

VIEWPOINTS ON INNOVATION

VIEWPOINTS ON

Digital Thread and Smart Connected MedTech

In a constantly evolving regulatory landscape, life sciences manufacturers are currently being pushed to implement systems that connect the enterprise, the value chain, and the product at every stage of its lifecycle. Standards and regulations like ISO 13485 & 14971, FDA's Quality System Regulation, and EU MDR/IVDR set expectations for companies to embrace the digital thread while verifying the risk/benefit ratio in a closed-loop fashion.



The digital thread has great potential in life sciences because it enables a seamless flow of data across the value chain, connecting clinical, product development, manufacturing, and post-market surveillance data.

However, there are challenges. Digital thread maturity is sporadic, and most companies are generally immature. Many still use paper-based or point systems. Most companies have no overarching enterprise architecture or digital thread roadmap to guide them based on strategic imperatives, compliance mandates and market demands. Others lack governance and rely on uncoordinated skunk works band aids to fix their problems. Rampant acquisitions and divestitures further exacerbate these challenges.

World class companies are already enabling the digital thread by leveraging the power of Internet of Medical Things (IoMT) and digital quality management systems (QMS) that connect the buyer, provider, patient and manufacturer. IoMT is estimated to save the healthcare industry \$300 billion annually.¹ Instead of using multiple point systems to achieve EU MDR/IVDR compliance, Digital QMS can consolidate everything into one single source of truth. And advanced analytics applied to that data can improve products, speed development times, increase production yield and revolutionize field service.

Now is the time.

Companies that want to remain competitive must move forward on their digital thread initiatives.

This compendium contains helpful advice on leveraging the power of smart connected products and systems, using advanced analytics to improve quality, and using digital QMS to foster a culture of quality that ensures the delivery of more effective, safer products that improve patient lives.

¹ <https://www.businessinsider.com/goldman-digital-healthcare-is-coming-2015-6>

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Digital Thread in Life Sciences: The Future of Product Innovation

by Shamina Merchant, Leo Moran and Dave Hadfield

Our world changes daily in front of our eyes. Since March, the world has been upended by COVID-19. It confines us to our homes, dominates every conversation, and changes how we live our lives. As businesses reopen in phases, we are redefining what our new normal will look like in the coming months and how this experience will change our lives in the years to come. Will we eat out as often? Maybe grocery and food delivery apps will become a permanent preference. What about school – will more students embrace online learning moving forward? Among all uncertainty, one thing is for certain... the future will be increasingly digital.

The Shifting Landscape in Medical Device

The open questions about the future are not unique to our personal lives. It's clear that today's challenges will drive lasting changes in the way we all work, especially within industries that are directly affected by the pandemic.

Imagine **Susan**, a 43-year-old mother of two. She has worked in the medical device industry since

2002 and has experience in various stages of the product lifecycle. Currently, she serves in a product management role and has spent the last two years developing a plan for the next big product for her \$2.2 Billion medical device company, Kuality Kare.



In March of 2020, the world she knew was turned upside down, and her focus became firefighting through a situation she had not yet had a chance to process. There were a million questions she didn't have the right answer to, and no textbook example to hold up as a leading practice.

How long would the freeze on elective procedures last? Should they rush to release the new device they'd been working on? How could she work with the FDA to make this possible? If it came to it, how would her team equip their distributors to get essential products to the most vulnerable cities to fill the rising global demand?

But more immediately:

How could she find the best tool for remote work? Was there anything she could do to limit how many of her employees had to go into the office?

And as if she didn't have enough on her plate already:

How did the quadratic formula work again? She needed to help her son, Ryan, prepare for his Algebra 1 test... and, of course, he would be taking it from home.

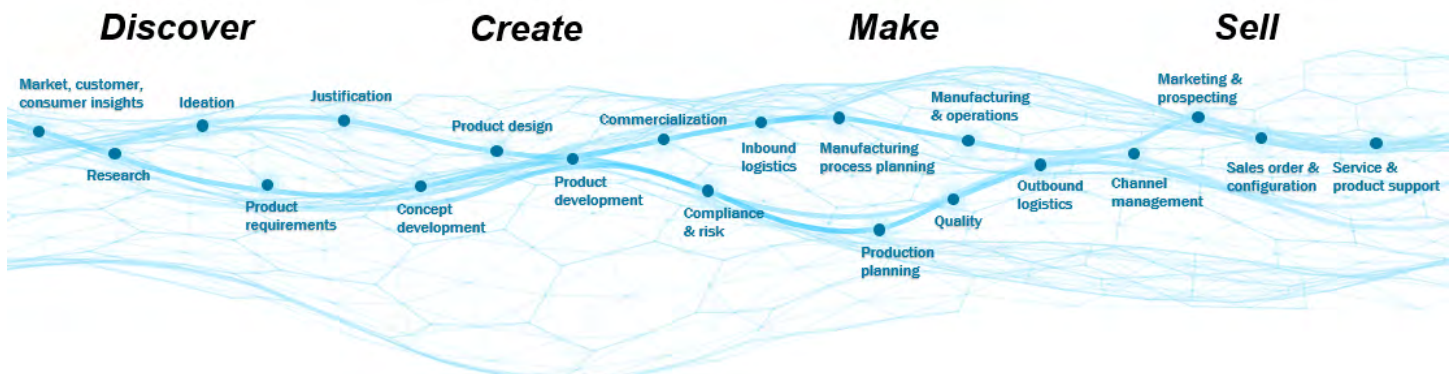
Susan's story is not unique. Companies across the medical device industry were disproportionately impacted due to the pandemic. Early in 2020, as healthcare organizations initially braced themselves for overcapacity, the industry struggled to keep up with the rising demand for essential products while also struggling to adapt to the implications of halting elective procedures. The industry reeled as workforces became remote overnight. For many, protecting employees came at the expense of effective collaboration. This not only impacted product development and manufacturing, but sales, training, and product servicing, as much of the industry was underprepared to solve challenges traditionally resolved in person in this new remote working environment.

It is clear that the companies who focused on building their digital capabilities in recent years have had a significant advantage in adapting in response to this crisis, but what does this signal for the future?

According to the Harvard Business Review, in 1958, the average lifespan of companies listed in Standard & Poor's 500 was 61 years. By the 1980s it was down to 25 years. Today it is less than 18 years. The reason for the sharp decline? The rate of change in the world has increased dramatically due to digital transformation. Life Sciences organizations must embrace digital transformation if they are to survive in this rapidly changing world.

Redefined Possibilities: The Digital Thread and the Digital Twin

So why do some companies fail to embrace a digital world while others thrive? The organic evolution of processes and technologies has resulted in a disjointed experience within the product lifecycle, from discover to create to make to sell. The solution is the digital thread.



If the value chain represents all the activities that a company completes to deliver a product to the market, then the digital thread is the fabric that holds it together. The stronger the fabric, the stronger the value chain. The focal point of the digital thread is the digital twin, or the virtual representation of the physical product. The digital twin can be used in design, testing, monitoring, servicing, and other functional areas to augment product management capabilities.

Reimagining Product Innovation with the Digital Thread

To examine how the digital thread enables innovation in the face of great challenges, let's jump back to the present and check back in with Susan and her colleagues at our fictional medical device company, Quality Kare. In this scenario, we assume they have a modern digital infrastructure in place, and this dramatically improves their ability to innovate and deliver.



Using advanced analytics, Quality Kare has identified a market need brought about by the pandemic. With minor changes to an existing product, they can help fill this crucial gap. If Quality Kare can act quickly, it can help the world combat the pandemic and serve shareholders by offsetting lost revenue to their elective surgery products business. Luckily, the company has spent the last two years investing in its digital capabilities, so Susan feels confident in her team's agility and preparedness for this challenge.



Susan's colleague **Bill** is driving new ways of working in product design. He recently led Quality Kare's shift to cloud-based CAD tools – which integrate seamlessly with their product lifecycle management (PLM) systems – and Bill is especially grateful to avoid the pains that come with traditional file-based CAD systems that limit collaboration. His rapid adoption of game-changing new features – like the ability for his design team to collaborate on the same CAD model in real time – allows them to iterate quickly as they adjust an existing product's design to fill the identified market need.

This CAD model is the basis for the digital twin – a concept that Susan is pushing at Quality Kare. Digital twins come in a variety of forms, often incorporating several discrete models threaded together. These representative models can be composed to work together, allowing organizations to simulate an object's behavior in a specified digital environment, subject to a known set of assumptions and conditions. Applying physics-based digital simulations feed incredible insights to product design that do not require the time and expense of physical prototype creation and testing.

Susan's intern **Rachel** has set up a demo to show the team how their 3D CAD models can easily be loaded into an augmented reality application, further expanding the use of the digital twin. Rachel explains how this would allow for a virtual product review that leverages the digital twin for an accurate and informed session in which reviewers need only their phone to participate. These models can then be leveraged again later in the product lifecycle to help with sales, training, and servicing.



Key Elements of the Digital Thread

Susan takes a deep breath. She knows that the strong digital infrastructure at Quality Kare will help her team quickly get this new product to market and support patients in crisis.

Her son has started back at (virtual) school, and as she watches him work through math problems, she thinks through some key elements for success as her team prepares to release their product.

Product Development

1. **Foundational PLM Systems** – These foundational systems manage product data across the lifecycle. In Susan's situation, PLM enables their product concept to move into production through an efficient engineering change management process, designed to provide the right information to the right people at the right time. As the product moves to production, sourcing managers can access the BOM in order to communicate effectively with suppliers and ensure that the right materials arrive where and when they are needed. Simultaneously, manufacturing engineers will use the digital twin along with factory simulation tools to prepare for manufacturing at scale.
2. **Extended Reality** – Sales professionals may not be able to enter the hospital, but they can provide a virtual demonstration of the product leveraging the digital twin and augmented reality, so that their customers can assess the product's real-world capabilities. These models may also be used to train healthcare workers in the field without requiring an in-person training session.
3. **Servicing Excellence** – When a nurse realizes that a device is not working properly, it disrupts patient care and needs to be fixed ASAP to treat critical patients. But there are challenges. Devices are in short supply. There's no time to send the product into a servicing center, and they cannot bring in an outside technician. With a digital thread in place, a nurse simply scans a code on the product to connect virtually to a remote technician. The technician diagnoses the problem based on feedback from [IoT sensors in the device](#) and walks the nurse through a simple repair using directions relayed in an augmented reality app on an iPad.
4. **Smart Connected Products** – Kuality Kare can run predictive analytics on data from smart devices and alert technicians of devices that are at risk of malfunction before critical issues take them offline. This allows technicians to proactively

service the product and reduce downtime. This is made possible by sensors placed in every device that transmit data back to Kuality Kare's IoT Management System. The data collected can be analyzed to uncover patterns and trends, identifying scenarios that accurately predict the next time a product will require proactive servicing.

Manufacturing

Susan has prioritized critical aspects of the digital thread important to her business (and her product development focus) at this time, but she understands that there is more work ahead in Kuality Kare's digital transformation journey.

For the next phase, Susan has the goal of eliminating paper-based tracking systems on the factory floor and has the following digital capabilities on her radar:

1. **Manufacturing Execution System** – The MES is the solution that will help Susan's company [digitally manage the production process](#). It connects, monitors, and controls all physical systems in place for the manufacturing process. An important output of this system will be the Device History Record that proves Kuality Kare correctly applied quality controls throughout production and conforms to regulation 21-CFR-820.
2. **Industrial IOT** – Working with manufacturers to enable IIOT can help Kuality Kare 'get smart' about the [manufacturing process](#). With sensorization, Kuality Kare can monitor the production of equipment and find ideal operating conditions to increase production yield. Other opportunities include optimizing energy consumption at the asset level and using edge analytics to improve quality control.

One thing is certain to Susan – the many capabilities the digital thread provides to Kuality Kare add up to a sizable advantage that will help the company manage the current crisis while building more resiliency as they prepare for the future.

The Prescription for Digital Thread Success

Unanticipated disruptive events like COVID-19 have made the digital thread more important than ever. The challenges we face today serve as a call to action for the life sciences industry to invest in its future, but the path forward is still not clear.

How can organizations move from their deeply entrenched legacy systems to a state-of-the-art digital ecosystem? More importantly, how can they train their people to embrace and make use of these tools?

Here are some basic tips for implementing the digital thread and digital twin successfully.

- 1. Don't worry about starting with a digital transformation roadmap.** Instead, have an initial digital strategy, or hypothesis, about where digital concepts can have the most impact for the organization. Building a broad digital transformation roadmap is a hard place to start because it's difficult to tell how each step along the way will ultimately impact the organization.
- 2. Don't focus on technology (and proofs of concept that demonstrate technology).** Focus instead on creating digital proof points with measurable business value. Think about the application of the technology, and the purpose and value of solving a particular business challenge to drive big impact. For example, don't demonstrate augmented or extended reality technology. Instead, demonstrate the ability to operate a surgical robot remotely or to conduct training remotely with the goal of limiting physical presence in hospitals during a global pandemic.
- 3. With an initial digital strategy and proof points established, next define the capabilities the organization needs to have the greatest business impact.** This is a combination of people, process and technology that will support an actual digital transformation that is sustainable and scalable, no matter what the future brings.

Susan has done a lot of this work already. Her next step will be to seek ways to extend and build value across the value chain – both within Quality Kare and to the value chains of suppliers, distributors, and customers. Although Susan's story is fictional, companies that follow her example will reap the benefits now and position themselves to continue to outpace the competition.

How to Build Internal Support for an IoMT Program

by Rodney Holmes, Chad Markle and Pravin Kumar

Healthcare is transforming as Internet of Things (IoT) technology advances and smart connected products are deployed into the hands of doctors, nurses, field technicians, caregivers and patients. This transformation has carved out its own subset of IoT, known as the Internet of Medical Things (IoMT).

The Internet of Medical Things (IoMT) brings together smart connected medical devices, advanced analytics and people (healthcare professionals, caregivers and patients). It's the network of a multitude of medical devices connected by communications technologies. When implemented correctly, the IoMT results in systems that can monitor, collect, exchange, synthesize and deliver valuable new insights like never before.

The IoMT provides a more coordinated, connected healthcare system where technology empowers providers to deliver better care to patients throughout their health journey and where better patient outcomes are delivered at increasingly lower costs.

But how do you get there? The opportunity is huge, and there are many potential starting points. If you're involved in medical device field operations and are responsible for IoMT strategy, we've got your back. Here's our advice for building a business case for IoMT initiatives, based on our experiences at the top medical device manufacturers in the world.

Four Essential Elements to Building Internal Momentum

Taking full advantage of all that IoMT has to offer requires changes in the way stakeholders use, manage and maintain smart connected medical devices. Unfortunately, large-scale change efforts fail more often than they succeed. So what distinguishes IoMT programs that have tremendous success? There are four essential elements.

1. Tell a Compelling Story

First is a compelling story, because stakeholders must understand the rationale for IoMT and embrace it. One of our clients focused on communicating service response times and planned improvements; another focused on being a market leader with a modern servicing platform for a smart connected surgical robot.

2. Role Model Desired Behavior

Next is role modeling, because stakeholders must also see leaders and colleagues they respect operating in new ways with IoMT. One Kalypso client used customer testimonials from a highly ranked hospital describing the results they saw from IoMT as a way to help encourage other customers in their adoption process.

3. Create Supporting Mechanisms

Third is supporting mechanisms, because processes, roles and incentives must be in line with the new IoMT program. A leading medical device company worked with Kalypso to create personas for each stakeholder in their IoMT program and then revised workflows to take advantage of new IoMT value.

4. Build New Capabilities

Finally, new capability building is required, because stakeholders must have the skills required to embrace the IoMT operating model. Companies we work with that leverage our compelling IoMT training and education, and that take ownership of the ongoing training requirements, always end up stronger and more capable.

As with any transformational initiative, the move to the IoMT has huge benefits, but many potential challenges along the way. With so many considerations, including infrastructure, interoperability, data privacy and security, it can be easy to lose sight of the bigger picture.

At the heart of this transformation is the desire to improve patient care. Companies that invest time and effort to build internal momentum will move faster and achieve much greater success.

Solution Architecture Strategies for IoT in Medical Devices

by Wayne Posner and Jordan Reynolds

Implementing an IoT solution can be a challenging initiative. Implementing an IoT solution within an industry bound by numerous rules, regulations, and restrictions can add significant levels of complexity.

Fortunately, with a well-planned and carefully architected solution, an IoT initiative can be designed to work within the rules and regulations. This means that businesses, such as those within the medical device industry, can begin to realize the enormous benefits gained through this transformative strategy.

IoT Architecture

IoT solutions are generally defined by a three-tier architecture including:



Private/public hosted IoT hub software solution, responsible for managing data received from remote IoT-enabled physical devices

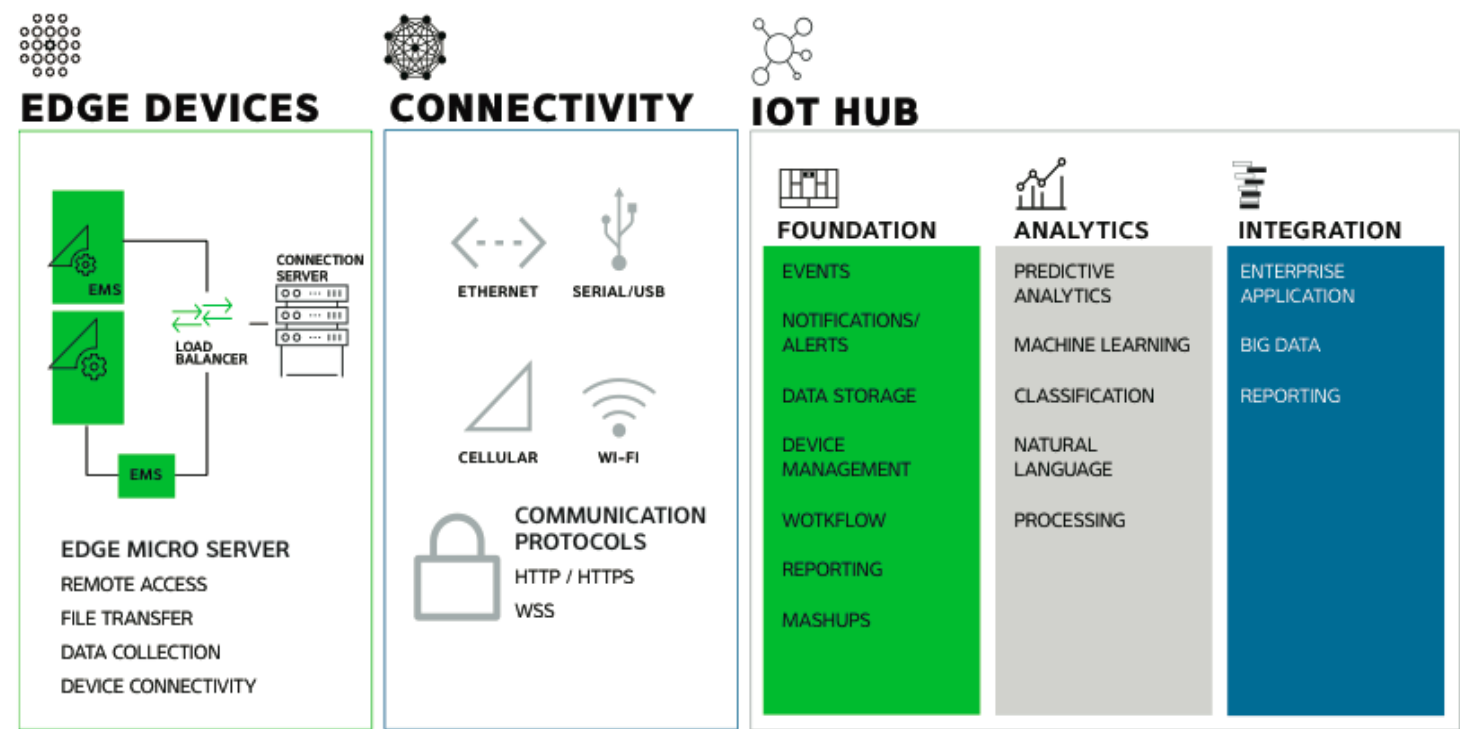


An edge gateway, to enable communication between the physical devices and the IoT hub



Physical (edge) devices

Depending on the scale of the IoT implementation, there may be other architectural components such as load balancers and connection servers.



Medical Device Architectural Considerations

Within the medical device industry, there are additional architectural considerations.

- Does the device store patient data or can patient data be derived from examining device log data? If so, HIPPA compliance is a factor and must be addressed.
- Are there any legacy devices lacking networking capabilities?
- Does the environment in which the device is utilized implement any sort of network? If so, are there network security restrictions that preclude the device from connecting to the network?
- Are there government regulatory export restrictions that limit how where device data can be accessed? If so, a federated architecture with user location based security must be considered.

Security and encryption is always a key architectural consideration for any IoT solution. Many companies have strict constraints restricting specific data to users within specific organizations. Files transferred between the IoT hub and remote devices should be protected by strong encryption algorithms compliant with FIPS 104-2, while in flight, and validated against at least a CRC-256 checksum (SHA-256 hash is preferred), while at rest, to ensure malware has not been introduced.

Most medical devices deployed within a hospital environment are currently restricted from operating in an “always on” connectivity state. These devices operate in an “offline” mode. Working with these devices is a manual process. The typical use case for communicating with offline medical devices is that a qualified and/or authorized user will physically establish a connection between the device and a laptop or tablet.

The laptop or tablet will allow the user to interact with the device data using custom software. Finally, the laptop or tablet will sync the device data with a custom server solution once it establishes network connectivity.

IoT Solutions for Medical Devices Operating Offline

How can an IoT solution help to optimize this type of manual process? There are three possible solutions that work within the confines of devices operating in an offline mode.

Embedded Edge Micro Server

Install an edge micro-server directly on the device, provided the device has built-in networking capabilities; when a connection is required between the device and the IoT hub, temporarily enabling network connectivity is the only requirement. This solution is the most ideal and requires the least amount of customization; however, network security protocols must allow for medical devices to temporarily establish network connectivity when necessary.

Attached Edge Micro Server

Install an edge micro-server on a computer that is always connected or can quickly be connected to the device via a serial or Ethernet connection. Some medical devices may lack network connectivity or the additional resources required to run an edge micro-server, or may not run an operating system compatible with micro-server frameworks such as Java, C, or .Net. A small computer running Linux can be used to host the edge micro-server and establish a serial connection with the medical device. Like the first solution, network security protocols must allow for this computer to temporarily establish network connectivity so that it can communicate with the IoT hub.

Custom Software

Create/Update custom software running on the laptop and/or tablet to enable it as an edge device that communicates with the IoT hub while also adding enhanced cache management functions. This allows the IoT hub to automatically receive cached data from the laptops and tablets (with an active network connection) and push updates down to be cached until the laptop and/or tablet reconnects with the device. Of the three solutions, this is the most complex and time intensive due to the amount of required programming.

Implementing a robust and scalable IoT solution requires a well-planned and thoughtfully designed architecture. Highly regulated industries such as Medical Device have additional architectural requirements to be considered. Through careful design and thoughtful understanding of the governing rules and regulations, it is quite possible to introduce devices that regularly operate outside the IoT paradigm as part of an enterprise IoT solution.

Securing the IoMT – Nine Strategies You Can't Afford to Overlook

by Bryan Kissel and Chad Markle

The headlines are full of stories about companies that fail to live up to the expectations and legal obligations of information security. Compliance is complicated, and it changes a lot.

For medical device companies with an Internet of Medical Things (IoMT) strategy, it's even more complex. Combine recommendations and frameworks like ISO 27001 and the PCI DSS with regulations like HIPPA, GDPR and MDR, and the magnitude of the challenge becomes very clear.

Companies are tasked with protecting both the connected devices in the field and the data they generate and transmit. So today's compliance strategies must include risk-based security practices protecting sensitive data and communications-based compliance practices around reporting, recording and archiving sensitive data.

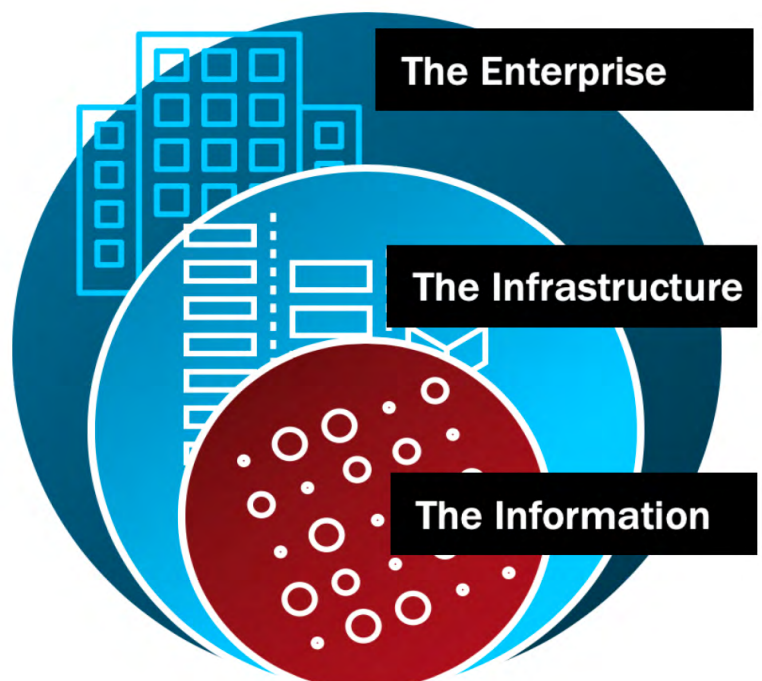
Protecting devices in the field requires an innovative approach to comprehensive information security, along with compliance practices that can evolve alongside changing formfactors, design principles, connectivity solutions and management strategies. And on top of all this, interoperability and legacy device support is an ongoing, pressing need.

Nine Strategies to Secure the IoMT

When physical security experts secure a house, they think in terms of concentric circles. The tree line or fence would be your outer-most ring - whatever constitutes the perimeter. Next would be the front door and anything on the inner-perimeter, like cameras, a storm door or window locks.

The inner-most ring would then be a panic room or secure space within the home. Each ring poses a more significant barrier than the last until you ultimately have your human assets within the inner-most ring protected by the increasing degrees of scrutiny as you move inward.

IT and Security professionals should approach security in much the same way. As you move closer to the center of the concentric rings, security controls should become increasingly strict, impeding risk vector access within each ring.



Securing the Outer Ring (The Enterprise)

In the outer-most ring is the true first line of defense – the policies and education practices of the enterprise. Enforcing strong, secure policies should be a part of any company's DNA, but here are a few strategies that must apply to this ring.

1. Use 'exceptionally' strong passwords

Eight-character passwords and mnemonic devices have led to many breaches, and most incidents are still user-related. Phishing, weak credentials and lost devices... we can do better.

2. Avoid common, shared accounts

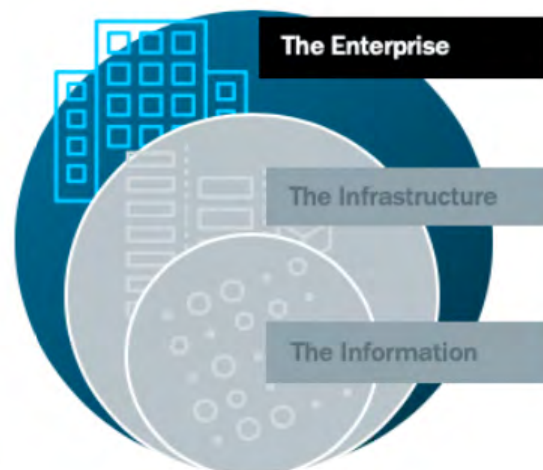
Shared access, passwords on Post-It notes and 'admin/password' accounts represent the old ghosts of information security risk management. Don't sacrifice security in the interest of deadlines or ease of use.

3. Have a Data Privacy Officer (DPO)

Some companies try to put DPO responsibilities on the CISO or a System Admin, but there's enough strategy, policy and education required to justify this role. Plus, GDPR actually requires businesses to have a named DPO responsible for managing Personally Identifiable Information (PII) and protected health information (PHI).

4. Enforce education, policy and values

Educating the workforce must evolve to create a culture of compliance at every level of operation. A clean desk policy is no longer enough, and users that access data in any form have a duty to protect that data and use it appropriately. The enterprise (led by the DPO) must deploy strategies that educate the workforce, monitor for user compliance and report incidents in real-time.

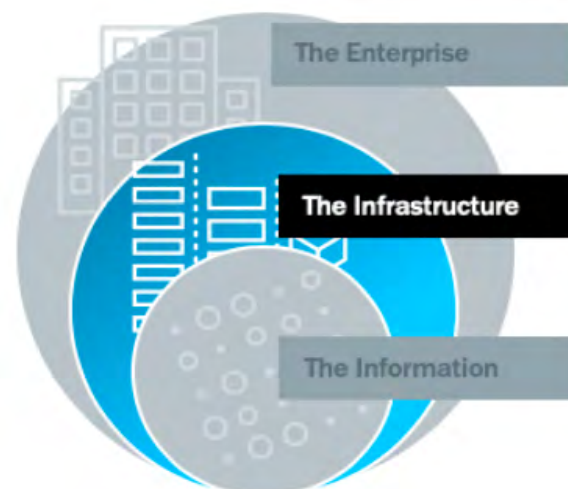


Securing the Inner Ring (The Infrastructure)

The inner ring represents the infrastructure – the hardware that supports applications and devices, secures pathways and manages traffic to assets. Innovation in this ring is critical to the longevity of connected medical devices and the operability of legacy devices still in use. There are many security strategies that apply specifically to this ring – here are some of the most important.

5. Innovate encryption strategies for micro-formfactor devices and implantables

Some of the most common medical devices, like implants and wearables, are the most vulnerable. Tiny Encryption Algorithms (TEA), system-derived passwords and self-encrypting devices are some options on the bleeding edge of device security, since many of these devices are too small to handle large encryption schemes.



6. Encrypt all the blind spots on the information superhighway

As more and more industries move toward cloud-based solutions and services, data managers must ensure that data is fully protected at every point in its lifecycle. Each system, node and relay must be demonstrably 'as-safe' as the last, from end to end.

7. Secure development of the entire IoMT ecosystem

A secure network or secure out-of-the-box solution is insufficient today. The complete ecosystems that support devices must be implemented with mature information security policies, governance, role-based access controls (RBAC) and deep documentation to ensure compliance across operational regions. Design with security in mind to always be 'audit-ready.'

Securing the Center Ring (The Information)

The center ring protects the most important asset at the heart of the IoMT – the data. Security at this level should be a nearly impenetrable shield of role-based access, attribute-based asset control, data type-specific archiving and retrieval, and comprehensive records retention.

8. Evolve and mature records management practices

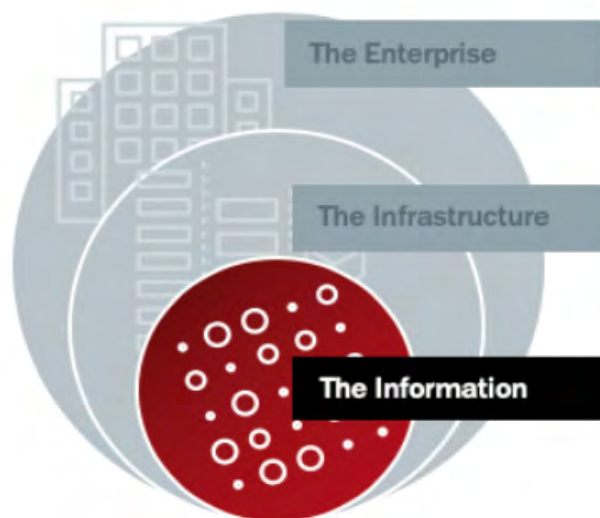
Identifying and organizing data is the first and most important step to achieving compliance in any regulated industry. In the US, companies are tasked with securing data according to the risk associated with a breach. Considering the life or death implications of some connected medical devices and the truly personal nature of the data these devices generate, the medical device industry should expect the highest degree of scrutiny from auditors, legislators and even patients. New practices for records management – including documenting design, solution, architecture and audit materials – allow the DPO to demonstrate a reasonable and proactive approach to data security and privacy that lays the foundation for achieving compliance.

9. Manage the data like the high-value asset that it is

Insights gleaned from advanced analytics are the main ROI opportunity. To capitalize on this, data must be managed as a high-value asset. Protected health information and personally identifiable information should be considered as precious as secret business data, proprietary CAD elements, or IP.

In the age of Ransomware and PHI sales on the dark web, the question is no longer when a breach will occur, but how much an eventual breach will ultimately cost. As the IoMT evolves, isolated information security practices are a liability. Interoperability and security practices must extend to every point of the data lifecycle and be capable of growing alongside a maturing and ever-changing device landscape. As data privacy and information security continue to become almost inseparable, the offices of the CISO and DPO must evolve together, presenting a unified front against digital threats and a cooperative partnership in support of audit and compliance operations.

As medical device companies build and evolve an IoMT strategy, these efforts can help minimize risk while fostering a culture that mitigates information security risks, improving overall operational effectiveness, compliance posture and audit readiness.



New Frontiers for Medical Device PLM Systems: Leveraging the Power of Machine Learning

by Dave Hadfield and Jordan Reynolds

Medical devices are essential to our modern society. They give us healthier, more productive, and more independent lives. But the companies who make them face many headwinds; adhering to strict regulatory standards, proving that their benefits outweigh risks, and achieving efficacy and safety standards. To succeed, they must constantly innovate, drive down costs and navigate complex regulatory pathways.

All of this has been the driving force for medical device manufactures to automate and integrate disparate engineering, quality, regulatory, manufacturing and post-market capabilities into a single consolidated product lifecycle management (PLM) system.

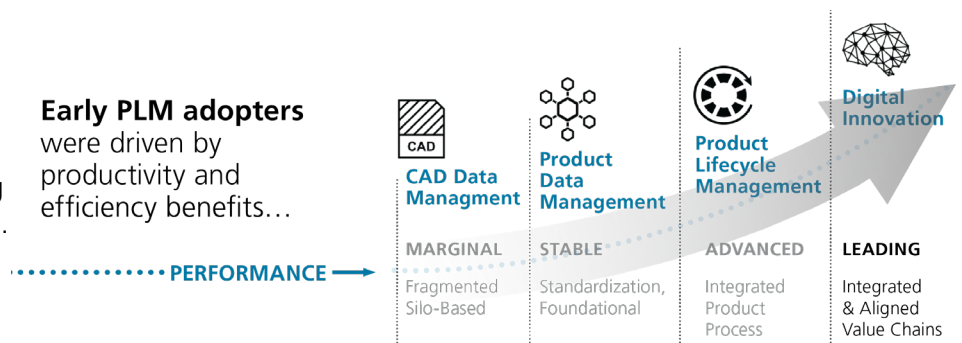
Building on a PLM Foundation

Adopting PLM remains a missed opportunity for much of the medical device industry, with [the potential to drive long term transformational success](#). But we're rapidly approaching a time when PLM alone is not enough.

The product lifecycle is captured as data – including at its heart, a three-dimensional math-

based model of the product. Companies can extend and gain new insight about these product models using new digital technologies, including machine learning, the Internet of Things (IoT), and augmented reality. These technologies have made extraordinary progress in the past few years. By evolving PLM to embrace digital tools, companies gain strategic insights while facilitating the creation of breakthrough products and services.

Early PLM adopters were driven by productivity and efficiency benefits...

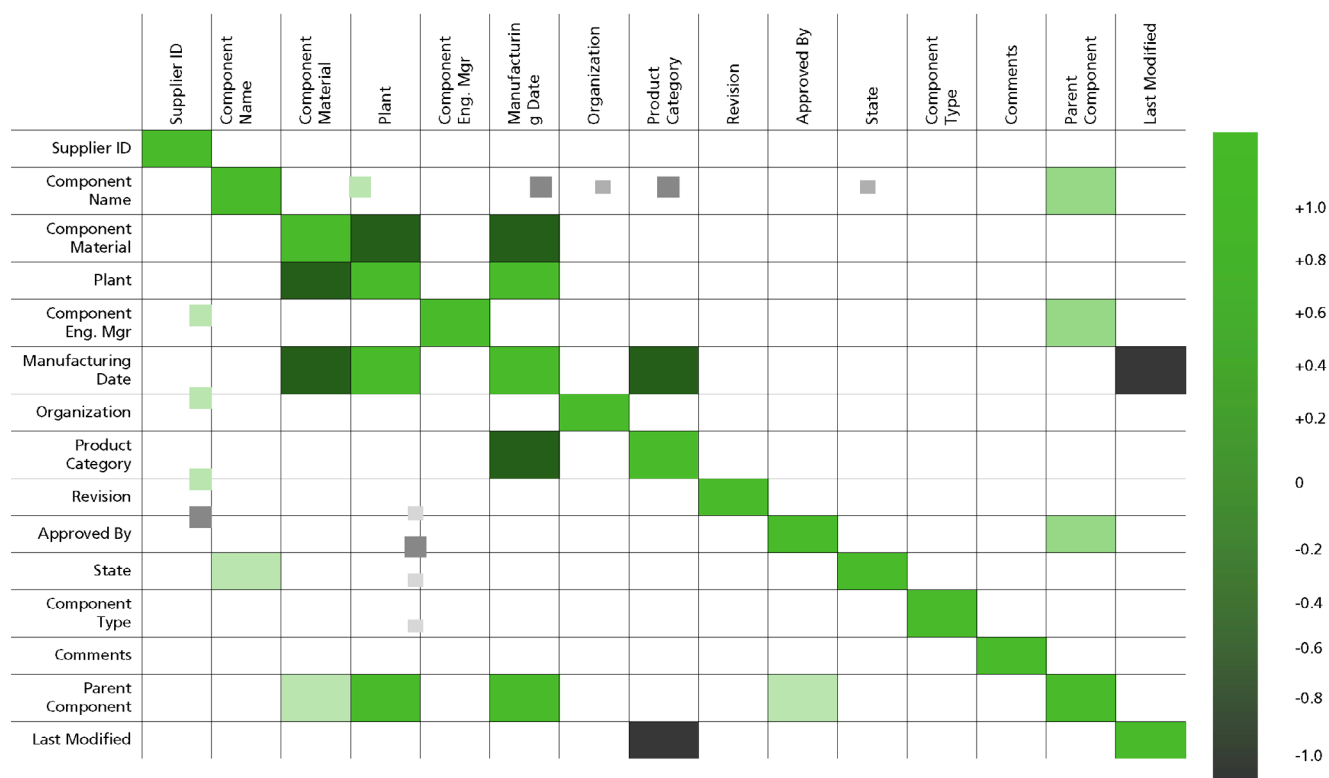


Machine Learning and PLM

In a typical medical device company, research, engineering, quality engineering, supply chain, operations planning, and post-market surveillance activities produce large sets of structured and unstructured data. Intersections of those data sets can produce over 750 potential points of data correlation. These large, complex, dynamic sets of data are exactly what machine learning analytics algorithms were built for. Any large, mature PLM system with robust processes and data has almost countless applications to drive value from machine learning techniques.

Potential Applications of Machine Learning to PLM

Apply Machine Learning to PLM Data to Improve Product Development Results



PLM provides the potential to gather large amounts of structured product data, and integrate it with data about post-market quality issues. This gives valuable information to improve products, accelerate the resolution of issues and improve quality outcomes.

But even with advanced integrated and automated processes, it's not easy to identify potential correlations across multiple related data sets. With machine learning performing advanced analytics on PLM data, companies can predict outcomes and improve product development results by understanding the causes behind non-compliances, problem reports, product failures and quality issues.

Understand the Nature of a Product's Evolution using Natural Language Processing

Any given product may go through thousands, even tens of thousands, of iterations with each change recorded in PLM. By parsing language inside changes (tapping into the same type of technologies that make Siri and Alexa successful), we can understand the historical nature of product improvements and draw insight. This can be helpful in new product development efforts, shaving off design cycles and driving innovation.

Find Winning Product Features

What conclusions can we draw from on market sales to identify correlated user experiences? By combining part sales information (say by region) with PLM feature information, we can zero in on market success and tie it to specific product attributes.

Suggest Parts without a Search

Use machine learning to suggest parts based on specification data, and present them to the user. This is similar to how Google Search works when you enter a search term. But this goes beyond search and uses machine learning to identify potential candidates.

Drive Lean Processes

The system can learn process and corresponding workflow behaviors over time and by user, site, division, product, etc. From this it can identify points of delay and recommend potential process optimizations. Combined with flexible PLM applications, users can apply optimizations that are sensitive to cultures, locales, product types or even individuals to help processes like change, New Product Development (NPD) and Corrective and Preventive Action (CAPA) run more effectively.

Think Forward. Act Now.

Medical device companies have unique challenges. As they strive to differentiate themselves with new and innovative products, they can get benefit from a strong PLM foundation. With PLM, medical device companies collect large quantities of diverse data as they develop products. But PLM alone can't provide true insight from this data.

To accelerate results in a digital world, medical device manufacturers need to think forward and act now. Those who identify opportunities to apply machine learning and advanced analytics to PLM will unlock new insights to outpace their competition.

Apply Machine Learning to PLM with Product Lifecycle Intelligence: A Medical Device Use Case

by David Wolf, Jordan Reynolds and Sajid Patel

Worldwide regulations are changing at an alarming rate. One way for global medical device manufacturers to remain competitive is by optimizing change notice lead times. Today, the ability to apply machine learning to Product Lifecycle Management (PLM) systems can help them better understand and drive insights from product data that has been collected over many years.

Product lifecycle intelligence (PLI) is an evolution of PLM that applies artificial intelligence and automation to help PLM users extract meaningful insights from product data, formulate predictions, recommend improvements, and automate actions within systems and processes.

The potential value is immense because with PLI and machine learning, medical device manufacturers can proactively prevent delays and failures.

This article details how one manufacturer addressed their global challenges with a unique three-phase approach, driving measurable business results.

The Company and the Business Challenge

A top medical device manufacturer wanted to enhance transparency of the change control data stored in their PLM system. The process required a transformation to how they aggregated and displayed data such as

aging and cycle time throughput. The organization used PLM dashboards, spreadsheets and shared hard drives to analyze their change control data; a process plagued with common data replication issues. The problem was intensified by the fact that there was no easy way to perform analytics on data without a massive effort and an extensive approval process - which is typical with traditional Master Data Management (MDM) and Business Intelligence (BI) solutions.

Although PLM systems store change data that may be used for auditing purposes, the core platform does not provide advanced analytics capabilities - like machine learning - that can aid in predictive analytics, root cause analysis and discovery activities.

The company decided to execute a proof of value with a role-based application that used a state-of-the-art app to aggregate data and optimize change notice lead times. Just like many medical device manufacturers, the company hoped to optimize their change management process and predict the likelihood that a product would fail or succeed in production.

A Strategic Three-Phase Approach

To address the challenge, the company used a strategic approach based on Kalypso's hands-on experience helping global medical device organizations benefit from emerging technologies. The three-phase approach is designed to drive maximum value from digital initiatives both in the near-term and for future growth, with an iterative crawl-walk-run cycle.

Phase 1: Start with a Proof of Value Workshop

This phase starts by defining a small scope of business objectives (engineering change cycle time, rejection/rework rate, etc.) The company provides data extract from PLM and Kalypso demonstrates a high-value use case leveraging PLI to drive insights from the data. With a clear link to a strategic business objective, it's easier to show results that help obtain executive sponsorship for the next phases.

Phase 2: Test a Minimum Viable Product (MVP) Pilot in Production

This phase builds on insights generated from connected systems, leveraging machine learning and artificial intelligence to proactively predict and prescribe actions that prevent future crises.

Phase 3: Scale Pilot to other Business Units and Manufacturing Sites

In this phase, knowledge is transferred from the first two phases, enabling multiple use cases, while leveraging medical device connectors, role-based apps and advanced analytics. It is the phase at which the enterprise-wide business value is realized, and the benefits of a strategic digital program start to accrue.

Phase 1 Results

In less than six weeks, Kalypso addressed phase 1 with a medical device role-based app solution using the ThingWorx platform to capture and aggregate real-time data related to the change management process. An analytics engine was used to create a change management algorithm, providing immediate insight into lead time variation within the product and proof of value for leadership support.

This is just the start. In addition to optimizing cycle time, PLI can predict the rate of approval from the implementation board based on the tasks and rework cycles within the change implementation plan.

The company could reduce costs from poor quality through the ability to simultaneously optimize cycle time, streamline the change process and remove

bottlenecks before they occur. As a result, the company could expect to provide consumers with a safer and more effective products, resulting in positive brand reputation and increase in market share.

It's important to recognize that using machine learning with artificial intelligence allows an effortless change management process, significant error-reduction and protection of data integrity.

Mergers and acquisitions are commonplace in the medical device industry. For this company, ThingWorx smart connected systems and PLI can eliminate siloed environments, secure data and help prevent quality events.

Maximizing the Value of PLM

PLM can do a great job of managing product data through rapid change, but it's not perfect at putting that data to work through datamining and analytics. For many discrete manufacturers, this means they are sitting on months or even years of untapped R&D product data. By combining PLM with product lifecycle intelligence, companies can bridge the gap in PLM analytics capability today, allowing them to understand current performance, historical averages, and the variances across different business units and functions.

These insights can help them develop more meaningful customer experiences, while driving business and product value. As an organization iterates through product development efforts, their database grows to be robust and the value of PLI grows accordingly.

Companies that continuously strive to maximize the value of PLM – by pursuing PLM system consolidation, looking for more opportunities to leverage insights from data using [PLI](#), and expanding the use of apps to augment consolidation strategies – will continue to expand the return on investment.

How to Use AI to Augment Field Service Operations in Life Sciences

by Stuart Gillen and Dave Hadfield

Even before the current crisis, life sciences companies were adopting artificial intelligence (AI) into daily service activities. As companies adjust to the reality of increased remote engagements, they can accelerate the trend towards connected field operations.

AI augments the service engineer, allowing him or her to make more informed decisions, better predict outcomes such as personnel scheduling and parts shortages, and identify and respond to product quality issues before they become critical for end users.

In a survey conducted in conjunction with Astea, Field Service Medical (FSM), and WBR Insights, the Internet of Things (IoT), AI, and preventative maintenance accounted for 63% of the top three items executives consider when purchasing a Field Service Management platform.

Here is how we see AI impacting day-to-day operations, both through and after the recovery.

Drive Out Complexity

It has been well documented that companies are losing skilled service personnel at a faster rate than they are backfilled, largely because baby boomers and Gen Xers are retiring, and millennials are not interested in field service work.

In a report by Manpower Group, 70% of the companies interviewed said they expected a skills shortage over the next 10 years. In addition to the loss of talent and knowledge, the sheer complexity of modern machinery makes it difficult for subject matter experts to keep abreast of best practices. Tools based on AI must be used to augment the SMEs' capabilities and bridge the skills gap.

The growing complexity of modern systems increases multi-mode failures which describe how many causes of failure act together to affect the performance of a system. With such complexity, it is almost impossible for one person to fully understand the intricacies of equipment operation, and historical service practices that used procedural lists and rules of thumb are ineffective in diagnosing root cause analysis.

I recently witnessed a hidden problem while helping diagnose a highly complex piece of equipment using AI. After the issue was resolved, root cause analysis identified two items:

1. The problem was severe enough that the organization wanted to ensure new models used in the field were fixed too. But as service engineers were deployed to fix the issue, they discovered the manufacturer of the equipment had already addressed the situation without updating them. Therefore, any rules which might have been developed to address this specific failure would already be obsolete on newer models.

2. Risk analysis indicated the severity was high, the mechanism for detection difficult, and the likelihood low (which is becoming the norm as machines become more complex). The sheer number of rules needed to catch these potential failures would require months of effort and become outdated with any new software and/or hardware revisions.

With AI, companies can quickly evaluate and visualize complex data sets to help uncover complex failure patterns never observed before. Artificial Intelligence augments the knowledge of highly skilled SMEs and guides them towards identification of multi-mode failures.

Significantly Improve Customer Satisfaction

For many companies, it used to take several hours to review service calls, support tickets and voice mails from angry customers to understand where the hottest fire was.



Today, connected devices provide enriched sensory information like operating hours, internal operating temperatures, fluids dispensed and diagnostic alarms. This means service organizations can apply AI algorithms to predict when a failure will occur.

Customer satisfaction ratings dramatically increase because technicians can provide guidance on impending breakdowns and organize maintenance around the customer's schedule.

In one example, a predictive maintenance package alerted the manufacturer to a tube failure of a CAT scanner seven days before it occurred, saving hospitals \$100k/catch in replacement costs (not including labor and downtime costs). Moving from reactive to predictive maintenance can lead to 20-40% reduction in downtime and 15-30% reduction in maintenance costs. These AI-driven preventive maintenance alerts have a significant impact on reducing the cost of poor quality.

Optimize Spare Part Inventory (with a Flock of Seagulls?)

Spare parts management and optimization is important because it creates a more efficient process of identifying both availability and location of spare parts. Predictive maintenance algorithms identify when something is going to happen (to a specific model, in a specific region, with a specific failure mode), but before the technician gets in the truck, she is going to need to procure a specific part to fix the client's device.

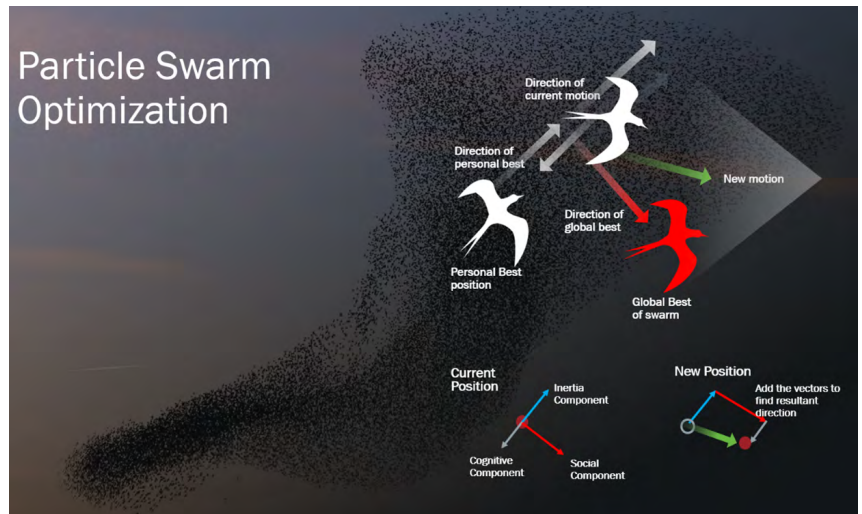
The question becomes: **Is that part on-hand?**

Although it might appear less expensive to simply buy and keep parts in stock, imagine the costs if the enterprise is running global operations. The costs to store parts in multiple field locations becomes expensive and the strategy quickly becomes impractical.

For the answer we can turn to nature and the majestic seagull. With advanced genetic algorithms and particle swarm optimization (PSO) techniques that mimic the behavior of flocks of birds, we can optimize the availability of stocked parts.

Imagine a swarm of birds, such as a flock of seagulls, seeking out their next meal. Many behavioral, social, and historical inputs exist which lead the group to finding the optimal solution given their current state.

If you consider a single seagull, it will try to seek food in one direction based on historical learnings and memory. But when you have the social component of the group, you capture the combined history of the flock, leading the swarm in the optimal direction. The flock gets to their dinner quicker than if all that existed was the information from a single individual.



These high-end optimization techniques can be applied to everyday service situations as well, seeking input from sources of field asset health data, cost data, service engineer availability, etc. By automatically executing millions of combinations and constraints, algorithms can generate optimal maintenance schedules along with part quantities that will minimize inventory carrying costs or enterprise impact costs. These AI-based optimizations ultimately allow companies to operate optimal predictive maintenance schedules with spare parts inventory, where the right parts are available in the correct quantities at the required locations.

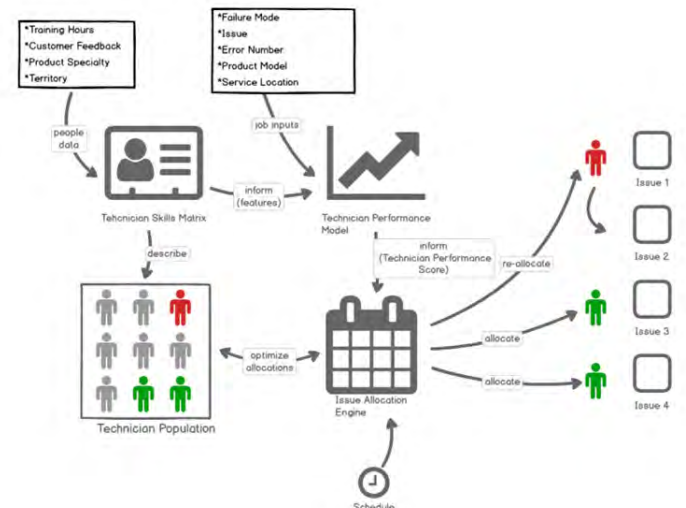
Achieve Efficiency via Intelligent Scheduling

Skilled personnel are retiring at a rate faster than positions can be filled. This forces organizations to maximize all available resources and overbook appointments to reduce overtime and unnecessary costs. With AI, organizations can put their most skilled people in the right locations at the right time.

This helps companies:

- Reduce travel times, fuel costs, and vehicle maintenance
- Ensure work orders and technician skillsets match, thus reducing the cost of lost appointments
- Avoid costly Service Level Agreement (SLA) penalties

Personnel scheduling has historically been a very manual, ad-hoc process that requires evaluating incoming jobs, allocating appropriate resources, and performing rudimentary sequencing and scheduling. There are several inputs in this equation including technician availability, the type of service required, device-specific training, and the expected service time per issue, which make scheduling a highly complex optimization problem for anyone.



And even once a schedule is defined, employees who are unwell, stuck in traffic, or delayed at other sites can cause them to start the process over again. There are too many variables for any single person to adjust all the levers, so an advanced analytics approach can help efficiently optimize the scope.

This image proposes a method where inputs from a digital skills matrix describe each technician in a workforce population. Skills including training hours performed, customer satisfaction metrics, product specialties, territory, etc., are used to build a technician performance model.

The model provides input to the Issue Allocation Engine which examines the entire population of technicians and work orders (using the [Hungarian Algorithm](#) for example) and optimizes the right set of resources based on the job inputs (failure mode of equipment, model type, service location, job duration).

With this type of optimization algorithm, we've seen our clients service organizations improve productivity from 10-20%.

Getting Started with an MVP Approach

There are clear benefits for companies that connect devices using AI and machine learning. But when it comes to getting started, there are a few key things to keep in mind.

The most important thing companies can do is consider current business challenges and apply an AI lens. When AI is used to help solve real, compelling business challenges, companies can realize real value quickly with a minimim viable product (MVP) approach.

The MVP approach is based on the idea that depth of value beats breadth of application. Instead of focusing on building a broad base of foundational AI capabilities generalized across multiple use cases, the MVP approach builds a full stack of capabilities and value focused on a narrow, high-priority use case.

This full stack starts with foundational connectivity and data models, and also includes descriptive analytics, root cause analysis, predictive modeling, and all the way up to prescriptive modeling and optimization.

When value is realized for the high-priority use case (ideally linked to a significant business challenge), companies can then scale for additional use cases.

Successful service companies are thinking about AI now. Part of adapting to the new normal will be adapting strategies to put remote work first. This might come from an MVP around predictive maintenance of failures, which would allow technicians to be onsite for only the most critical of issues. It may come from improved technician scheduling, minimizing windshield time while maintaining or exceeding customer satisfaction metrics during this challenging time.

AI doesn't have to be a mystery. Avoid black box approaches based on proprietary, 'behind the scenes' data sets and analysis. Instead, provide business context and a strong value case, and apply an agile MVP approach. You'll enable platforms and methodologies that will sustain ROI for years to come.

Drive a Culture of Quality with Digital Quality Management

by David Wolf, Kevin Van Doren and Max Huff

It's time to raise our standards on product quality and patient safety. As the medical device industry continues to shift toward value-based healthcare, the traditional focus on compliance is not enough. It's time to unify quality processes and data across the product lifecycle with a [digital quality management system \(QMS\)](#), fostering a culture of quality that ensures the delivery of more effective, safer products that improve patient lives.

Benefits of Consolidating Quality Management and Product Lifecycle Management (PLM)

It's widely known that quality management and PLM interoperability significantly reduces the cost due to poor quality. When engineering groups have visibility to quality issues tied to product information, they can design those issues out of future product versions.

The challenge is that getting to that interoperability requires a transformation from disparate systems to an integrated closed loop architecture, while maintaining a very complex software roadmap and market leadership at the same time.

But we know it's worth it. Industry analysts have completed several studies to articulate the benefits

of this closed loop architecture. One such benefit is reducing both internal and external failures by up to 50%, according to the Aberdeen Closed Loop Quality Management study. A significant portion of this benefit comes from PLM software vendors providing cloud-based solutions with a full suite of quality management modules. This enables transformational change to happen more quickly and with less disruption to the business.

In fact, the latest digital QMS architecture helps drive a culture of quality by shifting from a compliance-centric view to a closed loop framework. This means moving from reactively addressing quality issues to proactively seeking opportunities to prevent issues through better process, product design and customer feedback.

When quality data is shared between processes and systems, companies can reduce quality costs, improve visibility, contribute to more accurate root cause analysis, reduce rework/scrap costs, provide predictive insights that help prevent compliance issues, and drive improved product and process design. And as quality becomes tightly aligned with the development and support processes, the cost due to poor quality is significantly reduced.

The Necessary Shift from Compliance to Product and Process Quality

The cost of poor quality comes to life year after year, as nonconformance, complaint and CAPA processes are among the top ten most frequently cited reasons for FDA warning letters. And it's a global problem.

One key area the [European Union Medical Device Regulation \(EU MDR\)](#) focuses on is risk-based post market surveillance (tracking quality management activities after the product has been released to manufacture).

The disconnect? Historically most quality departments focus primarily on ensuring compliance. Too few manufacturers view the primary role of their quality department as driving product and process improvements. However, The FDA Case for Quality (CfQ) initiative states that manufacturers need to focus more time on product quality versus pure compliance. A closed loop digital QMS approach drives improvement in product quality across the product lifecycle by encouraging collaboration and providing visibility.

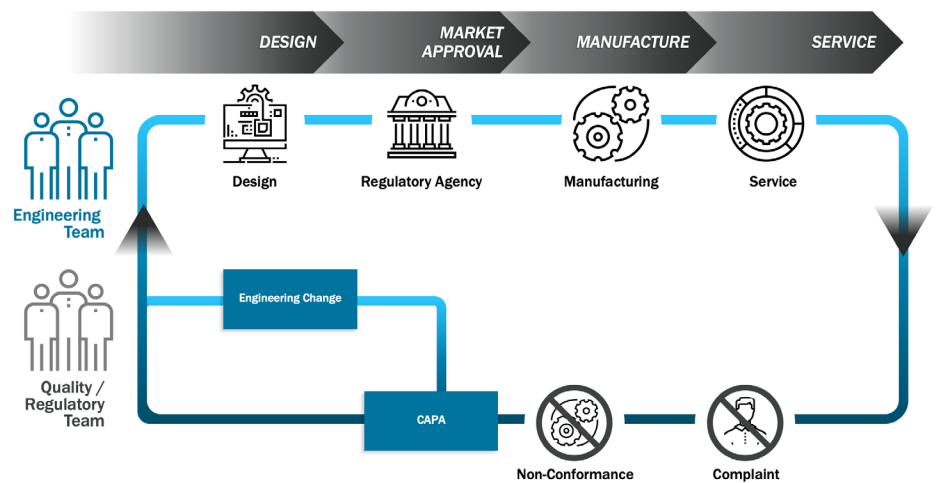
How Digital QMS Reduces the Cost of Poor Quality

Harmonizing business processes and quality management data across the organization is very complex when manufacturers maintain paper-based siloed systems. This complexity is only exacerbated by mergers and acquisitions.

McKinsey released a study in 2011 that states the medical device industry's opportunity to improve quality costs is between \$4.6B and \$6.0B. Improving quality costs requires a dedicated cross-functional team effort to plan, fund, and replace siloed quality management functionality while doing business as a regulated medical device manufacturer.

One of the major benefits of implementing a cloud-based digital QMS system is the immediate value companies get by leveraging leading practice workflows with reduced maintenance. This latest cutting-edge technology helps companies to consolidate product development, manufacturing, quality and regulatory processes in one closed loop architecture.

This closed loop approach improves product and process collaboration while enabling real time quality management visibility into how devices are performing in the market. The cloud makes it possible to implement multiple digital QMS workstreams in a very short period, minimizing the risk of business disruption.



The Digital QMS Architecture Enables Benefits Now – And in the Future

PLM is the product quality and compliance backbone for leading medical device manufacturers and enables companies to track CAD-based, critical-to-quality characteristics over the product lifecycle. The digital thread and digital twin enable device manufacturers to pair CAD models with enterprise data to improve the quality of training, remote service, and virtual design reviews. Remote service is a competitive differentiator for manufacturers because of the improved cost savings, brand reputation, and ability to better serve customers. An advanced remote service capability provides accurate, real-time updates that prevent issues from occurring in the first place.

And with a digital QMS architecture in place, manufacturers can implement machine learning and predictive analytics, driving insights at scale. The proven benefits now and in the future are significant, but re-imagining the people, processes and technology to get there can seem daunting.

Building Up Digital QMS Maturity

Device manufacturers will see higher success rates when they establish and harmonize quality processes and solutions in the following order.

- Product information foundation – the first phase typically consists of enabling document control, design control, risk and change management processes, and [regulatory information management \(RIM\)](#) with product and quality management solutions.
- Connected closed loop – starting in parallel or soon after, the next phase includes manufacturers implementing nonconformance, complaint, corrective and preventive action (CAPA), supplier corrective action request (SCAR) and the audit management functionality required to integrate and maintain siloed QMS point solutions.
- World class predictive quality management – this phase integrates QMS solutions with enterprise PLM, ERP, MES systems and digital technologies such as [role-based app connectors](#) and [IoT smart connected devices](#) to perform federated searches and return critical device data to the manufacturer, helping augment the long-term consolidation strategy.

Rapid deployment of a cloud based digital QMS solution is possible. As a manufacturer matures through the maturity phases, they can more easily use advanced analytics and machine learning to drive predictive insights and better configure core solutions like PLM in parallel. By connecting enterprise systems, they can track quality characteristics over the product lifecycle.

As the industry transforms their expectations of quality departments from a focus on compliance to product quality, manufacturers can expect a higher level of collaboration, mitigated risk, better product design, and enhanced quality management transparency. Companies that reach this maturity are poised to leverage additional technologies like augmented and virtual reality, machine learning and predictive analytics to achieve top-tier status.

Digital QMS provides a state-of-the-art platform for sharing data across integrated processes, helping device manufacturers institute an improved culture of quality across the digital thread. When will you start your journey?

Seven Leading Practices for Risk Management in Medical Device

by David Wolf, Dave Hadfield, Shamina Merchant and Blake Snell

Medical device manufacturers must follow a highly structured and rigorous risk management process, mandated by the FDA, EU and ISO. To track risk-related data over the entire product lifecycle, companies currently use a variety of risk management solutions, from sophisticated software packages to simple spreadsheets and shared drives.

As regulatory requirements continue to evolve and get stricter, it is more important than ever to effectively manage risk. Despite this increased need, leading risk management practices are not implemented routinely in their product lifecycle management (PLM) systems due to more foundational elements like change management, BOM management, regulatory reporting, and quality management taking priority. This is a missed opportunity for the industry, because those that can do this well will generally be ahead of most of their peers.

Even for companies where sophisticated risk management is implemented, information is trapped in siloed systems, which makes it difficult to analyze, escalate and resolve safety issues. Things are now more challenging from a business governance perspective as well, with companies acquiring each other more rapidly than ever. This makes the enterprise technology landscape for large medical device manufacturers very complex and broad, even for basic company functions.

Effectively managing risk in the medical device industry can be challenging and complex, but it's becoming increasingly important. Doing it well is often a key strategic differentiator, so we've outlined seven things that we've seen industry leaders do that set them apart.

Seven Things Risk Management Leaders Do

- 1. They use FMEA, 5-Why and Hazard Analysis as their main risk management techniques.** They integrate risk data – regardless of source – into their PLM solution to harmonize design control, process control and post market surveillance components. This supports recent regulatory emphasis on improved trending, management review and escalation of risk management-related issues after release to manufacturing and the market.
- 2. They layer advanced analytics on top of structured quality and product data stored in PLM to move from *corrective* to *predictive* risk management.** This speeds time-to-benefit during a PLM implementation and greatly extends the value. Machine learning can also be used to verify the risk controls are working correctly, improving the safety and efficacy of the products themselves.
- 3. They are making moves to capitalize on the *Internet of Medical Things (IoMT)* and smart connected products.** They use predictive analytics to improve healthcare outcomes, driving huge business value.

4. **They leverage advanced analytics on top of structured product, quality and risk data to answer quality-related questions, moving from descriptive to prescriptive insights.** With basic analytics, they can explore and explain how often quality issues arise and where they typically occur. Advanced analytics applied to structured data across the life cycle is called [product lifecycle intelligence \(PLI\)](#) and it enables manufacturers to ask much more advanced questions that yield prescriptive results. For example, they may gain insight on what design features they should avoid to make sure their products don't fall victim to common failure modes. PLI can also drive data-driven insights to answer similar questions for other business functions, including R&D, manufacturing and supply chain. This in turn leads to more efficient and accurate root cause analysis by enabling quality personnel to diagnose multi-mode complex failures, which often occurs when sophisticated device and manufacturing data is managed in multiple databases.
5. **They [design](#) their risk control system for minimal risk.** They use a PLM system with integral QMS and post market surveillance risk-based information. This is the most complete closed-loop methodology for designing out previous failures, safety issues and nonconformances.
6. **They use role-based app connectors along with IoT and analytics.** This helps enable a closed-loop vision. For now, these tools can be a competitive advantage over traditional risk management methods, but they will soon become expected and enforced by regulatory bodies as an additional way to improve patient safety.
7. **They take a pragmatic approach to risk management.** They create and follow a roadmap that leads to more refined levels of automation over time instead of a big bang approach. With this approach, value can come early and often throughout the journey – not just at the end. Data is becoming the "oil" of the 21st century, but leveraging data to derive key risk insights requires short, mid and long-term strategies. Companies that lead the way start by connecting siloed data sources and continue to strive towards a long-term harmonized data landscape goal.

Current risk management system maturity is irrelevant. Companies must harmonize risk management data with PLM processes and data, regardless of the complexity of their current solution. Embracing digital capabilities such as advanced analytics, machine learning, and role-based apps can move companies from corrective risk management to predictive risk management.

Risk Management eBook

The journey to closed-loop risk management may be intimidating, but it is critical and very much possible. All companies want to better understand, balance and quantify risk when bringing devices to market, in turn optimizing the safety and efficacy. Our downloadable eBook, [The Future of Risk Management in Medical Device](#), provides additional information on the evolution of risk management. Check it out for detailed examples and advice on getting started with a pragmatic approach.



14 Reasons to Unify Regulatory Information Management with PLM

by Sajesh Murali and Nate Reisch

Medical device companies have many unique challenges, including rapid growth by acquisition. As product portfolios expand, they must efficiently manage information on new and existing products, all while considering stringent regulatory requirements and global distribution challenges.

In many cases, these manufacturers don't know every place where products are registered or need to be registered. They also struggle to provide international affiliates or divisions with all the information they need to register products.

When regulatory and product development information are not aligned, there are numerous financial and quality impacts, including loss of international sales, increased regulatory risk like recall notices or unauthorized shipments, and a strain on resources due to the manual effort required to collect information to support the regulation needs.

But it doesn't have to be like this. By aligning regulatory information management (RIM) with product lifecycle management (PLM) systems, companies can gain significant benefits, reduce regulatory risk and improve international sales.

A Quick Refresher on PLM and RIM

PLM, at its core, is more than just a software system or solution. It's a set of unified business processes that interconnect all of a product's data from the time of conception until obsolescence. The benefits of a global PLM solution, driven by leading practices, are numerous and well-documented. Importantly for this discussion: with a PLM system in place, the foundation for RIM system is already laid.

RIM, at its core, is a unified process of handling product development data that is required to register a product that complies with regulations of every country or region where it will be sold.

From strong governance to high data quality, a global PLM system provides visibility across the entire product lifecycle. When connected to a RIM system, companies gain visibility to the regulatory ecosystem in the same way.

14 Benefits of Unifying PLM and RIM

System Improvements

1. Consolidate Systems

In general, it's a well-understood leading practice to consolidate data between systems. Benefits include lower cost of ownership, easier transfer of information across business processes, and common user experiences.

Statistical Improvements

2. Reuse Product Master Data

Leverage a single source of truth for all product data - from early design throughout the lifecycle - for easy re-use in design dossiers and submission packages.

3. Increase International Sales

Register products in more international markets, with greater speed and less effort. Easily maintain registration status and expiration notices on an ongoing basis.

4. Improve Regulatory Support of Business Planning

Gain global visibility to registration information (status, plans, etc.) to help the business drive decisions and to support better collaboration and alignment between business and regulatory planning.

5. Streamline Submission Package Management

Enable easier creation and management of submission packages (510k, tech file, etc.) with all the data integrated in one place. It's easier to maintain technical files and international submission packages even as product data changes, because it's directly linked to the master source.

6. Reduce Manual/Duplicate Effort

Reduce time spent finding and communicating registration information across many different functions. Reduce redundant efforts between countries, ensuring proper communication and availability of the right information at the right time. For example, clinical trials performed for one country may be shared with another country for reuse.

Procedural Improvements

7. Reduce Unauthorized Shipping

Integrate registration within the design, commercialization, and distribution processes. This reduces the risks and regulatory penalties that occur when products are shipped to countries where they are not registered, or where the registration is not active.

8. Improve Planning and Communication

Limit the number of review cycles and changes to improve global submission planning and communications across different functions.

9. Share Country Requirements during Product Development

Enable design teams to understand and plan to meet all the different country requirements during the product development process.

10. Notify of Country Requirement Changes

Notify design teams of country requirement changes that might impact products. Help plan the changes accordingly to reduce delays in renewals and time back to market.

11. Plan for Product Obsolescence

Enable better obsolescence planning by taking related registration information into account and ensuring there are no active products in the field at remote locations.

12. Faster Regulatory Affairs Resource Planning

Achieve more accurate and faster planning by giving regulatory affairs groups full visibility to upcoming registration activities.

13. Enable International Change Notifications

Enable more efficient and integrated processes for notifying international teams of design changes by broadcasting a message to all countries.

14. Change Impact Assessment

Give design teams full visibility to assess if and how a design change will impact compliance. With an integrated change process, international regulatory affairs groups are notified and engaged earlier.

Which Comes First - PLM or RIM?

First, your starting point doesn't greatly affect the expected outcomes or benefits. Companies can start with RIM or PLM and still expect similar results.

However, implementing a RIM system alone will not deliver transformational results. Companies must also address organizational (people), statistical (data), and procedural (process) dimensions to fully realize the potential of a comprehensive regulatory information management solution.

It's also important to not think about RIM and PLM as individual functional areas, business process, or systems. Break down the old school, siloed school of thought. Approach both regulatory and product lifecycle information management from a holistic perspective focusing on the interactions between the two and the areas where they have traditionally broken down.

Getting Started: Key Questions and Guidance

Do your organization's current RIM and PLM processes use an integrated approach to sharing information or a "throw it over the wall" approach, where the two groups don't collaborate or interact during the commercialization phase of the product lifecycle?

Most companies still operate with a "throw it over the wall" approach, which wastes time when people must re-find or re-create information that already exists. By collaborating at the right time and with the right data, time-to-market and regulatory filing errors can be drastically reduced.

Does your company currently use common and consistent roles between RIM and PLM processes?

Functional areas should not have largely standalone functions that have no connection or place in the greater organization. Roles and skill sets should be consistent across the organization. The greatest improvements to innovation results often come from cross-collaboration with employees working outside of their standard, boxed-in ways of thinking.

Is your organization ready to fully integrate RIM and PLM into a single system?

Depending on your organization's current maturity level and strategy related to mergers and acquisitions, now may not be the right time to invest in a single platform for all functions. But companies can gain benefits and reduce costs by first defining integrated people and process strategies prior to fully integrating the systems. And when the time is right, the integration will be faster and cheaper with this pre-work complete.

Final Thoughts

Today's regulatory submission process is complex, but with integrated PLM and RIM solutions, companies can implement inter-connected processes and share information through product development and all the way to the distribution cycle. Companies that do this well focus not only on the systems and data in the merging of these processes, but also on managing people and change.

And all the effort is worth it. Embracing this transformation and embedding safety and compliance into every step of the medical device innovation process, will ultimately lead to better results for patients.

Leading Practices for EUDAMED and Basic UDI

by David Wolf and Erin Halleran

Big regulatory changes are coming to the way medical device companies sell their products in the European Union (EU). Previous product management strategies are becoming antiquated with exponentially increased risk. The changing landscape demands urgency and comprehensive strategies based on informed opinions.

As a part of the changes in the EU, Unique Device Identification (UDI) and Basic UDI (BUDI) will be a requirement for medical devices. The new regulatory initiative falls under the EU Medical Device Regulation (MDR) and supersedes the Medical Device Directive (MDD), which previously had no provisions on traceability of medical devices, so the steps necessary for compliance are completely new for the EU market.

As deadlines to comply quickly approach in Spring of 2020, let's explore the context, basics, and best practices to adapt to this new normal across the industry.

How Did We Get Here?

To better understand the context of Basic UDI, it's important to understand the origin of UDI in the United States. UDI first came into use in 2007, when the US Congress passed legislation directing the Food and Drug Administration to develop regulations establishing the UDI system for medical devices. In an interview on July of 2013, a Senior Adviser for Patient Safety at the Center for Devices and Radiological Health stated that the underlying issue was the lack of a consistent, standardized way to identify devices. There was no explicit device identification for use in adverse event reporting or post-market surveillance. On September 24, 2013 the final FDA rule took effect in the US.

In the case of the FDA, UDI is the link that connects FDA-regulated medical device products and tracks critical quality characteristics over the entire product lifecycle. UDI aids in digital product definition and makes it possible to perform advanced analytics when scoring vendors in the FDA's Case for Quality initiative. There's no doubt that the FDA UDI regulation serves as a blueprint for the EU and other evolving regulations expected to be released in China, Brazil, Australia, Japan, etc. However, each is expected to introduce new attributes according to specific intentions, and we see this in the EU.

The Basics of Basic UDI (BUDI)

In addition to implementation of their own UDI, EU MDR went one step further with Basic UDI-DI, the key identifier in EUDAMED. Basic UDI-DI is defined as “the primary identifier of a device model. It is the DI assigned at the level of the device family. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.” [MDR 2017/745, Annex VI, Part C]. So the DI improves the traceability of a family of medical devices over their product lifecycle.

The improved oversight will enable BUDI to act as the glue for improving safety and efficacy, making the well-being of the customer or user more transparent and the ultimate priority. For this reason, a main priority within BUDI is the identification and grouping of products. There is no stringent clarification about the size or specification of categories. A default option seems to be grouping based on already-established product families or franchises, which could result in benefits for different groupings, and more clarity around the consequences of categories. By grouping products effectively, adverse event reporting limits further harm of associated products that could have similar risks.

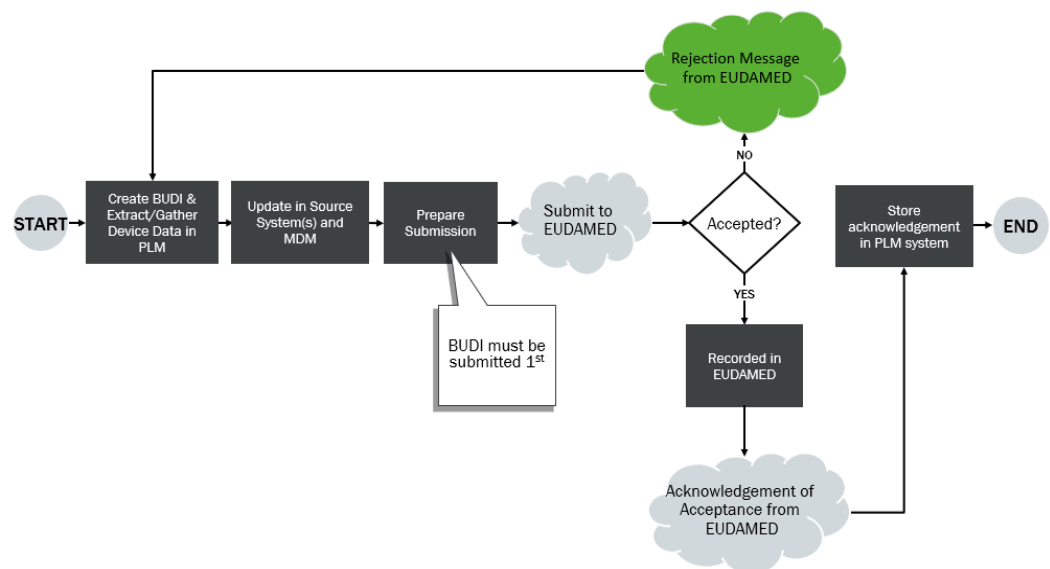
Practical Tips for BUDI Submissions

There are many interdependencies between other EUDAMED components and the BUDI. Based on EUDAMED requirements, a BUDI can be initiated using a Manufacturer Single Registration Number (SRN). An SRN is generated by EUDAMED once a manufacturer is registered in EUDAMED as an Economic Operator. Approved certificated information must be added to the submission package before a BUDI can be submitted for approval to EUDAMED.

Sample Workflow to Create, Store, Submit BUDI UDI Device Data

The image to the right represents a sample workflow for using a product lifecycle management (PLM) system to address BUDI creation, storage, and submission.

Master data management (MDM) provides a common definition of an asset and all its data properties to eliminate ambiguous or competing data policies, and to give the organization comprehensive stewardship over its data. MDM provides mechanisms for consistent use of master data across the organization and is designed to accommodate and manage change. Many larger life sciences organizations use MDM as their data hub to support UDI/BUDI, but it's not mandatory. Most small- to medium-sized businesses use alternative solutions for their data hub needs.



The Basic UDI-DI will not be labelled on packaging or in the supply chain; instead it is a regulatory identifier used in the Declaration of Conformity (DoC), technical documentation, Free Sales certificates, and in the Summary of Safety and Clinical Performance (SSCP).

EUDAMED will be the EU MDR-specific database, centrally collecting information about medical devices. In addition to the Basic UDI-DI, there are also the device identifier (UDI-DI) and production identifier (UDI-PI). A single Basic UDI-DI can be linked to multiple UDI-DIs, while a UDI-DI can be linked to only one Basic UDI-DI.

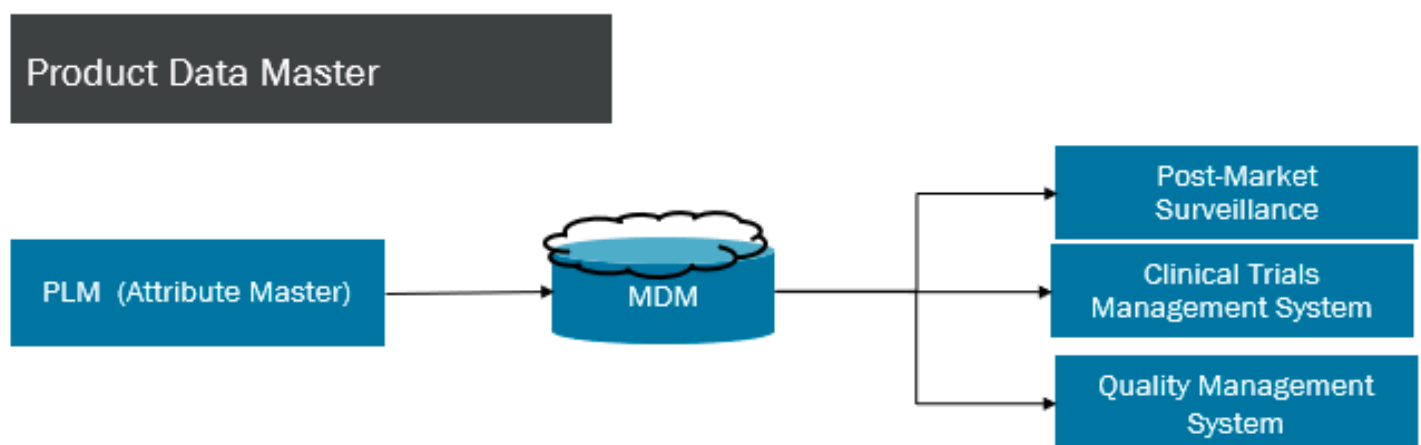
The Basic UDI-DI will connect relevant medical device information and provide a single source of truth for patients, healthcare professionals, notified bodies, competent authorities and the supply chain. The UDI-DI is to be included in the labelling and in the EUDAMED database. Device identifier is specific to manufacturers and device. Any lack of complete clarity requires a new unique UDI-DI. In addition to the UDI-DI, the UDI-PI is to be included in the labeling and if applicable, in the implant card. Production identifiers identify unit of device production.

The Broader Initiative for Regulatory Information Management

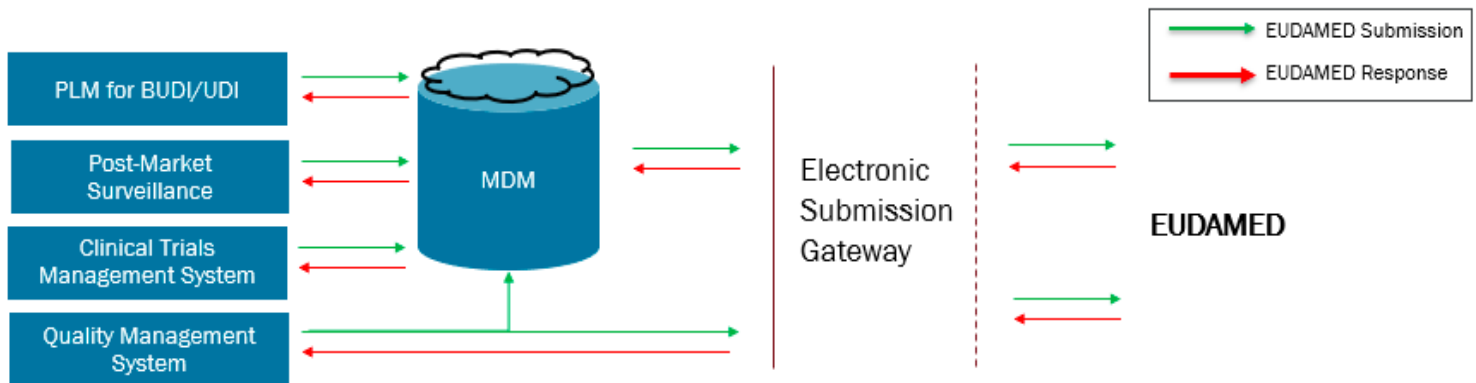
Since tech doc submissions and certificate management is also a critical part of EU MDR, Regulatory Information Management (RIM) systems and processes have also become critical to efficiency in compliance towards EUDAMED. RIM systems manage regulatory data and documents throughout the product lifecycle. RIM is more focused on technical documentation than BUDI, and BUDI does need to be referenced across UDI-DI, product registrations, technical documents/certifications/DoC, the SSCP, or in vigilance and post-market surveillance. Therefore, BUDI should be registered as a precursor to all the other processes. BUDI has its own submissions and lifecycle that trigger submission to EUDAMED.

Companies that maintain their product data in a PLM system, and who may have associations that represent product families, should implement a workflow process that can be kicked off to start the BUDI request procedure. As an alternative and a part of the device identification process, a regulatory team can identify and associate a BUDI to a product, and then trigger a workflow for approval and subsequent submission.

The following images show solution architecture and product master data infrastructure that directly address submissions to EUDAMED by strengthening initiatives around data management.



EUDAMED Submission and Response



The Bottom Line

As a guiding document, the final regulations will be subject to the interpretation of the Court of Justice of the European Union. With so much at stake and a lack of precedent, organizations must focus on risk mitigation through improved processes.

The question then becomes around the alignment of this BUDI process in Europe. EUDAMED requires about 50 attributes in approved submissions for the product family BUDI registration listing storage and approval; are these submissions going to be unique?

Soon there could be hundreds of attributes required for an international organization. Already, we expect 350+ new UDI attributes to be required (future and present) with the six pending UDI initiatives in 28 EU countries.

To address the growing challenges of regulatory warnings while maintaining profitability and global competitiveness, medical device manufacturers are leveraging a variety of initiatives. These include a focus on the FDA case for quality, strategic integration of current and planned systems to normalize metadata, and efficiently and effectively tracking worldwide product submissions and registrations (with RIM). For all of these initiatives, a strong PLM backbone improves success, and opens opportunity for future initiatives including digital app connectors, machine learning and predictive analytics.

Unlock Innovation with Smart Connected MedTech

Leveraging the power of IoMT expands opportunities for new functionality, far greater reliability, much higher product utilization, and capabilities that cut across and transcend traditional medical device product boundaries.

Companies are driving value through:

- **Reimagining** how value is created and captured through new medical technology use cases, value chains and business models
- **Engineering** "smart" components such as sensors, microprocessors, data storage, software, embedded operating systems and enhanced user interfaces
- **Connecting** disparate devices and applications to enable access to multiple data sources
- **Building** complete IoMT solutions and Augmented Reality (A/R) experiences quickly and easily
- **Analyzing** complex device data for real-time insights, predictions and recommendations
- **Experiencing** and engaging with devices in a more contextualized, actionable way
- **Managing** the performance of smart connected devices, processes and systems
- **Servicing** equipment remotely, speeding up resolution time and eliminating the costly field service technician visits
- **Accelerating** time-to-value and return on investment (ROI) of IoMT initiatives



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We work across the full healthcare ecosystem including provider groups, medical device suppliers, pharma/biotech companies and payers, bringing unique insights and extensive domain expertise to our clients.

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