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UNITING QUALITY AND PLM IN MEDICAL DEVICE

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Controlled innovation, including broad patient participation in clinical trials, has been key to the success of every medical device manufacturer. Quality in this context means much more than simply driving down the costs of line failures, scrap, rework, and warranty claims. Though critically important to profitability, reducing the costs of poor quality is insufficient without also delivering positive patient outcomes, reducing the number of adverse or severe events, and the ability to rapidly respond to an event should it occur. With European Medical Device Regulations (MDR) deadlines closely approaching, the task gets even harder. This knowledge brief explores how the digital thread, with a foundation of PLM, can be leveraged for improving quality management in this innovative, but regulatory-oriented, environment.

Are You Quality Driven?

The medical device industry is often characterized by relationships: between organizations, with companies in other industries, and with the people installing and utilizing their products. There are steep barriers that prevent new companies from breaking into this industry: high R&D costs, patents, and FDA regulations. Thus, competition is concentrated among the handful of large organizations that dominate the industry. Furthermore, the electronics and high-tech, biotechnology, telecommunications, and other industries influence innovations within the medical device field — requiring companies in this space to both collaborate as well as compete with those outside the space. Medical device companies also have the unique opportunity to collaborate with physicians and patients for research and data gathering purposes — expanding their reach among consumers.

To maintain their relationships, medical device manufacturers must be hyper-focused on the quality of their products. Low-performing products or poor-quality management processes can close doors with cooperating industries
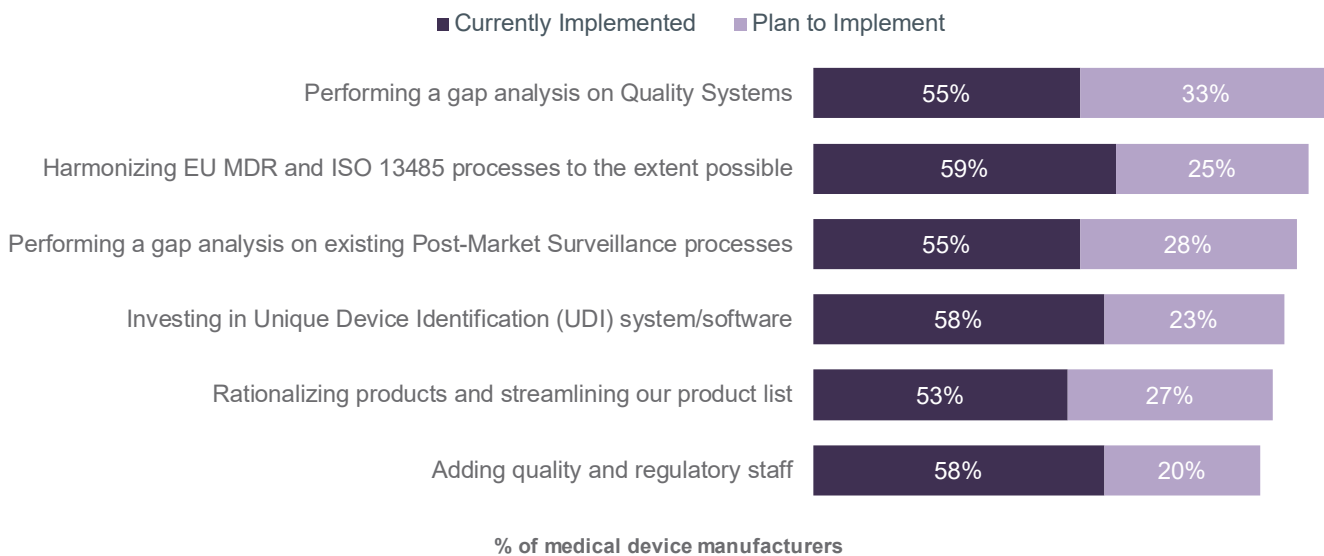
and consumers, and open doors for the competition to capitalize on these mistakes. Quality and safety measures are also at the forefront of the medical device field because of EU MDR, which goes into effect in May 2020 and will influence a wide range of production, distribution, and data collection processes.

Analysis of preparations for EU MDR show how organizations are revamping quality management. Best practices for implementing these changes are valuable for medical device manufacturers to optimize PLM capabilities. By examining how quality is integrated with PLM, specifically for medical products and by determining methods for strengthening connections between QMS and PLM systems, companies can successfully improve the entire product development cycle.

Preparations for EU MDR Revolve Around Quality

EU MDR deadlines are quickly approaching. Over the past three years, manufacturers have been working tirelessly to recertify current devices with the new regulations as innovation continues to progress. Data from a previous Aberdeen survey on PLM digitization reveals the specific steps organizations have been taking to prepare for EU MDR (Figure 1).

Figure 1: How Medical Device Manufacturers are Preparing for EU MDR

■ Currently Implemented   ■ Plan to Implement

	Currently Implemented	Plan to Implement
Performing a gap analysis on Quality Systems	55%	33%
Harmonizing EU MDR and ISO 13485 processes to the extent possible	59%	25%
Performing a gap analysis on existing Post-Market Surveillance processes	55%	28%
Investing in Unique Device Identification (UDI) system/software	58%	23%
Rationalizing products and streamlining our product list	53%	27%
Adding quality and regulatory staff	58%	20%

% of medical device manufacturers

n = 393, Source: Aberdeen, March 2020

Gap analyses and consequent adjustments to quality systems are at the top of the list, indicating that quality systems are the first areas that need to be updated for EU MDR compliance. Building in EU MDR compliance capabilities or converting to a QMS platform with inherent EU MDR compliance are two paths for ensuring compliance moving forward.

Post-Market Surveillance is also a critical quality procedure. Gap analyses on these processes will enhance manufacturers' ability to gather the required amount of quality data set by EU MDR. Increasingly more detailed and accessible reporting for devices which are already on the market will also improve relationships with consumers. If physicians and patients can access real-time data from their devices, customer satisfaction ratings may increase.

It is clear that key quality processes must be updated to meet EU MDR standards, but how are these processes linked to PLM? With visibility into quality data across R&D, production and service, medical device manufacturers are better equipped to respond to problems quickly and expedite the release of product updates. However, linking PLM with medical device quality is not a priority for many organizations.

Linking PLM and Quality Processes Throughout the Digital Thread

Because of the high stakes of implantable devices as well as tight regulations such as EU MDR, medical product quality processes are extremely intricate in comparison to those for other products. Despite the need for more intensive data collection in the field, which is valuable for research and production teams, these quality processes are often disjointed from PLM platforms. Companies are more likely to establish systems of record than truly unify quality and PLM platforms to build the Digital Thread with all product related data associated with parts (Table 1).

Table 1: Linking Key Medical Product Quality Processes to PLM is a Low Priority

PLM Processes to Support Medical Product Quality and Compliance	% medical device respondents
Automate and enforce design control process	75%
DHF (Design History File) management	64%
DMR (Device Master Record) management	64%
System of record for products, policies, procedures, and documents	63%
System of record for Risk Management	59%
Key quality processes managed separately but link to PLM	53%
Key quality processes and PLM are unified in a single platform	50%
At least one quality process is unified with PLM in a single platform	48%
Key quality processes are managed separately with no linkage to PLM	47%

Automation of design control processes is important for manufacturers to consistently monitor quality compliance as new designs come into the factory. With EU MDR on the horizon, it is no surprise that automating quality checks of new designs is top-of-mind for many manufacturers. Yet, only 50% of medical device manufacturers have unified quality processes and PLM in a single platform — meaning one-half of companies still have not combined these platforms, potentially having trouble collaborating between teams regarding quality because of a broken digital thread of data.

With a unified PLM and quality platform, data collected from devices can easily be sent to teams across the business: R&D teams can quickly redesign device models and adapt to quality issues, production teams can react promptly to changes in designs, and service teams can communicate appropriately with physicians and patients. A single source of truth for all product lifecycle data, especially quality, is extremely beneficial for fostering and strengthening both internal and external relationships.
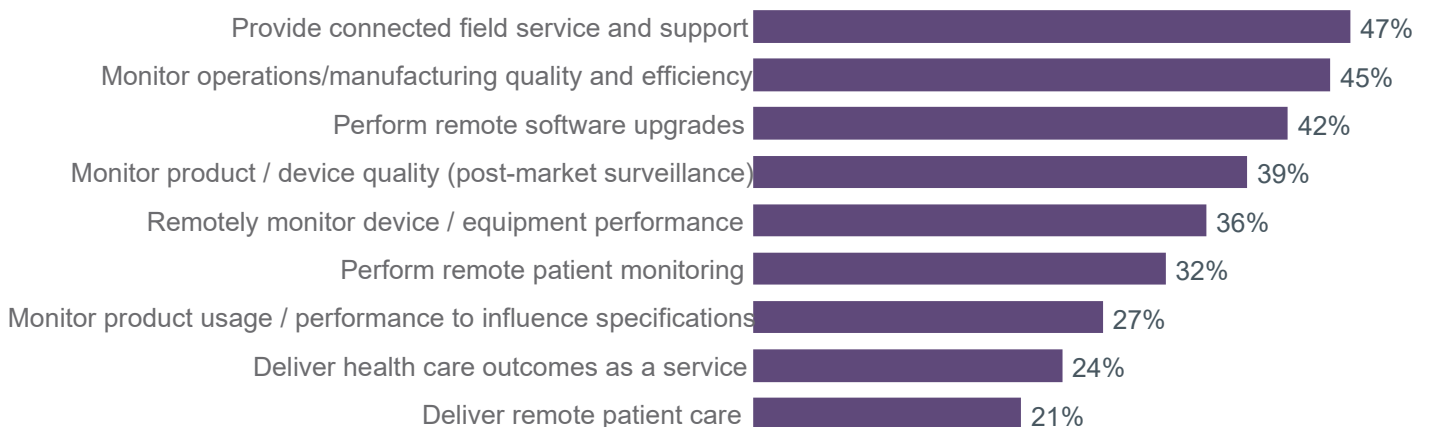
IoT Eases Integration

Between siloed data sources, growing product complexity, and the pressure to maintain customer satisfaction, the path for integrating QMS and PLM has many roadblocks. One method for smoothly transitioning to a single platform is IoT. With IoT, quality data can easily be transferred into the PLM platform and shared among the organization, collaborating companies, and end users.

Despite concerns surrounding the security of connected medical devices, medical device manufacturers have found a variety of ways to incorporate IoT into their processes (Figure 2).

The most common use case, connected field service and support, strengthens relationships with consumers. Technicians are the face of the organization and interact with consumers on a daily basis. Equipping technicians with IoT capabilities allows for better job performance, higher staff confidence, and an externally evident promotion of company values.

Figure 2: Current IoT Use Cases for Medical Device Manufacturers

Use Case	%
Provide connected field service and support	47%
Monitor operations/manufacturing quality and efficiency	45%
Perform remote software upgrades	42%
Monitor product / device quality (post-market surveillance)	39%
Remotely monitor device / equipment performance	36%
Perform remote patient monitoring	32%
Monitor product usage / performance to influence specifications	27%
Deliver health care outcomes as a service	24%
Deliver remote patient care	21%

% Medical Device Manufacturing Respondents

The second most common use case is quality and efficiency monitoring. Connecting quality to the rest of the product lifecycle through IoT allows technicians to continuously connect quality data in the field and relay that data back to engineers to inform modifications and upgrades. Combining quality and PLM through IoT is an efficient solution to many integration challenges.

Moving Forward

As EU MDR is finally coming to fruition in this relationship-dependent industry, quality is more important than ever. Using IoT as a catalyst for quality integration is one path companies can take to ready themselves for changes and respond to the impact these changes have on the market. Additionally, companies should focus on these three areas of quality management:

▶ Data Management – Data quality and accessibility to accurate, up-to-date product information is critical for driving continuous improvement and preventative quality control activities.

▶ Processes – Standardize and associate your quality processes with parts leveraging PLM. Virtually every responsibility in the organization can be tied to a process, including purchasing, by taking a part-centric approach

▶ Design and Document Control – With PLM as the foundation, look to tie together your strategic systems with the digital thread establishing the traceability and governance to prove performance objectively.

For more information on instituting closed-loop quality in manufacturing, read the full report, *Weaving Quality into the Digital Thread*. Quality management shines bright in many of these options because of its ties to efficiency, cost, and compliance. Focusing on improving quality can aid medical device manufacturers in their pursuit of a desirable image and healthy relationships within this concentrated, competitive, and innovative market.

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