6 Key Steps Medical Device Manufacturers Must Take To Successfully Navigate The Digital Maturity Curve

A White Paper from Kallik

KALLIK

Pressure from internal and external forces are changing the medical device landscape

Today's medical device companies face a host of challenges to their operational and financial success. Medical device products are becoming increasingly complex and technical, requiring companies to invest significant sums into product design, development and testing. This expensive R&D then necessitates enhanced protection of sensitive data and intellectual property against cyber-attacks, counterfeiters and other threats. These issues are underpinned by the constant threat of costly product recalls.

More time-critical is the raft of new legislation and regulations coming into force throughout this decade. Compliance is non-negotiable – whether this is for the phased implementation of the European Union's Medical Device Regulation (MDR) and In Vitro Device Regulation (IVDR) or upcoming UKCA marking requirements to sell products into the UK market.

Setting aside other industry challenges, the scale of these compliance efforts alone is now far beyond the capabilities of a manual team to handle quickly or comprehensively. Disruptive technologies may be posing industry challenges of their own, but for many C-suite leaders, they also hold the answer to addressing these ongoing threats to business.

Digital transformation comes to the fore post-pandemic

The COVID-19 pandemic placed digital transformation firmly at the top of the agenda for many organizations, faced with the task of effectively shifting to mass remote working and operations overnight. Indeed, C-suite research conducted by global consultancy McKinsey revealed the pandemic has accelerated digital transformation of both internal business processes and external services by up to four years.

For many medical device manufacturers, COVID-19 also marked a rapid strategic shift in the range of products developed, manufactured and sold – with ever-changing market demands in multiple geographies. The need to shift or scale-up production for products such as PPE, ventilators and other critical supplies significantly increased the demand for agility within these companies to survive challenging, fast-moving market conditions.

Beyond the pandemic, the focus on collaboration software, remote access and productivity tools for home working, will not stop the drive towards greater digital transformation. Tech analysts Gartner confirm this – global spending on cloud services alone is set to grow by over 18% to pass $304 billion in 2021.

Medical device companies are not immune to this wave of digitization, they must be part of it. Many organisations in the industry still operate paper-based systems or bloated spreadsheets for business-critical tasks. Technology's increasingly central role in delivering positive business outcomes, and replacing manual and legacy systems with paperless alternatives, means that by adopting centralized cloud-based solutions, medical device companies will find themselves on a much stronger footing to deal with future disruption and industry change. They need this firm grounding because there is bound to be more regulation and change to come.

Label and artwork management – the unsung hero of medical device companies

Label and artwork management (LAM) operations – responsible for creating, distributing and managing all labeling – is one such area that is ripe for extensive digital transformation.

LAM has not traditionally been viewed as its own discipline within medical device companies, despite its complexity, broad remit and business-critical nature. LAM is responsible for labeling and artwork on all labels, information leaflets and instructions for use placed on packaging cartons, pouches and corrugated materials. Many of the medical device companies Kallik works with manage upwards of 10,000 assets, with some of the largest international companies surpassing 100,000.

Despite the scale of the task, in many medical device companies LAM is today managed by disconnected teams and stakeholders scattered throughout the organization – often on a global scale. Their ongoing burden is routinely made heavier when accounting for labeling challenges caused by an increasingly global supply chain, extensive M&A industry activity and asset changes demanded by regulatory changes.

Limitations of a 'traditional' LAM approach

Paper-based and siloed label and artwork management poses extensive issues to any company working to respond to industry changes or improve internal business processes.

Many upstream systems do not integrate with outdated manual LAM processes, making it difficult to track, edit and reuse assets. As label and artwork design is a highly collaborative process that often requires multiple versions and edits, having these assets stored in siloes significant slows down the review and approvals process, leading to outdated or unapproved content slipping the net, slower go-to-market times for new products and a significant bottleneck for artwork teams.

At the management level, businesses struggle to extract and act on business intelligence to drive improvements in the product lifecycle due to these disconnected LAM processes. This throws up repeated issues on visibility and reporting at every stage of the label and artwork creation and review processes – all at a time when users are compelled to make large-scale manual asset changes to comply with legislation.

Yet getting LAM 'right' can unlock significant ROI and business value when compared to medical devices companies still hindered by poor and outdated LAM practices. As Kallik experts have previously highlighted, there have been over one million items recalled globally due to labeling errors alone. Looking at the broader medical sector, U.S. Food & Drug Administration data shows labeling issues also account for 14.9% of all drug recalls.

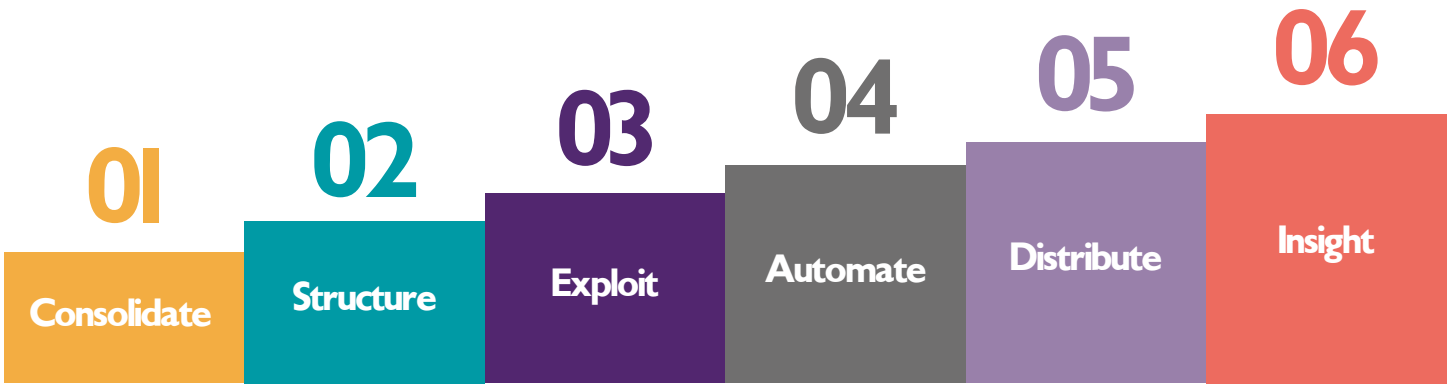
The Digital Maturity Curve – a six step pathway to digitized operations

The shift from legacy systems to a single digital, centralized solution cannot happen overnight. A measured approach is needed to systemically identity project goals, track affected assets and evaluate new technology.

The bulk of investment into label and artwork management has taken place in response to an issue or threat to existing operations. This must be replaced with a proactive strategy to transition from manual operations to a future-proof alternative that will not require constant fixes.

Businesses do not need to rush into extensive outlay for technology and consultancy expertise. By following the Digital Maturity Curve – a best practice, step-by-step guide spanning the evaluation, preparation and deployment stages of digital LAM – medical devices manufacturers can take gradual steps into assessing their business landscape and transitioning to digital solutions.

The Digital Maturity Curve can be broken down into six core steps:



1. Consolidate

Before rushing ahead with technology deployment and integration, it is critical organizations can bring together all legacy labels, artwork and associated data such as phrases, translations and symbols. For large medical device companies, this data will often be held in different systems across the enterprise, usually in inconsistent formats. This initial stage will be the most challenging and time-consuming; tracking down and identifying data siloes for consolidation into a single, digitized source of truth. Yet this is the critical first stepping-stone in the shift towards digital maturity.

All data must be standardized into cleansed, structured datasets in a repeatable format to ensure any central system using this information is consistent and searchable. Third-party consultants are a useful addition to the process to ensure an objective opinion is available when identifying and standardizing relevant assets.

2. Structure

Following the consolidation of labeling data, siloes can now be eliminated in the switch to a centralized digital system with structured and controlled datasets. All labels, artwork, and any associated imagery, phrases and translations should be centrally controlled and managed in a single system, driving consistency and quality across the LAM process. This 'single source of truth' will unlock greater business efficiencies as further features and integrations are scaled up. Best-practice approval workflows should be put in place to make any updates to datasets. Access management, search features and content orchestration can also be established at this stage to improve accessibility and reuse of all labels, artwork and associated data.

Business leaders must also consider traceability on a global scale to support supply chains and teams scattered worldwide. Asset translations, for example, can now be automatically linked back to a master language for ease of management and to avoid publication of any outdated or unapproved local language content.

When evaluation a system to act as the central repository for label and artwork data, business leaders in the medical device space should carefully consider how they will migrate their new, consolidated dataset into their digital system. If using a software partner, they should be able to provide proven tools and services to ensure this is a straightforward process.

3. Exploit

Once all assets are centralized, work can begin to put in place total brand and regulatory compliance – a critical step for organizations looking to digitize during the EU MDR and IVDR era. With a cleansed, structured and accurate repository of all label data, this provides a solid foundation upon which to run LAM processes, enabling labels and artworks to be creating by drawing on this dataset.

These efforts must be conducted on a global scale – once completed, pre-approved assets can be readily reused in all geographies without concerns over non-compliance. Asset templates can also be enriched with omnichannel content to accelerate contextual media delivery.

4. Automate

At this stage, automatic generation and creation of labels and artwork can be introduced, cutting generation times down to mere seconds. Work outsourced to third-party design agencies can be reduced or even eliminated completely as internal artwork generation capabilities come online, introducing significant sustained cost-savings as internal asset creation and editing is scaled up.

Manufacturers can now plan for reduced time-to-market for new product ranges as automated label and artwork generation eliminates design and review bottlenecks, including risk of human error. When the inevitable regulatory changes occur for labeling, business leaders will have already established a resilient and robust change process capable of updating thousands of artworks in a fraction of the time it would have taken without automation. Major label change projects such as EU MDR or IVDR, which would have otherwise taken months or even years to complete, can be turned around in a matter of weeks.

5. Distribute

Assets have now been centralized, updated to ensure full compliance and approved, meaning all assets managed through the centralized LAM solution are now suitable for publication. The next stage is to ensure distribution of the final approved label or artwork is managed and controlled effectively, giving end-to-end traceability of the entire LAM process. Distribution is the final piece of the LAM process and should not be overlooked. The distribution of labels and artworks, whether this is printing basic black and white shipping labels in a manufacturing site, or sending a pre-press ready file to a third-party printer, should be completely linked with upstream artwork creation and approval processes.

6. Insight

Full deployment of a centralized LAM solution and associated capabilities such as automated artwork generation will lay the path for new high-level business insights. End-to-end integration of all systems helps management begin analysing and actioning data to better optimize product operations.

This availability of new data streams can be leveraged to continually refine business processes and the value chain, delivering greater ROI and the knock-on effect of improved upstream processes.

Scalable benefits over time

Businesses do not have to progress through all six stages of the Digital Maturity Curve to realise initial business improvements, yet completion of a full LAM digital transformation project will unlock sustained cost and time efficiencies.

Adopting a centralized LAM solution with a high degree of automation consistently reduces capacity and money spent on creating, editing and managing assets – and also eliminates reliance on third-party designers. Greater agility is also introduced for making changes to products, bringing new medical devices to the market and expanding into new geographies, helping companies react faster than competitors to emerging market opportunities.

Crucially, a fully digitized system will help mitigate the impact of legislation. Any regulatory change will require every affected labels or artworks to be identified, updated and reissued. Companies actively using 10,000 artworks would previously be burdened with a manual compliance project spanning months – using a digital LAM solution, the identification process is cut to a single day, with changes and approvals being made centrally within weeks. Compliance deadlines can be comfortable met – avoiding financial penalties, regulator inspections and even sales bans.

Moving to a centralized system also eliminates the issue of siloed assets and LAM processes hindering business intelligence. End-to-end integration helps management drive greater value across business processes, introducing intelligence at critical stages to unlock new insights, such as optimal label placement on products.

Small to medium-sized businesses that establish good practice today and put in place a strong LAM foundation by ensuring good data and asset management from the get-go will reap the rewards in the future as their businesses scale. Having this strong LAM foundation will allow businesses to more easily achieve enhanced digital maturity in line with business growth.

Case in point – manufacturers unlock benefits on a global scale

Although many medical device manufacturers are still assessing how to begin their journey across the Digital Maturity Curve, early adopters are already feeling the benefits. One major company that has worked with Kallik experts to establish digital LAM enjoys significant efficiencies through automated artwork generation, cutting time spent from weeks to just minutes and delivering global artwork consistency across all brands.

Using the 'where used' feature built into Veraciti™, users are able to quickly identify and update assets impacted by regulatory changes such as EU MDR. This also aids with capturing product Unique Device Identification for effortless submission to the FDA's Global Unique Device Identification Database.

Another global medical device company has already demonstrated quantifiable benefits of heavily streamlined LAM. Artwork generation has been accelerated to create 10,000 new assets in just 14 days, while the number of label templates required has been consolidated by over 90% to just 14. This successfully cut approval cycles from 18 weeks to just 5. Indeed, insights gathered from the Veraciti platform demonstrate sustained operational efficiencies – one leading medical device company can process a typical monthly workload of over 8,000 artwork creation jobs at an average rate of one per 37 seconds, in turn cutting average label and artwork project completion time from 52 to just 26 days.

Despite a rising volume of assets caused by business acquisitions, management complexity has not risen – transparency is maintained across multiple artwork studios. All assets are accompanied by time-stamped audit reports to eliminate traceability concerns, ensuring minimal delays when adapting products for entry into new markets.

Summary

For medical device manufacturers faced with a perfect storm of increasing regulation, agile competitors and siloed legacy systems reaching end of life, it has become increasingly clear that the 'traditional' approach of manual and disconnected processes is no longer feasible.

Moving towards a more digitized organization can seem like a daunting challenge, but by following established best practice to navigate the Digital Maturity Curve and engaging with proven expert consultants in the industry, the path forward becomes clear and manageable. The end goal should be a comprehensive, highly accessible label and artwork management solution such as Veraciti, providing users with powerful capabilities accessible 24x7 and a single source of truth within a centralized platform.

Successfully reaching this milestone will put medical device manufacturers in a strong position to deal with future industry disruption and regulatory demands, while also reaping the ongoing rewards of streamlined label and artwork operations.