



**KALYPSO**

# **Achieve Market Advantage While Streamlining Regulatory Compliance**

**EU MDR STRATEGIES REVEALED**

By David Wolf and Jennifer Petrosky



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## Executive Summary

When the EU's new Medical Devices Regulation (MDR) was published 2017, it set in motion a three-year countdown to full compliance by May 2020. Here are our practical recommendations for achieving market advantage while streamlining regulatory compliance.

The medical device industry is undergoing a transformation as the new European Union Medical Device Regulation (EU MDR) is set to replace Medical Device Directives (93/42/EEC) and Active Implantable Medical Device Directive (90/385/EEC) by 2020.

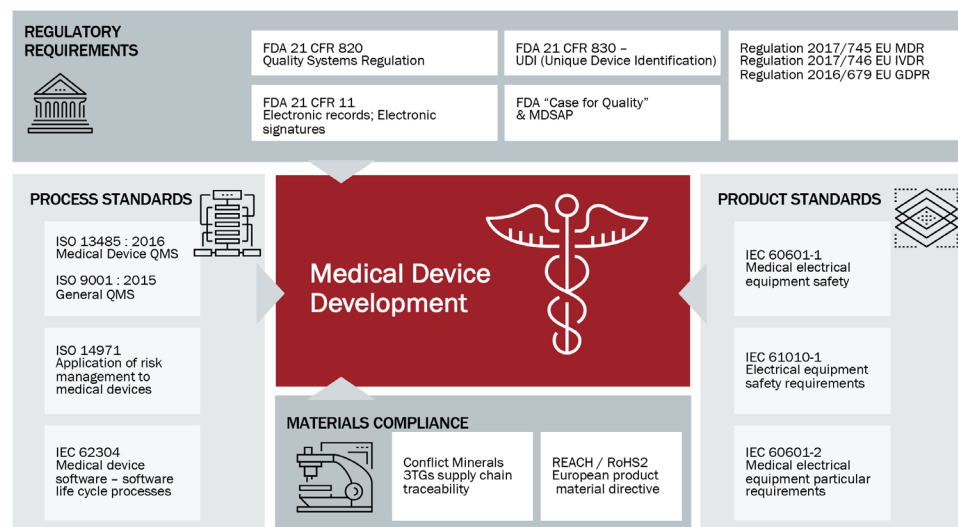
The EU MDR, which was published in the *Official Journal of the European Union* on May 5, 2017, is aimed at restoring confidence in the European regulatory system after widespread safety issues and corrupt notified body engagements. These regulations are directed to increase post-market surveillance, expand the use of unique device identifiers (UDIs) and provide better oversight of notified bodies.

Grandfathering previously-approved medical devices is not allowed, and non-compliant companies worldwide will be unable to participate in the EU market until they are certified. Considering the significant size of the market (Maetrics estimates \$16.469 billion), risking non-compliance is clearly unwise.

Of course, compliance is just one piece of the puzzle. In addition to new EU MDR regulatory requirements, medical device companies will have to comply with evolving regulations in other regions of the world, all while solving the number one goal at hand; making safer and more effective devices and transitioning to an outcome based innovation model.

Companies can't afford to ignore or delay EU MDR compliance, but they also can't afford to stop thinking about how to innovate and stay competitive. As companies rethink their current strategies amidst the evolving regulatory landscape, there is a sizeable opportunity to proactively take market share from competitors by becoming an EU MDR compliance pioneer.

### Current Regulatory Challenges for Life Science Companies



## WHAT'S STOPPING US?

The challenge is not new. Medical device companies have always had to drive growth in a complex regulatory landscape. But the traditional ways they've approached this issue may no longer be sufficient.

Many companies have taken a people-focused approach, since many potentially high-value resources are often wasted on low-value or redundant tasks. There's certainly no reason for an engineer to redesign a simple part that already exists, or for regulatory personnel to spend hours creating documentation they can easily get from a proper quality system. But is a people-focused strategy enough?

Others have focused on process and technology, working to connect the enterprise with a common data-centric approach. The major stumbling block

here has been around accessing data stored in different systems, especially for companies with more than one product lifecycle management (PLM) system due to mergers and acquisitions.

In today's digital, connected world, new technologies like role based apps, IoT and advanced analytics show promise and early value in connecting the enterprise, but many executives are cautious to adopt given strict regulatory requirements.

So, what's the solution? Can companies rapidly overcome the challenges of multiple data systems? Is the promise of fully connected digital enterprise real? How can medical device companies innovate through compliance?

## A BETTER WAY FORWARD

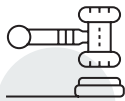
There is a better way. Companies can achieve EU MDR compliance and innovate with new digitally-enabled products, processes and business models. With a strong PLM backbone in place offering cleaner, more consolidated product data, leading companies can capitalize on key IoT use cases like post-market surveillance, automated standard regulatory reporting, real-time asset monitoring, and connected manufacturing operations.

**Success requires a phased approach to consolidating, connecting and harmonizing cross functional teams, systems and processes.**

## EU MDR: A Review of What's Changing

It's worth restating some of the key requirements that will change with EU MDR, which puts a growing emphasis on product quality and post-market surveillance.

### WHAT'S CHANGING?



1. Stricter premarket scrutiny and controls with the involvement of a pool of experts at the EU level



2. Requirements and oversight of notified bodies



3. Increased liability for authorized representative



4. Inclusion of some aesthetic devices (risk-based)



5. Improved transparency (Eudamed and UDI)



6. Improved patient communication via implant cards



7. Reinforcement of the rules on clinical evidence



8. Coordinated procedure for authorization of multi-center clinical investigations



9. Stronger post-market surveillance requirements



10. Improved coordination between EU countries in the fields of vigilance and market surveillance

The clock is ticking, and for many companies there's a lot to do to achieve compliance. By leveraging a phased approach with a strong PLM backbone, layering in pre-built software accelerators, and taking advantage of key digital technology, medical device companies can be compliant while positioning themselves to compete in the long-term.

## Start with a Strong PLM Backbone

Today's leading companies leverage PLM systems to efficiently manage the product quality and compliance backbone, which helps facilitate the compliance journey.

PLM can close the loop and provide full product traceability from 3D CAD-based digital product definition through regulatory information management (RIM), post-market surveillance and back to product development in one integral process.

This holistic PLM foundation allows companies to optimize their core business processes while managing mechanical, electrical and software bill of materials (BOMs) over the entire product lifecycle.

For the PLM backbone to support and enhance quality processes, **there are two main considerations: getting data out of siloes and harmonizing PLM and quality management systems (QMS).**



### Get Data Out of Siloes

The most common challenge with implementing PLM holistically is consolidating data within siloed systems and standardizing common processes across multiple departments. Siloes compound product complexity which results in increased quality costs. In fact, McKinsey estimates the opportunity to improve the total quality costs for the medical device industry is \$4.75 to \$6 billion, as documented in The Business Case for Medical Device Quality.

Product data is typically spread among numerous systems including legacy PLM, computer-aided design (CAD), enterprise resource planning (ERP), and manufacturing execution systems (MES). Product data can also be hidden in home-grown systems, shared drives, Excel files, and embedded in email communications.

The key to overcoming siloes while becoming compliant with new regulations is to perform a data assessment that's harmonized with portfolio rationalization efforts. This strategy provides a prioritized roadmap of consolidation, integration and migration efforts on a product by product basis. With this roadmap in place, companies can choose to leverage digital technologies like product lifecycle intelligence (PLI) or robotic process automation (RPA) to clean up, structure, migrate and validate data. Getting data out of siloes is necessary for optimizing product quality and compliance as well as preparing the organization for future growth.



### **Harmonize PLM and Quality Management Systems**

Harmonizing PLM and QMS is a critical step in closing the feedback loop. When companies incorporate corrective and preventive action (CAPA), complaint, and nonconformance data within a holistic design process, they begin the shift from corrective to preventive, thus reducing the cost of poor quality.

Further integration with regulatory management functionality completes the backbone of product quality and regulatory compliance. Product quality integrated with product compliance expedites the regulatory submission process and provides traceability to registrations across multiple jurisdictions. The regulatory documentation data package no longer lags engineering innovation but instead becomes a direct output of the design process.

## Layer on Accelerators

With a solid PLM backbone in place, companies can layer on additional capabilities to accelerate benefits and get the most out of the system. Pre-configured accelerators leverage industry-leading practices to solve specific compliance challenges quickly, with minimal customizations.

These leading practices are based on experience in the field; implementing leading edge technologies and leveraging frequent benchmarking.

**Accelerators are designed to answer specific strategic questions like these.**

### ► WHERE ARE MY PRODUCTS REGISTERED?

Today, most medical device companies struggle to understand which products are approved for use in which markets. It can take days to track down this information, especially when it is scattered in spreadsheets across the globe. A regulatory information management (RIM) solution can help organizations plan and track the status of worldwide product registrations by fully integrating regulatory and product development landscapes and processes.

RIM can be integrated with ERP systems so shipping controls are harmonized with regulatory status and product change control. The International Medical Device Regulatory Forum (IMDRF) Table of Contents can be dynamically linked to the Design History File (DHF) to enable easy construction of regulatory submission packages and regulatory files (such as EU MDR Technical Documentation). Advanced searching, reporting, notifications and auditing features allow organizations to track pending expirations, analyze cycle times, spot key trends and identify problems in their infancy stages. RIM solutions offer a lot of potential benefits but can be more effective when deployed via an accelerated, leading-practice delivery model. A RIM accelerator is a great starting point for organizations beginning their EU MDR journey and helps foster an environment that can be easily expanded to incorporate design controls, document controls, supplier controls and quality management.



## ► WHAT IS MY PRODUCT STRATEGY?

There has been tremendous consolidation across the medical device industry in recent years.

One widespread implication is that companies fail to capitalize on positioning existing products from separate business units in new markets.

Product Lifecycle Intelligence (PLI) connects the dots between the newly consolidated systems as well as the multitude of siloed legacy systems and allows companies to gain immediate insight in current product and portfolio strategies. By applying advanced analytics to structured PLM data with PLI, companies can prevent quality and regulatory compliance issues from impacting patients and medical facilities.

PLI can also be used to generate a compliance cost model based upon existing compliance gaps using advanced analytic algorithms. This can help determine which product lines to update or retire, and more accurately identifies the true root cause(s) of compliance problems.

Once integrated to existing systems, PLI can be used to prevent issues from leaving the factory or from occurring in the first place, saving significant amounts of money that are otherwise lost due to the cost of poor quality.

## Predict Success and Mitigate Risks

Best in class companies are leading with exciting, strategic uses of digital technology including smart connected products and operations, augmented reality, the digital twin and embedded Internet of Things (IoT) platforms. These new technologies help them comply with evolving regulations while maintaining a competitive advantage, so they can deliver advanced innovation more quickly without sacrificing quality and reliability.

Manufacturers have huge volumes of data collected as part of the product development and manufacturing processes and beyond. Companies can leverage this data via advanced analytics to predict and prevent issues from occurring in the first place. This is extremely important, as the FDA Case for Quality (CfQ) has plans to score medical device manufacturers on common KPI's, and to reward or punish firms based upon their product data. Manufacturers with top scores may be allowed to self-audit and perhaps streamline a pre-audit inspection prior to releasing their product to market. Those on the bottom will be forced to complete a type 2 audit and lengthy pre-approval inspection process.

### **The FDA Case for Quality and UDI developments in the United States is a blue print for the new EU MDR governance model.**

Companies can leverage CfQ-based PLM with PLI to strengthen analytics capabilities to diagnose root causes, predict future performance and prescribe improvements that reduce cost of quality, enhance compliance, and offer assurance into the performance of their products and the outcome of critical procedures.

Early pioneers are using advanced analytics to track signature failures in products using algorithms. Companies can place watchdogs for the exact data patterns captured by PLI to prevent specific quality issues.

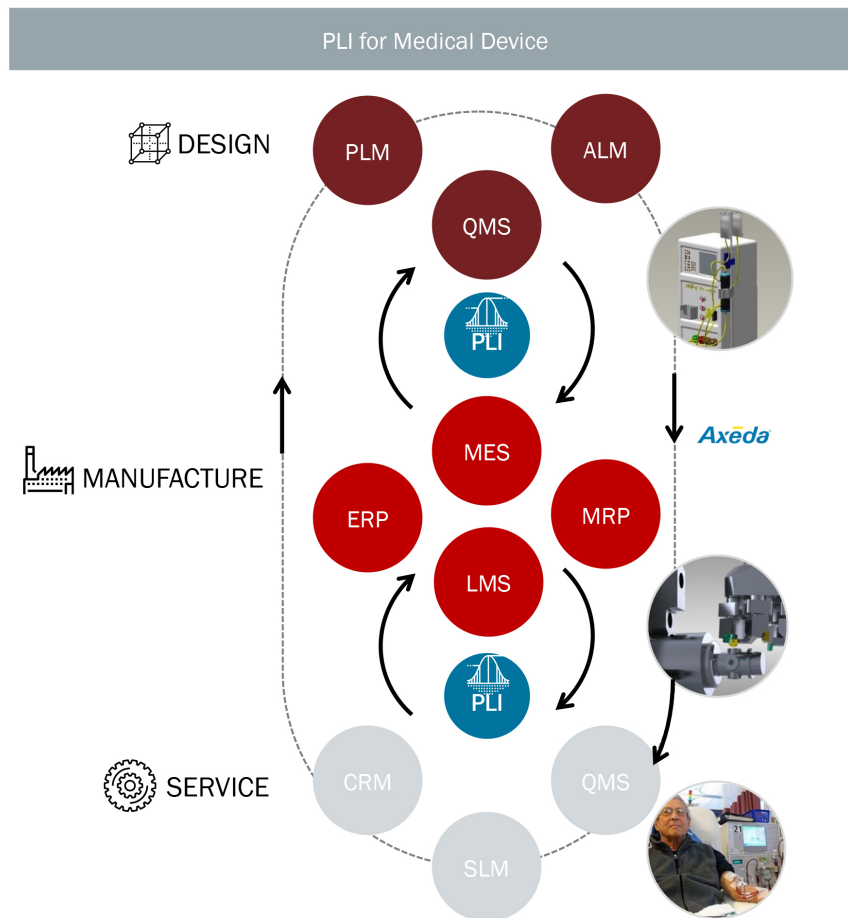
The next stage of PLI can be used to capture data across ERP, MES, and master data management (MDM), to generate data failure patterns across multiple systems, expanding failure detection capabilities. This also aids companies in identifying root causes of failures in a shorter time frame to contain quality issues and reduce recalls by being nimble with their quality data.

Beyond detection and root cause analysis, PLI has additional use in monitoring post-market surveillance data and field data from sensors embedded in devices. Role Based Apps make it easier for 80% of the users to find information when they don't need super user access to various systems like ERP, PLM and MES. They provide a simplified user interface, which helps companies achieve better adoption rates with new software and can be accessed via hand held devices.

Detected failures may be defined and acted upon. PLI can define the harms, hazards, and risk priority numbers on the actual product that is managed in PLM which is directly associated with a 3D CAD model. As soon as failures occur, service technicians can be deployed, and the criticality of the failure can be readily assessed. For example, in the case of a critical failure on high risk products, regulatory reports can be autogenerated and corrective actions prioritized, reducing the chance of a warning letter for late regulatory reporting.

**Cutting edge companies are also using IoT and PLI to reduce up to 30% of their service costs. When an issue occurs, they can send software patches or reboot devices remotely instead of sending out a service technician.**

### Role Based Apps & PLI Algorithms



Medical device companies can use PLI to help navigate their current compliance journeys and create a sustainable set of solutions to rapidly assess and prepare their product portfolios for future regulations. When coupled with the consolidated PLM and harmonized product quality and compliance systems, PLI will push companies from corrective and preventive actions, reduce the cost of poor quality, and expedite new product introductions across multiple regulatory jurisdictions.

## Conclusion

To remain innovative and competitive while keeping up with evolving regulatory changes, companies need to pioneer cutting edge software solutions while consolidating core enterprise systems that store key compliance and quality data.

By exploring new capabilities and gaining greater maturity in PLM with cleaner, more consolidated product data, today's leaders manage compliance proactively and leap frog the competition.

In addition, these companies can capitalize on this data holistically to deploy key role-based applications – like RIM and advanced analytics. This helps medical device manufacturers become more flexible and responsive when responding to new regulations, with the additional benefit of creating a repeatable process that can be leveraged for future regulations.

Companies can get started with a variety of key initiatives, including data migration assessments, consolidation of source systems, harmonizing regulatory information management and using new technologies like role-based applications, IoT and advanced analytics. Every company has a different set of products, processes and architectural landscapes, but most are looking for a common repeatable process to achieving compliance with new and evolving regulations.

We strongly recommend considering role-based applications and advanced analytics for EU MDR requirements such as Unique Device Identification/Basic UDI (UDI/BUDI-DI), Periodic Safety Update Report (PSUR), Summary of Safety Clinical Performance (SSCP), Trending Reports, Periodic Summary Reports, Post Market Surveillance Reports, and Registrations/Submissions.

**However you decide to get started, waiting is no longer an acceptable strategy. We're excited about the massive potential for medical device companies to leverage cutting edge digital technologies to enhance regulatory compliance, compete and win with innovation, and better serve patients.**



## Getting Started with EU MDR Compliance

The best recommendation we can offer is don't wait. You can develop and implement a proactive EU MDR strategy right now.

### HERE ARE SOME LOGICAL STARTING POINTS

1. Perform Quality System and Data Management system infrastructure gap assessments
2. Identify a data migration strategy and start moving on it now
3. Develop a communication plan for use at the program, division and business unit levels. Make sure to adapt the following messages to their corresponding audiences:
  - What is the MDR?
  - Why was it released?
  - When will it be implemented?
  - How will it impact the organization, customers, products, and the quality system?
  - What is the company doing right now to prepare?
  - What is needed from each level of the company?
  - What measures are in place to ensure issues are escalated and addressed transparently?
  - What are the positive outcomes to expect following transition?

You can also run a mock audit to assess the product portfolio and understand the cost of compliance. Create a team of cross functional subject matter experts that will be responsible for specific processes and user adoption. Pick your notified body and schedule your EU MDR certification based upon your portfolio strategy. Get involved with groups like MedTech Europe and partner with experienced professionals to help guide you through your EU MDR compliance journey.



## About the Authors

### Jennifer Petrosky



Jennifer Petrosky is a Senior Manager at Kalypso and brings over 18 years of professional experience to our clients.

She is responsible for driving revenue and developing new business for the Life Sciences industry by developing and supporting global marketing strategies which include conducting market research and identifying market opportunities for Kalypso services and offerings and working with marketing team, partners, and business development leaders to drive revenue.

*jennifer.petrosky@kalypso.com*  
*+1-704-773-9780*

### David Wolf



David is a Senior Manager and Biomedical Auditor with over 25 years of experience in the life sciences industry.

He's designed 3D assemblies, manufacturing toolpaths, submitted patents and personally worked with doctors all over the world to validate and release several product lines.

*david.wolf@kalypso.com*  
*+1-720-320-7340*

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Kalypso has a long history of supporting medical device companies and they improve innovation performance that delivers sustained results and bottom-line growth.

We partner with our clients to implement innovation capabilities throughout the development lifecycle in order to deliver commercially successful devices, products and services that meet today's evolving healthcare needs.

We do this by developing and operationalizing strategies, organizational structure and processes; aligning them with regulatory requirements; and enabling with technology.

**PLEASE REACH OUT TO DISCUSS STRATEGIES TO HELP  
YOU ADDRESS YOUR EU MDR REQUIREMENTS TODAY.**

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