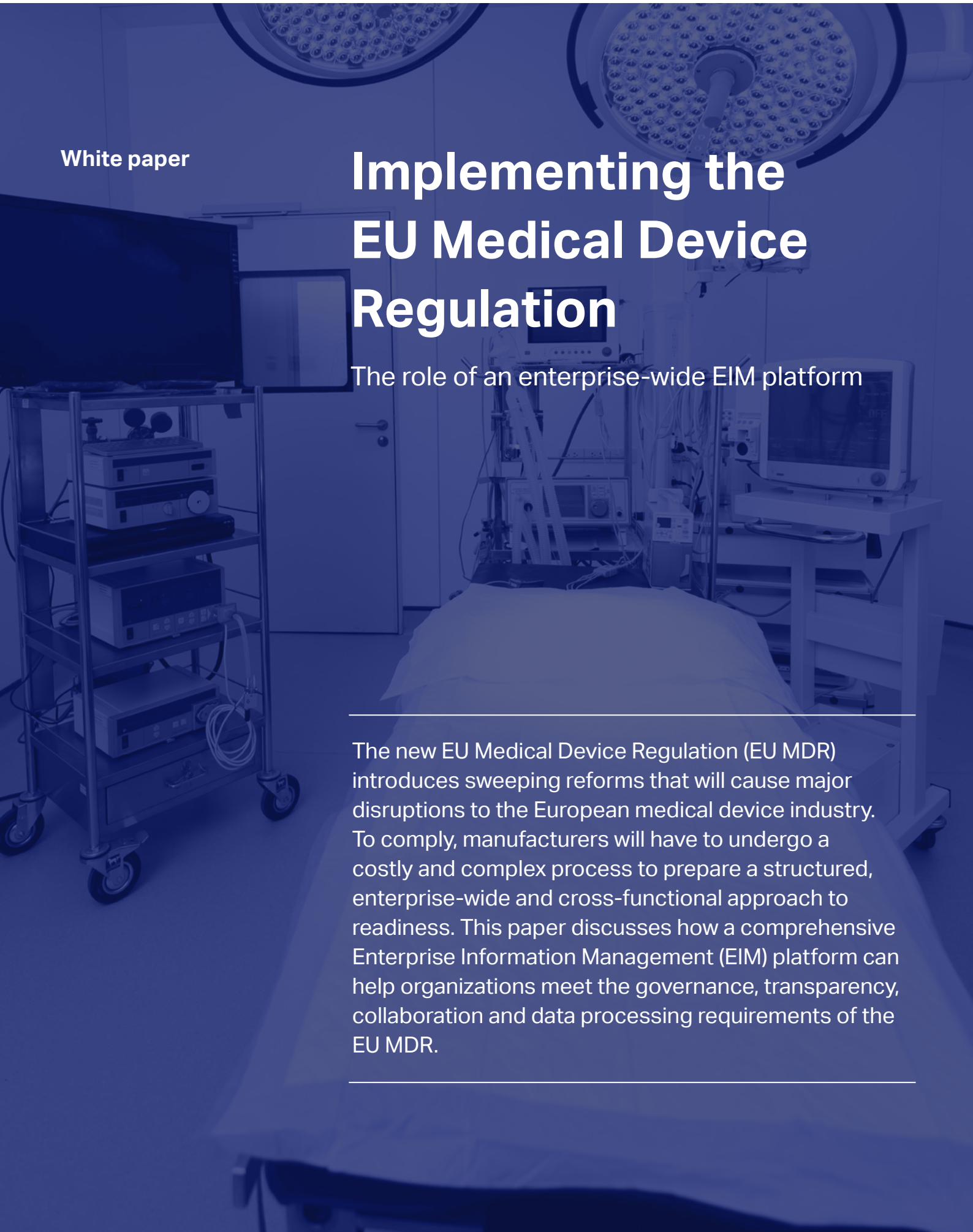
opentext™

White paper

Implementing the EU Medical Device Regulation

The role of an enterprise-wide EIM platform



The new EU Medical Device Regulation (EU MDR) introduces sweeping reforms that will cause major disruptions to the European medical device industry. To comply, manufacturers will have to undergo a costly and complex process to prepare a structured, enterprise-wide and cross-functional approach to readiness. This paper discusses how a comprehensive Enterprise Information Management (EIM) platform can help organizations meet the governance, transparency, collaboration and data processing requirements of the EU MDR.

opentext™

Contents

opentext™

EU MDR: Risk or opportunity?

The EU MDR came into force in May 2017 and the industry is now in a three-year transition period. The regulation replaces and updates the Medical Device Directive (MDD) and makes compliance a legal requirement in all of the 28 EU member states. With a wide impact, the scope of the new regulation will require significant investments and new ways of working for all medical device companies. As well as business processes, the EU MDR requires new enterprise-wide technical capabilities. How should manufacturers and their partners respond?

Analyst group EY describes the EU MDR as 'a complex change program–a paradigm shift even–after which nothing will look quite the same'.[1] There is no question the new legislation is needed, as it replaces and updates a medical directive from the mid-1990s. In fact, its introduction was accelerated by a series of high-profile incidents regarding medical device safety which undermined public trust in the industry.

EU MDR: A timetable for transitions

2017	2018	2019	2020	2022	2023	2024
EU MDR published in European journal	Notified Bodies start issuing certifications	ISO 13485 . 2016 effective	EU MDR required for new devices and recertification	MDD Annex IV certifications expire	All MDD certifications expire	EU MDR required for all devices

A focus on data and information

The new regulation is designed with two key tenets in mind. First, it aims to increase patient safety. Second, it increases the transparency of the business operations and supply chains of medical device manufacturers to help build public trust. Under the new regulation, medical device companies will have to:

- Provide substantially more clinical evidence to get products to market and ensure legacy products remain available.
- Present a structured approach for data and content within technical files.
- Ensure a great deal of product and business data is made publicly available, mostly through the EUDAMED database.
- Introduce unique identifiers and substantially re-label all products.
- Increase the communication, collaboration, data sharing and visibility across their supply chains.
- Establish an enterprise-wide Quality Management System (QMS).
- Improve information provision, communication and collaboration with Notified Bodies (NB) and Competent Authorities.
- Expand post-marketing surveillance activities and enable faster vigilance reporting.

1 EY. *How the new EU Medical Device Regulation will disrupt and transform the industry (2016)* http://www.ey.com/Publication/vwLUAssets/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry/$FILE/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry.pdf

While new regulations are often seen as the domain of the regulatory or compliance departments, organizations need an open, cross-functional approach to implementing the EU MDR, including production, marketing and supply chain management as well as distributors, importers and other economic operators in the supply chain.

Global consulting firm, North Highland, says "a strategy that starts with both holistic business and technology architecture can establish a foundation for true compliance and sustainable efficiency".[2] While the business implications of the EU MDR have been widely discussed, the need for an enterprise-wide information management platform has yet to be fully explored.

Why every medical device company needs to embrace the EU MDR

While the EU MDR covers medical devices within the EU, it is a regulation that no manufacturer can ignore. Europe is the world's second largest medical technology market. It represents about 30 percent of the entire market–estimated to be worth €100 billion annually.[3] In the past, some manufacturers have brought their products to market first in Europe to collect clinical data to support their application for US FDA approval.[4] In order to continue operating within the European market, even as an OEM to Own Brand Labels (OBL), companies need to be EU MDR compliant.

EU MDR and Enterprise Information Management

Transparency is perhaps the key goal of EU MDR and is mentioned no fewer than seven times in a preamble statement for the regulation. The EU MDR gives the following definition:

Participating in the EUDAMED database is a key way to provide transparency. To fulfill their obligations, companies must provide a large amount of information and data, for example, device history and clinical investigations. Currently, all of that data is stored in a number of different formats in a variety of enterprise applications and databases. Companies must be vigilant on data entry as the data quality is consistently very high.

Enterprise information requirements for the EUDAMED database

EUDAMED							
Information requirement	eSystem for Notified Bodies and certifications	eSystem for registration of devices	eSystem for UDIs	eSystem for clinical investigations	eSystem for registration of economic operators	eSystem for post-market surveillance and vigilance	eSystem for market surveillance
Public Access	Open	Open	Open	Limited	Open	Limited	Limited

2 The North Highland Company. *Leveraging Regulatory Disruption (2017)* http://info.northhighland.com/hubfs/LeveragingRegulatoryDisruption.pdf

3 Klein, Thomas. Biocat Special Report 2015, *The medtech revolution: the European medical technology industry (2015)* http://informe.biocat.cat/en/the-medtech-revolution-the-european-medical-technology-industry/

4 EY. *How the new EU Medical Device Regulation will disrupt and transform the industry (2016)* http://www.ey.com/Publication/vwLUAssets/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry/$FILE/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry.pdf

opentext™

To meet the full range of information management requirements, companies need to implement an effective enterprise-wide technical platform. Modern EIM is perhaps the only platform that has the breadth of business process and technical capabilities to help companies:

- Manage and control all data and content centrally within the organization.
- Handle and exploit structured and unstructured data wherever it resides.
- Access structured and unstructured data seamlessly to enable effective digital business processes and workflows.
- Eliminate data silos by identifying and extracting information from wherever it resides.
- Create closer, more effective relationships with customers, suppliers and other trading partners.
- Deliver enhanced data security and data sovereignty for all corporate data.
- Use advanced analytics to improve performance and decision-making in areas such as product development and supply chain operations.
- Comply with global regulations, industry standards and customer mandates.

With EIM, digital businesses take full advantage of the information within their enterprise. Providing seamless integration with other key enterprise applications, such as ERP, CRM and PLM, it allows for end-to-end business processes that improve operational performance. Medical device manufacturers can implement a single, centralized platform to meet the technical requirements for data of the EU MDR.

The EIM ecosystem

Enterprise Content	Business Process	Customer Experience	Analytics	Discovery	B2B Integration
Manage, store and share all the information and data within your organization	Adapt and optimize business processes and workflows across your organization	Deliver positive omnichannel engagement for every customer interaction along the customer journey	Gain control and actionable insights from all your organization's data to drive improved decision-making	Quickly and efficiently search, extract, classify, review and analyze content anywhere in your organization	Deliver effective communication and collaboration with customers, trading partners and your supply chain

The role of EIM for key EU MDR provisions

Manufacturers should take time to understand how their technical architecture will help them respond to and comply with the many provisions within the EU MDR.

Technical files and documentation

Many technical files are sub-standard and issues are often missed by Notified Bodies. For the first time, the EU MDR prescribes a detailed format for technical documentation. All product information, whether for new or legacy products, will need to follow this format. Essential requirements will now be referred to as General Safety and Performance and all checklists will need to be revised. All product and product family files will need to be checked carefully and will require some level of conversion.

The role of EIM

An EIM platform will allow an organization to quickly identify and retrieve all technical files that need to be analyzed and to find any gaps. Organizations can quickly amend, approve and implement technical files to meet the new format requirements.

opentext™

"Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system."[5]

Clinical trials and evidence

The EU MDR greatly increases the requirement for in-depth clinical evidence, especially for Class III and implantable devices. For example, clinical investigations will be mandatory for all Class III applications and stored in interoperable systems with a new version of the European Clinical Trials Database (EudraCT). A robust process is required to update Clinical Evaluation Reports (CERs) with Post-Market Clinical Follow-Up (PMCF) data. Indeed, all products will require more focus on post-market surveillance activities.

The role of EIM

Clinical teams are often siloed, which introduces potential risk and uncertainty into clinical trials. EIM provides more clinical resource integration across the organization. Beyond compliance, an EIM platform can improve business processes in areas such as forecasting, risk management and external scrutiny from NBs and CAs. The platform can quickly provide a detailed analysis of what clinical data is available and where new data is required as well as demonstrate that the correct clinical data is available for products where organizations are claiming equivalence.

Device assessment and classification

The definition of medical devices has been significantly modified under the EU MDR. Devices that were previously excluded are now covered and existing product information is likely to need updating or changing. Detailed information, such as technical files, clinical data and product traceability requirements have to be considered. The new EU MDR requirements, such as the need for extra clinical trials data, may lead manufacturers to rationalize their product portfolios.

The role of EIM

An EIM platform can facilitate the process of updating information to ensure compliance of individual products and automate the process of maintaining compliance across the product's lifecycle. In addition, advanced analytics capabilities can quickly identify where there are information gaps and highlight products that may be costly to update to meet the EU MDR stipulation.

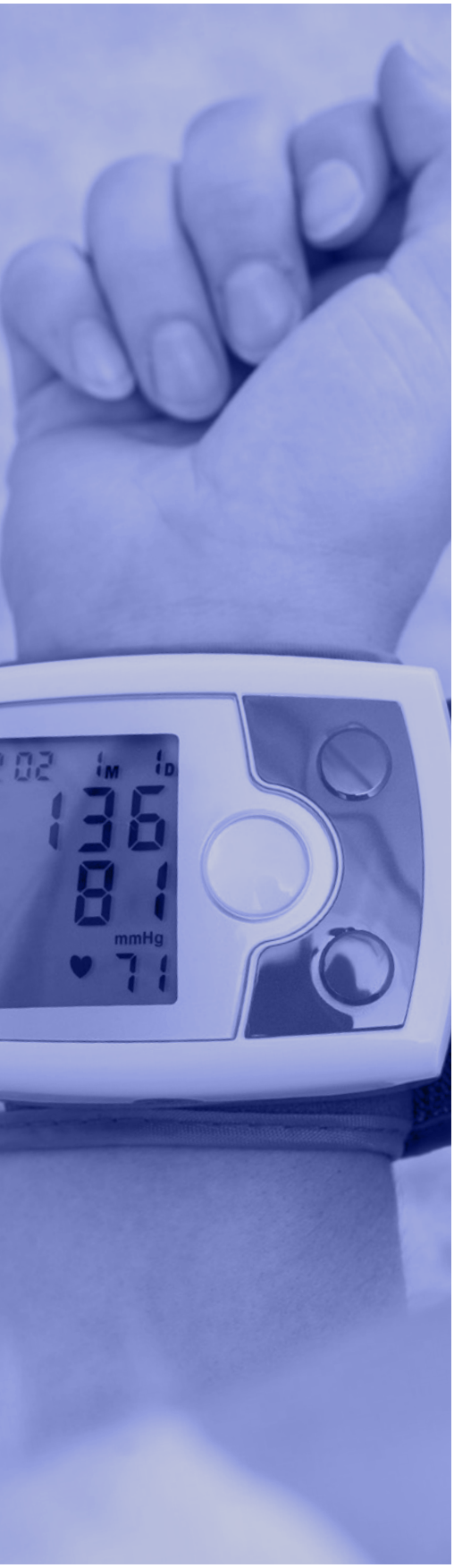
Quality Management System

EU MDR encourages the concept of 'quality beyond compliance' but, like clinical teams, quality has often become siloed across the organization. Manufacturers need to take an enterprise-wide approach that is coordinated across quality plans, manuals, documents and records to drive consistency and remove error and risk from operations. It is no coincidence that the EU MDR adoption has followed a similar timeframe to the implementation of ISO 13485:2016 (the standard for quality management systems deployed within medical devices organizations) as the EU MDR is really designed for the implementation of this standard.

The role of EIM

An effective EIM platform will integrate seamlessly into the manufacturer's chosen Quality Management System to provide in-depth document and records management capabilities. It will also be able to draw data from other enterprise applications to reduce risk while enabling information transparency and continuous improvement.

5 The European Parliament and the Council of the European Union. *REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (2017)* http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0745&from=EN



UDI and labeling

Product traceability is key to the EU MDR. The introduction of a Unique Device Identification system, likely to be similar to the US system, will allow manufacturers to track their products from production to patient. Manufacturers will have to add UDI information to all products on EUDAMED and importers will have to add their details to product registrations. In addition, the regulation stipulates that product labels include much more rich data. Manufacturers must ensure that appropriate information is correctly displayed on product labels, supporting materials and corporate websites.

The role of EIM

Organizations can automate the provisioning of UDI information from UDI suppliers and the updating of EUDAMED. All UDIs can be administered centrally to ensure ease of auditing and compliance. If required, the UDI can be associated with appropriate labeling information. With the EIM system, organizations can rapidly create and approve new EU MDR-compliant product labels and automatically ensure the correct label information is on the supporting marketing materials and corporate website in the acceptable languages for the countries where the product is distributed.

Supply chain visibility

For the first time, all 'economic operators' are covered by the EU MDR regulation and everyone needs to be compliant. This requires that all the products from suppliers must comply. A manufacturer needs to know their supplier and their supplier's suppliers are compliant. In addition, the manufacturer must work closely with importers and distributors to ensure that no part of the supply chain contravenes the legislation. Everyone involved in a product's supply chain will need to collaborate and communicate more closely than before and all contract provisions will need be reviewed to ensure supply chain activities are compliant.

The role of EIM

A central EIM platform provides a powerful and secure means for all trading partners to exchange all content and data. All documentation surrounding supply chain activities are managed in an EU MDR-compliant fashion. The manufacturer, as well as NBs and CAs when required, gain end-to-end visibility across all supply chain processes. Advanced analytics drive continuous improvement and pre-emptively highlight risk areas within the supply chain, improving the quality of decision-making.

Post-market surveillance and pharmacovigilance

The EU MDR places great emphasis on post-market surveillance and there is a clear expectation that manufacturers will implement systems and processes around clinical vigilance, field safety corrective actions and trending activities to allow for fast remediation where product issues are identified—especially for Class III and implantable products. The timeline for reporting serious incidents has been slashed to 15 days and new electronic vigilance forms are likely to be introduced to correspond with the new requirements. The mandatory submission of Periodic Safety Update Reports (PSUR), combining post-market surveillance, clinical and risk-benefit assessment data, adds to the administrative and cost burden of post-market surveillance for medical device organizations.

opentext™

The role of EIM

To perform effective post-market surveillance, organizations increasingly must draw data and information from a wide range of sources, including social media channels, wearable IoT devices and healthcare apps. They will be required to provide more accurate trending information. An EIM platform brings together structured and unstructured data from a wide range of sources. It can facilitate the creation and automated updating of key forms such as the PSUR.

Using EU MDR for competitive advantage

There is no doubt organizations must invest significant time, effort and cost to comply with the EU MDR. The investment is so substantial that it can't simply be written off as a "cost of business." Companies should see the road to EU MDR compliance as an opportunity to reassess business strategies and product portfolios.

Meeting the EU MDR requirements means adopting an enterprise-wide, cross-functional approach to change. If conducted effectively, this will result in a more efficient, agile and productive business.

This requires a comprehensive EIM platform that can connect everyone within the organization, as well as all relevant trading partners, to deliver the data and content they need quickly, efficiently and, most importantly, in full compliance with the EU MDR requirements.

About OpenText

OpenText, The Information Company™, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: opentext.com.

Connect with us:

- OpenText CEO Mark Barrenechea's blog
- Twitter | LinkedIn | Facebook

opentext.com/contact