The Future of PLM
Optimize the Product Lifecycle and Enable Digital Transformation with PLM
Over the last 25 years, product lifecycle management (PLM) has evolved from engineering-focused document management and product data management to more strategic and comprehensive innovation management capabilities.

Digital pushes the scope even further: because PLM manages critical product data throughout the product lifecycle and across the supply chain, **PLM now provides a critical infrastructure for the digital transformation of the end-to-end product development lifecycle.**

Meanwhile, the pressure to speed cycle time, cut costs, eliminate complexity, improve quality and reduce compliance risk has never been greater.

This collection of articles leverages industry-specific examples of how companies successfully move PLM forward with a comprehensive, integrated approach that combines business value, technology and organizational change.
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**PLM Today (and Tomorrow)**

Digital has disrupted innovation, fundamentally changing how companies discover, create, make and sell the products they bring to market. But even with all the new technologies and game-changing use cases, companies that fail to recognize the continued importance of foundational enterprise technology like product lifecycle management (PLM) will miss out on the full potential of digital transformation.

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**Maximize the Value of PLM with Advanced Analytics**

There is significant potential to drive more value across the product lifecycle with advanced analytics, but it’s easy to be intimidated by the complexity of the technology and the breadth of possibilities. Here’s how to get started with a holistic plan for data, and some ideas for practical applications of advanced analytics – with industry-specific examples – across the value chain.

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**Leverage a Strong PLM Backbone to Enable the Digital Supply Chain**

Regardless of industry, a strong PLM backbone is required infrastructure for companies seeking to apply digital technologies to the product lifecycle. Here are examples of ways companies can build and leverage the PLM backbone to enable business improvements across the supply chain while preparing for a digital future – including creation, manufacturing, operations and regulatory compliance.

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In Today’s Digital Era, Do We Still Need PLM?
by Daniela Ilieva and Sachin Misra

Digital has disrupted innovation, fundamentally changing how companies discover, create, make and sell the products they bring to market. But even with all the new technologies and game-changing use cases, companies that fail to recognize the continued importance of foundational enterprise technology like product lifecycle management (PLM) will miss out on the full potential of digital transformation.

Emerging technologies like adaptive intelligence, blockchain, internet of things (IoT), 3D modeling, 4D simulation, 3D printing, virtual and augmented reality and advanced predictive analytics are widely available and can create competitive differentiation in new ways.

Companies are justifiably excited about potential new capabilities. Who wouldn’t want to gather real-time feedback – whether it’s from the field, multiple manufacturing facilities or during transit – to improve a product, to proactively identify issues before they become problems, to optimize a product for manufacturability, or to model and analyze a product digital twin virtually before making a single physical part or committing to expensive tooling? The potential is enormous.

But with all the hype, many organizations overlook the role of PLM. It’s seen as the norm of the past, mainly used internally by design and engineering teams. Few see PLM for what it truly is – the core enabler of innovation in the digital age.

PLM still plays an important role in the innovation process. Companies improve their odds of creating differentiated products that improve business results when they deploy new digital technologies, intersect them with PLM, and continue to evolve their PLM solutions beyond the basic capabilities.

Digital + PLM = Better Together

For years, companies have adopted PLM to establish a central repository for the enterprise product data record and to streamline design processes, resulting in productivity gains and efficiency benefits. But while PLM enables some cross-functional collaboration and improves product data accuracy and access, it traditionally has limited impact on delivering more effective innovation or improving integrations and reuse between design and manufacturing, quality, or go-to-market.
Companies still miss innovation revenue targets as a result of launching me-too products or products that fail to meet core requirements because there is no direct voice of the customer input or product performance feedback. Products are still designed with little input from manufacturing and operations, causing production issues that affect time to market, and more importantly time to volume and projected yields.

When PLM and digital are integrated, the benefits multiply. Digital and PLM together provide exponential value by increasing the connectivity among functions in the product value chain, by enriching the product record with real-time data that comes from smart products, factories and customers, and by applying advanced and insightful predictive analytics.

For example, IoT generates a lot of real-time product and operations data, but this doesn’t provide competitive advantage on its own. Many companies are sitting on growing stores of product-related and operations data gathered through sensors – and while they are data rich, they are information poor.

When companies combine core PLM data with real-time data from IoT, in-market product performance data, and advanced analytics capabilities, they can get to true insights. By applying analytics to product design and product field data, companies can optimize the performance of products, create new ones, manage quality issues before product is released to market, and improve production ramp-ups. The availability of intelligent data and the ability to provide it to the right functions at the right time is what creates new opportunities to reduce risk, improve quality and accelerate innovation.

The Role of PLM in the Digital Innovation Era

Because PLM manages critical product data throughout the product lifecycle and across the supply chain, it provides a critical infrastructure for the digital transformation of the end-to-end product lifecycle.

With PLM as the design control hub and the system of record for product definition and change, companies can:

- Establish the thread that increases connectivity and availability of real-time data among functions in the product value chain (this is about establishing the digital thread for real-time digital innovation and business models with embedded decision support)
- Tie the virtual definition of the product with the real-world operation and experience of the product (this is virtual representation of the product – the digital twin – that helps manufacturers test and simulate product lifecycles in realistic situations without having to use any manufactured components or intersect with the physical world at all)
- Provide meaningful insights from existing data on how to further reduce cycle times, facilitate data-driven design, predict quality issues and prescribe solutions, and to correlate design decisions to manufacturing performance, product quality and more

Imagine a scenario where manufacturing yield and quality of product during manufacturing is lower than expected or predicted. More often than not, manufacturing slows or is halted as root cause analysis identifies the cause of the defects and corrective actions are put in place. This impacts the ability to ship product against market demand and leads to missed market opportunity and revenue. Design decisions made months or years ago are hard to identify or correlate to manufacturing defects and lowered yields.
The solution? Integrating existing captive manufacturing sensor (or real-time IoT sensor) data to product data and design decisions in PLM by leveraging IoT, adaptive intelligence, RFID and blockchain solutions. With this link, we can predict potential quality issues and take proactive measures with actionable intelligence, correlating manufacturing outcomes with design decisions already made or being contemplated. Overall, the integration can shorten root cause analysis, drive continuous design optimization, and improve product quality and customer satisfaction.

So, the question is not whether PLM has a role or not in digital innovation and in your digital transformation journey. The question is how you evolve your PLM solution and intersect it with new technologies to enable it to become the digital thread of your product value chain and provide the intelligent insights that will drive your business forward.
Want More Value from Digital Initiatives? Get Your Data Under Control
by JP Romero and Gaurav Arora

Digital transformation initiatives are starting to show some real business results.

Take this oil and gas case study for example, where smart connected operations enabled the company to rapidly drive insights from massive datasets and automate or simplify many processes and tasks in exploration and production activities. The retail industry is already seeing changes in the product development lifecycle in order to survive in a digital world. When it comes to initiatives around AI, machine learning or IoT, the potential is enormous.

But there is one common theme that spans across industries: for all digital efforts, data is the underlying raw material. And it’s time to get your data under control.

Justifying a Strategic Approach to Data Management

According to John Mancini, a former president for the Association for Intelligent Information Management, one of the reasons that both digital transformation and big data initiatives fail is that data is simply out of control[1]. Organizations must take steps to tame their data to succeed. The data involved – and its metadata – must be clear, auditable, trustable and easy to find throughout its entire lifecycle.

To do this, enterprise information management (EIM) and digital strategies must be carefully aligned. An ad-hoc approach to EIM – instead of constantly measuring effectiveness against a framework – will stall momentum of the EIM program and everything else that depends upon it. Even taking the first steps towards governing and setting up a certification process for data sets or reports will increase the probability that your digital initiative will succeed.

A recent report from Forrester found that this is part of the reason why digital transformation initiatives are a bigger challenge than just finding a vendor and buying a technology or using some open source libraries. It is more of a cultural and organizational problem[2]. This assessment might sound familiar, since this is a recurring theme in the EIM space. According to an EIM Readiness study from 2014, implementing an enterprise-wide EIM strategy is non-trivial and most organizations are struggling to achieve buy-in from departments and to enforce enterprise-wide policies and standards[3]. Anne Smith, from the Enterprise Information Management Institute cites cultural barriers as the first reason why data governance programs fail[4].

Getting Started

Depending on what you are trying to achieve, your EIM strategy will vary. For an enterprise struggling to speak the same vocabulary and arguing over semantics, it’s a priority to build a business glossary. For those that still do not have self-service analytics
capabilities because the data lineage is still waiting to be untangled, the priority is a metadata repository of physical data assets. This will clarify where data comes from and the hops it makes along the way.

A common approach to kick-start data governance is to identify KDEs – also known as CDEs for key or critical data elements – in order to prioritize the data elements that need to be crystal clear for the business to boost revenue, improve product quality or ensure compliance to internal/external regulations.

The Bottom Line

Just as it would be foolish to expect something you cooked with suspicious-looking ingredients to taste amazing, a digital initiative built with suspicious data is risky at its best. As tempting as it may be to dive into a new IoT or analytics initiative, consider EIM improvements in parallel to ensure visibility into data quality and governance metrics.

Learn More

Find how Kalypso can help you build your EIM foundation for your digital transformation

References


In the second video of our KNOW series, we explore the application of advanced analytics to product development data.

Using product lifecycle intelligence (PLI), we can now predict the outcomes of product development and prescribe recommendations to make the future better – both for companies that make products and the people who use them.

Learn More
kalypso.com/pli
Discrete manufacturers and R&D professionals have long viewed product lifecycle management (PLM) as a means to enhance manufacturing and design process management, data integrity and digital mockup. While these capabilities serve as a baseline to address operational challenges, current out-of-the-box solutions lack the maturity to maximize the value of product data and quickly tie it to business decisions. In increasingly digital environments, PLM solutions that can offer a broad suite of analytical capabilities appear well positioned to meet the needs of manufacturers.

In order to bridge the gap between the capabilities that are available today and those required to put the full potential of product data to work, we recommend an approach based on our Product Lifecycle Intelligence (PLI) framework. PLI is an application of advanced analytics across the product lifecycle to improve innovation results. It applies machine learning techniques to mine operational insights from product development data in business systems including PLM, ERP, QMS, MES and more.

Four Categories of Analytics that Draw Insights from Product Data

There are four categories of analytics that can be used to draw insight out of PLM data. First, descriptive analytics are the easiest to execute and involve using data to explore trends and performance after they happen. Most organizations already engage in forms of descriptive analytics with their PLM product data today. Diving deeper, the next level of analysis involves diagnostic analytics, which explain the reasons behind historical trends. This information can provide insights about which variables are most responsible for an outcome.

The third category is predictive analytics, which uses advanced machine learning algorithms to peer into the future and understand the most likely outcomes before they happen. For example, imagine an algorithm that could predict that a product in early stages of development will likely fall short of market expectations. Knowing this in advance through predictive analytics would allow resources to be diverted to R&D products that are more likely to be successful.

Finally, the fourth and most advanced category is prescriptive analytics, which makes evidence-based recommendations to help optimize future outcomes. Imagine asking your data to tell you how to decrease product cycle times, or which suppliers to use to meet demand needs on time.

The analytics offered by true PLI can take PLM data and use it to create models that can guide decisions to maximize value. As an organization advances from descriptive to prescriptive, the potential for results-driven insights, particularly before critical investment decisions are made, increases sharply. PLI helps organizations predict
the impact of product development decisions on key business performance metrics, like demand, cycle time, cost, quality, regulatory compliance, manufacturability and supply chain efficiency.

Put Product Data to Work with PLI

The PLM software on the market today does a great job of managing product data through rapid change and capturing this contextually, but is less stellar at putting that data to work through datamining and analytics. For many discrete manufacturers, this means that they are sitting on months or even years of untapped R&D product data. With product lifecycle intelligence, companies can bridge the gap in PLM analytics capability today.

Companies with less mature PLM or PDM implementations can also benefit from PLI. Even with small or moderate amounts of data, PLI offers the ability to understand current performance, historical averages, the variances across different business units and functions, and begins to paint an emerging picture of the root causes that are influencing performance challenges. As your organization iterates through product development efforts and your database grows to be robust, the value of PLI grows accordingly.

The imperative is now. Democratize the data by allowing front line users to generate insights that matter to them, thus maximizing the value from your product data—or wait for your competitors to do it first!
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.
Companies that manufacture consumer packaged goods are great candidates for driving real business value from advanced analytics. At this point, we all realize there’s potential value, but there’s still a lot of hype, and many of the technologies are complex.

Here are some real applications of machine learning and analytics for CPG manufacturers, along with some practical recommendations on how to get started.

**A Little Background on Advanced Analytics and Machine Learning**

Advanced Analytics is the examination of internal and/or external data sources using machine learning, natural language processing, and other sophisticated techniques to discover deeper insights, make predictions and/or generate recommendations. The capabilities of advanced analytics typically go beyond those of traditional business intelligence.

Machine Learning is an artificial intelligence (AI) technique that allows a computer program to learn without being explicitly programmed.

Machine learning algorithms are designed to learn new things in similar ways that humans learn – yet much faster, at a greater scale, and under more complex conditions. Unlike traditional computer algorithms, these grow and change when exposed to new data.

A great example is the 2016 machine learning breakthrough when an algorithm beat a Grandmaster at the game of Go. There are more possible positions on a Go board than there are atoms in the universe (10^360). Traditional computer algorithms could not handle such a challenge. At first, the algorithm was a blank slate. Then it was trained with historical real-life games. Then it was tested, and its learning was reinforced with game play. Finally, it picked a strategy to win based on statistics.

At the time, it took six weeks to train the algorithm to be a Grandmaster. Today, with the improvements in learning algorithms and computer processing, it would only take three days. For a simple game like Chess, it takes less than an afternoon to go from knowing nothing about the game to defeating a human grand champion.[1]
So What Does This Mean in a Business Context?

With advanced analytics, companies can drive actionable insights from data that comes from multiple sources and systems (both internal and external). And in the same way algorithms can be trained to make decisions to win a game of Chess, they can be trained to extract meaningful insights from product data, formulate predictions, recommend improvements, and even automate actions within systems and processes.

These predictions, prescriptions and automation can improve marketing effectiveness, increase sales team performance, improve forecasting, optimize the supply chain, and streamline manufacturing.

Three Valuable Use Cases for Consumer Goods Manufacturers

Here are three use cases we’ve seen drive real business value.

Product Lifecycle Intelligence

PLI is the application of advanced analytics across the product development lifecycle to improve results from innovation.

Most companies have collected product data for years, and it’s largely untapped. Data in enterprise systems like product lifecycle management (PLM) describes the decisions made on products, and there’s an opportunity to combine this with data from other sources like ERP, MES, and other systems. With PLI, companies can drive actionable insights from all of these sources to predict outcomes and prescribe actions to improve results. And it only takes minutes.

As an example, we worked with one company that was searching for ways to optimize R&D cycle time. With PLI, we helped them apply predictive and prescriptive techniques that not only optimized R&D, but also product development and quality processes, which drove substantial cycle time reduction. PLI can transform data management tools into an intelligent decision-making system that benefits the whole enterprise.

Here’s a six minute overview of PLI. Check it out to learn about structured data, advanced analytics vs. machine learning, and more about how PLI leverages these technologies to maximize the value of PLM data.

Watch the video here.

Robotic Process Automation

RPA is an automation tool that completes rule-based tasks in a business process. The traditional goal of RPA is to take the robot out of the human—to complete repetitive and rule-based tasks without human intervention. With RPA, these tasks are completed faster and with more accuracy.

We’ve seen companies apply RPA to automate and improve data migration to drive business value in the following situations:

- Data Standardization and Validation: With RPA, companies can quickly and easily improve data standards use across systems and validate them against publicly available data.
- Data Confirmation: An organization can leverage RPA to review and confirm information submitted to a central repository. This data can be from suppliers, consumers, customers, or an internal function.
- System Modernization: When sunsetting legacy systems or moving capabilities to the cloud, RPA helps create a better user experience on the front end while using different systems on the backend.

- Mergers and Acquisitions: RPA quickly migrates data to resolve overlapping systems and datasets, enabling platform consolidation and reducing licensing costs.

- Data Duplication and Reporting (for ongoing data migration):
  - Many legacy systems cannot support integration and require employees to enter data twice or use a manual migration format, like Excel or CSV. RPA eliminates that duplication.
  - Real-time data relevant to the CRM function can exist in multiple systems. With RPA, this data can be refreshed quickly by clicking a button that launches a bot to retrieve the data from multiple systems.

The RPA software robot (or bot) has a user ID just like a person. The bot typically has a single-business task governed by logic and structured inputs. Its rules do not deviate. It does not learn, but this technique has been successful in streamlining operations and freeing up staff spare time.

RPA can improve data migration by providing:

- **Ease of Use:** Most systems have a graphical user interface (GUI) and can be configured without advanced programming skills. Some systems are starting to apply machine learning, meaning the RPA can learn over time.

- **Data Quality Checks:** Most RPA solutions quickly expose inconsistencies in data and can use external data to improve validation. Some even leverage machine learning to make data quality checks better.

- **Traceability:** Data traceability is a concern, so many RPA solutions can produce a log file with a configurable level of detail in various data output types to satisfy data traceability needs.

### Always On Monitoring

This is an algorithm that monitors internal and external data sources, and then applies analytics and machine learning to provide insights around a specific business question.

Today, trends are more dynamic, consumer engagement models constantly evolve, channels are frequently disrupted, and regulatory shifts are common. With always on monitoring, consumer goods manufacturers can keep their finger on the pulse.

As an example, we have helped companies leverage always on monitoring to rapidly identify the difference between complaints and mentions that appear online. When they properly categorize complaints, they can feed the right insights back to product developers to improve future product revisions. So they get smarter insight without expanding headcount.

For one company, we helped to connect structured internal complaint monitoring with unstructured social media sentiment to analyze and assess the inputs received. The always on system continues to monitor activity, process new data, and refine the algorithm it uses to be more exact.
Getting Started with Advanced Analytics in Consumer Goods

Many companies believe in the value of machine learning and advanced analytics technologies but are intimidated by their perceived complexity and lack clarity on how to get started.

One of the most important pieces of advice we can give is to avoid black-box analytics services. There are many companies who will outsource data science if you provide the data, but the benefits of these services can be limited, and this approach prevents companies from building analytics capabilities in-house.

Here are some leading practices based on our experience helping our clients build and adopt advanced capabilities around predictive analytics, machine learning and artificial intelligence.

1. **Don’t be afraid to start with a minimally viable product (MVP)**
   You may need to prove to your leaders that investment can pay off

2. **Start with a Business Problem**
   Identify business needs that can be tied to clear analytical goals

3. **Quantify the Metrics Improvement for the Business Case**
   What does a 1% improvement mean to the business?

4. **Build a Cross-Functional Team**
   Data without domain and system experience is dangerous

5. **Quick Wins are Possible**
   Advanced analytics can sound daunting, but there are ways to build value in the short-term

Learn More

Product Lifecycle Intelligence (PLI)
Advanced Analytics and Machine Learning

Reference

Digital product creation (DPC) is the practice of designing, prototyping and verifying products in a virtual and collaborative environment. The value created by digital technologies throughout the end-to-end product lifecycle and across functions is significant, but so are the obstacles.

In a research report from Kalypso, the Indiana University Kelley School of Business Center for Education and Research in Retail, and Market Key, we studied leading product development practices in the retail, footwear and apparel (RFA) industry to see where leaders are focusing their transformation investments. In the research, DPC emerged as the practice area where most respondents have actively begun investing.

However, our research also indicates that despite the DPC investments being made across the industry, few have achieved scale in their efforts.

So once a company is invested in 3D, how can they successfully drive a program that achieves real business value?

Based on our experience helping clients drive DPC transformations, here are eight common pitfalls and how to avoid them.

**Pitfall 1: Failing to adopt a holistic, cross-functional strategy**

Companies need to develop a strategy that encompasses the entire product development cycle. Not only the create process, but the make and sell processes as well. The graphic below depicts the ideal end-to-end scope for DPC. Companies often focus on only one functional use case, when in reality, end-to-end DPC requires multiple initiatives across numerous functions.

The biggest trap many brands and retailers fall into is that they treat DPC as a deployment project rather than one focused on achieving company-wide adoption in support of a broader 3D strategy. Keep in mind that it’s not just about a single new innovative tool; it’s about enabling a whole new way of doing business and developing products.
Pitfall 2: Minimizing the importance of internal and external collaboration

Successful DPC programs are inherently cross-functional, so failing to collaborate outside of the product development team also means failing to realize all the potential business benefits.

Collaborate with downstream stakeholders, like marketing and sales, from the beginning. Any function that may benefit from 3D assets should have a seat at the table. Remember that 3D tools are not just a better way to design – they can transform how a company does product development. A DPC program requires a robust organizational change process, so cross-functional executive support is also critical.

External collaboration is a critical consideration. Collaborate with vendors and other stakeholders who play a role in the end-to-end process. Consider adding external resources to the product creation steering committee. A complex RACI model will clearly identify roles and responsibilities throughout the program and highlight when and where potential collaboration can occur.

Pitfall 3: Thinking that DPC is about just one technology

Foundational technologies like product lifecycle management (PLM) have a broad set of capabilities that facilitate the work of multiple functions, which means most companies choose one platform that meets most of their requirements.

But for DPC, there are potentially numerous categories of technologies involved. To achieve the breadth and depth of functionality required across create, make and sell, multiple visual technologies must be deployed, including 3D modeling, rendering, material virtualization, digital avatars, fit analytics, augmented reality, virtual reality and more.

Think of DPC as a suite of best-of-breed solutions that complement foundational technologies like PLM, digital asset management (DAM) and product information management solutions.

Pitfall 4: Insisting on the same standard process flows and tools for all categories

Keep in mind that DPC processes – and even tools – may vary across product categories like footwear, apparel and hardlines.

DPC tools for hardlines are the most capable, because similar solid modeling techniques have been used in automotive, aerospace and high-tech industries for decades. Apparel modeling tools have made great advances in recent years and are beginning to realize the ability to support a workflow from create to make to sell. Footwear is a complex product that shares characteristics of both apparel and hardlines. This complicates the modeling process and workflow, but many footwear companies continue to make great progress.

Just because a tool and workflow are successful for one category, it doesn’t mean they will work for another. Each category needs to be considered separately. Consider allowing the use of more than one 3D design solution within each of the product categories, like apparel, to improve collaboration with product vendors and to drive adoption from internal design team members.

Pitfall 5: Neglecting to build a solid data foundation

An alarming misconception that we often hear from clients and 3D software vendors is that PLM is not a prerequisite for DPC. Sure, it’s possible to experiment with 3D tools – and even run some compelling proofs of concept – without integrating to a PLM database. But scaling DPC capabilities and driving full value for the organization requires a strong, integrated data foundation.

Designers and developers need a library of materials, lasts, blocks and trims at their disposal, as well as a clear connection with product architecture. With the scale and speed at which retailers operate, a strong foundation of PLM and DAM is critical for DPC success.
Pitfall 6: Underestimating the impact of talent and organizational structures

DPC tools require a different skillset than 2D apparel and footwear design tools (primarily hand sketching or Adobe Illustrator). Given this steep learning curve, adopting DPC for design requires both upskilling talent and considering new organizational structures to support these teams during the transformation.

The most recent wave of students graduating from design schools are digital-ready. They expect to work in 3D, which is a big change from prior generations with deep skills (and preferences) for 2D. To address this gap, consider creating an in-house 3D design bureau or Center of Excellence (CoE) that provides 3D services to all categories, supplementing 2D designers instead of requiring them to retrain.

Not quite ready to commit to retraining or creating a CoE? The good news for retailers is that many manufacturers have anticipated 3D growth. Retailers and manufacturers can partner, with vendors providing the initial 3D image and retailers then editing or commenting.

Pitfall 7: Getting stuck in proof of concept purgatory

It’s a real place. Proofs of concept are necessary to validate techniques and capabilities, but they are not enough to support transformation. It’s relatively easy to run a proof of concept (POC) and declare success, but it’s much harder to apply the learnings of those small-scale efforts to the size of the businesses.

Since POCs tend to address one function at a time, they often fall short of a cross-functional approach. Make sure to establish metrics and success criteria before starting a POC. Establish and align on a vision for what happens if it’s successful. A POC is just one, very early step in a successful DPC program – don’t get stuck here. Be prepared to fail, learn, and adjust.

Because DPC has the potential to drive significant product development transformation, at some point it requires a vision, strategy, senior executive sponsorship, business case and roadmap in order to be successful. Focus on these elements to break out of proof of concept purgatory.

Pitfall 8: Adopting a wait and see approach

Successful DPC programs take time. Some of the most successful examples have taken seven or eight years to achieve value. However, the learnings from those early digital pioneers sets the groundwork for a new set of companies to follow in their footsteps and generate results faster. The next wave of companies is targeting a two- to three-year timeframe.

Don’t be hesitant to get started – a wait-and-see approach means an endless game of catch-up later. Start now, even with a POC, and leverage people in your organization that are forward-thinking to help lead the transformation.

The Bottom Line

The RFA industry is at an inflection point – DPC tools have advanced and these capabilities are gaining momentum as companies show proven results. The bottom line: start now, think holistically, and strive to avoid these pitfalls along your transformation journey.

Learn More

Digital Product Creation - Create, make and sell products in a virtual, collaborative environment
Video: Digital Tools to Transform Retail Product Development
Smart factories, enabled by digital technologies and concepts, may not be as futuristic as you think. More and more companies are seeing real business value from initiatives related to augmented and mixed reality, overall equipment effectiveness, product lifecycle intelligence, and robotic process automation.

Need inspiration to get started? Here’s our vision of the factory of the future, and the people and processes that will be impacted.

Two years ago, we published an article about The Factory of the Future: A Day in the Life of a Plant Manager in 2020, which introduced our vision for what the factory of the future could look like. Now that two years have passed, it’s time to revisit Bill and his team at Stuart Sprockets to see how they have continued to improve their operations.

6:20 AM

Bill sips from his tall mug of coffee as he squeezes through the turnstiles on his way to his office in the Stuart Sprockets plant. Bill always feels pride walking into the plant where he had spent his whole career, starting as a maintenance technician over 20 years prior. Bill rose quickly through the ranks at Stuart, and in his current role as Senior Director of Development/Operations, he is responsible for the design and production of all the products that are produced in the facility. Bill has long held a reputation as a visionary when it comes to implementing digital technology to drive steady improvement in his plant’s results, and consequently, his plant had become a kind of staging ground for experimenting with big new ideas.

Bill has always found something magical about walking on the shop floor in the calm minutes before production begins for the day. He soaks in the sights for a few more seconds before switching on his mixed reality smart safety glasses and scanning the floor. Real-time results on several key performance indicators and other metrics overlay his field of vision, allowing him to quickly spot process issues.

In recent years, Bill has invested in a mixed reality system, and now all associates wear a pair of smart safety glasses daily. Through this program, Bill unlocked immense value by making real-time data and information available to everyone, along with many benefits including improved data-based decision making, faster training of new associates, and giving everyone the tools to be a problem solver.

As Bill’s eyes scan across Machining Center #1, across the aisle he notices some particularly good numbers. “Morning Bill!” comes a cheerful voice from behind a floating green 9 from the quality metric on Bill’s display. It’s Christine—the plant’s maintenance manager. When Bill joins her (after crossing the aisle in a designated crosswalk), Christine highlights the results from the previous night’s run on that equipment. It’s a new record output for a single shift.
“Good stuff Christine,” Bill says. For the past five plus years, Bill and Christine have integrated more and more of their plant’s equipment into their Internet of Things (IoT) platform. They started by simply collecting data and using it to draw conclusions on production runs that had already happened (much like what they were doing right now). Eventually, they used the data along with a machine learning algorithm to predict when machine components would break down. Additionally, in the past year, Christine’s team has started to use the data to optimize the production settings of their machines to reduce scrap. The model has grown to be more and more sophisticated, taking into account factors like ambient temperature and humidity, the variable properties of raw materials, and which operators are running the machines. As the pilot for the program, Machining Center #1 has shown very promising results. They have plans to roll this program out to the rest of the factory over the next year.

7:10 AM

Much can be said about emerging technologies, but there is still no substitute for people being co-located to solve problems. For that reason, Bill considers the daily production meeting to be a critical part of every day. Stepping into the designated corner on the shop floor, Bill scans the walls with his smart safety glasses. The walls are set up to be overlaid with the production results from the previous day, including trends and production alerts. Bill has arrived a few minutes late, and the stamping department manager, Jose, is giving his daily report. The centerpiece of the report is a single metric—overall equipment effectiveness (OEE).

OEE is a single metric that factors in the availability, performance and quality of a plant. OEE is not a new concept—it originally came out of the total productive maintenance systems that began in Japan in the 1960s. However, it never really caught on at Stuart until recently. As it essentially reports how effectively a manufacturing facility is utilized, Bill has found that OEE is a great way to measure the improvements that his multifaceted smart factory initiatives have made in his plant’s bottom line.

OEE is now calculated daily for each department, and for the plant as a whole. Bill sees it mostly as a metric for self-improvement. There is little to be gained by comparing the raw numbers across departments or plants, but Bill expects each of his managers to improve their department’s OEE each quarter. He has seen his plant’s OEE creep up over 80% in recent years, which he considers to be approaching world class, but he knows there is still much work to do to get there. After the meeting’s conclusion, Bill mingles with his managers for a few minutes before heading back to his office for his next meeting.

11:15 AM

In order to build strong connections with his people, Bill tries to eat lunch each day with a different group within his team. Today he is hoping to sit with some members of his product lifecycle intelligence (PLI) task force. He is presenting the exciting results of their work to the CEO in two weeks and wants to check in on how things are coming along. He sees several PLI team members at their usual table in the corner of the cafeteria and slides into an unoccupied seat.

About 10 years ago, Stuart Sprockets invested in an enterprise-wide product lifecycle management (PLM) system to capture product data from the early stages of sales and design through manufacturing and customers in the field. Then, one year ago, after attending a consulting training seminar on data analytics, one of Bill’s managers came back with an exciting idea. He knew that with years of product design and change order data in the PLM, they were sitting on a potential treasure trove of actionable insights that could be unlocked by employing data science techniques. They launched a PLI initiative based on the concepts presented in the training session, and set up a task force to study how they could put the data to use.
The PLI task force started slowly. As a pilot project, they decided to try to optimize the lead time for product change orders. They pulled 10 years of change over and workflow data from the PLM system and used it to build a model designed to optimize lead time. They performed historical diagnostics and gained some unexpected insights, including: “If the month a change order is initiated is Nov or Dec, it takes 60% longer,” and “If there is an international resource assigned to any task, it takes 70-80% longer.” These insights were fed to the product engineering management team to help aid with their work scheduling.

Next, the team amended the model to predict how long change orders would take based on the characteristics of the change and the resources that had been assigned to it. Over the past four months, the PLI team has been validating the results of their predictive model by comparing predictions with how long the change orders actually took. While the preliminary results are very promising (they currently see a correlation of around 0.7 between the model and reality), they are gaining additional insights and tweaking the model to make it even better. The expected end results include faster product development times and more accurate line scheduling.

The next steps are twofold: first, they are working with IT to embed predictive analytics results in the PLM system so that change owners can see predicted lead times before creating change orders. And at the same time, they are working on making the model prescriptive. Bill’s vision is that in the future, the system will recommend the optimal resources when creating a change order.

Satisfied with what he hears from the PLI team (and his excellent Chile con Carne and baked potato), Bill steers the conversation topic away from work and towards the increasingly hopeless prospects of the local football team. Bill is confident that his upcoming presentation to the CEO will go well, and assuming it does, he plans to institutionalize this new capability by transforming the task force into a department during the next budget funding cycle.

3:20 PM

Walking back towards his desk, Bill notices a flashing red production alert in his smart safety glasses above a machining center two aisles over. He can see that the supervisor has been alerted, and that maintenance and engineering support are on their way. With confidence that the issue is handled, he continues towards his desk.

As Bill steps into the main plant office on his way to his desk, he reflects on how different the space looks compared a decade ago. What was once a room packed from wall to wall with tight rows of cubicles, is now mostly open with some desks and many shared workspaces. The transition started when Bill’s predecessor as plant manager ordered most manufacturing managers to relocate to the shop floor, so they would spend more time problem solving and engaging with their team members.

However, since Bill embraced the potential to automate administrative tasks very early on, this effort has yielded the biggest impact. As a maintenance technician in his early days, Bill was on the front lines of the automation of the plant’s manufacturing processes. He installed countless robots which proved capable of producing parts at lower cost and higher quality level, while enabling workers to focus on problem solving instead of loading parts. Bill knew that these same principles would also apply to administrative tasks, and several years ago engaged a business partner to help him study what could be done. The team identified the most repetitive and rote parts of administrative roles—like purchasing and line scheduling—and began to streamline them. Several tasks were automated using a robotic process automation (RPA) toolset, which freed workers to spend their time on more critical activities like problem solving, new product introductions and design transfers.
Bill knows from his maintenance days that automation is not a cure-all. The key is simplifying processes before automating, while being mindful in the design of human-computer interfaces. Additionally, great care must be taken in selecting which processes to automate—in order to minimize the risk that removing the human element from a process may lead to a loss in creativity. However, the results have spoken for themselves. Administrative headcount has dropped by 15% since the beginning of the RPA journey, and workers in affected roles reported higher job satisfaction because they could spend more of their time on creative problem solving as opposed to repetitive clicks in a system.

5:30 PM

Bill makes a few final touches to the monthly presentation that he had been working on all week and sends it off to the CEO. He is proud of the strides his plant has made in the past two years, particularly in embracing technological advances in smart connected manufacturing and data analytics.

Bill packs up his things and heads to the parking lot, destined for his daughter’s final soccer game of the season. He knows that as one of the leaders of Stuart’s transition to a fully digital manufacturer, he needs to continually evaluate new and emerging technologies to stay in front of the competition. In a digital world, Stuart cannot continue to rely on traditional manufacturing methods to compete and win in the market, and it is the responsibility of leaders like Bill to guide the team through the digital wilderness.
Practical Starting Points for Industry 4.0

A Plan for the First Steps in a Successful Smart Connected Manufacturing Journey

by Nick Ward, Joe Dury, Michael Glessner and Nate Buyon

Industry 4.0, widely considered the 4th Industrial Revolution, is the current trend of automation and data exchange in manufacturing technologies to create smart factories featuring autonomous controls. It combines cyber-physical systems, the Internet of things (IoT) and cloud computing, and has the potential to affect every aspect of manufacturing business. The pace of change is staggering, but companies that commit to learning from others can succeed.

Our first article, Positioning for Success with Industry 4.0, focused on learning from others outside of one’s own industry to get started with Industry 4.0. Here, we discuss how to create commitment and buy-in while addressing fundamental changes to collaboration and culture, as you work to advance Industry 4.0 within your organization.

Creating Commitment and Executive Support

As discussed in our first article, companies must first do an honest assessment of current capabilities and understand where you stand relative to competition. The next step is to gain executive support. Senior leadership buy-in requires a strategic vision that demonstrates how you’ll evolve from where you are today to where you want to be in the future, and articulates the imperative to begin the change journey now. The best plans have a short-term focus with a long-term vision. Regardless of what that plan looks like, there needs to be a strong commitment to allocate capital for new technologies along with required talent to implement and refine the solutions.

To build the vision and plan, prove out the value by developing concrete use cases with a strong link to business value.

For example, a common use case is using Industry 4.0 to maximize the value of existing data by leveraging investments in Product Lifecycle Management (PLM) and Enterprise Resource Planning (ERP). Leaders in the space connect disparate data sources into a flowing structure of data for every product. A true bill of information connects design requirements and details how a product fulfills these needs through models, simulations, processing and field data. Also, linking manufacturing data to the product record can enable insightful visualizations and processing optimizations.

Linked data structures enable managers and operators of smart factories to ‘see’ operations in an entirely different manner. Blending the physical world with superimposed digital characteristics or dimensions provides managers with actionable, real-time insights to improve product quality, productivity, and profitability.

This journey can typically be achieved using existing PLM and ERP systems (with some improved datasets), leading to a high return on investment. These initial
returns or “quick wins” can be used to build consensus within the organization and gain executive support for digital manufacturing, setting the stage for future initiatives to further enable Industry 4.0.

**Considerations for Collaboration and Culture Change**

The shift to a digitally connected manufacturing organization will cause the company’s value chain to condense and become more connected. Divisions and departments that have historically operated in silos will need to become interconnected. Collaboration is essential to the success of developing smart, connected products leveraging a digital manufacturing process. Product development must be tightly connected to customer experience, procurement, and operations teams. R&D and engineering groups must work closely with marketing and IT to create a unified vision and roadmap for the future. Collaboration and focused communication will be necessary to successfully navigate this change.

The work of individuals within a smart connected manufacturing value chain and upgraded factory will look and feel very different. Individuals will see their duties shift, and will need to collaborate with their colleagues across the organization more frequently. For example, individuals in product engineering and manufacturing operations groups will be in frequent communication with each other to optimize the product design and manufacturing processes. These new communication channels will be enabled by technology and interconnected information systems, but will require a concurrent cultural change to fully realize their potential.

As with any significant cultural change, digital leaders should expect to see pockets of resistance across the organization. Embracing Industry 4.0 will be a big change and will require dedicated and proactive change management to overcome opposition. A shift in organizational structure may be needed to align to the changes. In the HBR article “How Smart Connected Products are Transforming Companies,” the authors introduced the term DevOp to describe combining the functions of product development and operations to foster collaboration and coordination. The flexibility to reposition key influencers to the places in the DevOp organization where they can add the most value, will also be critical to the success of Industry 4.0.

**Understanding the Digital Imperative**

Embracing the shift to Industry 4.0 is a substantial opportunity for companies to seize a competitive advantage. Investing in innovation is a key for sustainable long-term growth. However, the window of opportunity is closing. The pace at which companies adopt Industry 4.0 will be highly dependent on how fast managers and executive leaders embrace the challenge and leverage the technologies that are available today. Lagging firms may find themselves fighting for their survival or swallowed by more advanced players. The journey to integrate digital manufacturing technologies into existing processes will take time, but it is critical to take these initial steps now.

If you do not have the capability to make these changes or need guidance along the way, seek out trusted advisors with industry knowledge, experience, and an appreciation for what is possible for your business. Speed is essential—learn, fail, and make adjustments quickly.

You will want the history books to show how your company identified, reacted, and thrived during these disruptive times. Winston Churchill said, “History will be kind to me for I intend to write it.” Industry 4.0 concepts offer the next opportunity for the savvy manager to create history.
At its core, the digital twin is exactly as it sounds; a digital replica of a physical asset. To be a true twin, it must match the physical copy in every way. Every way, that is, except for being physical. It models the dimensions, properties, manufacturing sensitivities, and performance parameters just as they exist in the physical world.

The concept of a digital twin has proven successful in the semiconductor, aerospace, and automotive industries and has now begun to gain traction in industries like retail and consumer products where it is used to model key parameters. Successful companies have found that a digital twin enables them to make design adjustments prior to beginning mass production, and factory adjustments during production. For example, clothing companies are using a digital twin to model the fit of different fabrics and how they lay, then adjusting the material, cut, and pattern before bulk ordering fabric or sending the design to third party manufacturers.

The benefits are significant:

- Better returns for products sent to market due to higher quality designs and tailored products optimized for the target consumer, which leads to increased sales
- Reduced design cycle times decreasing the number of iterations and not having to wait for samples to arrive and send physical samples back and forth with adjustments
- Increased ability to get products to market faster
- Better knowledge of what is going to market, and ability to vary products with confidence (ex: color)

Despite the novelty of the digital twin in other industries, this concept has been leveraged in semiconductor design and manufacturing for decades. Hardware description languages like VHDL and Verilog, along with simulations and pre-silicon verification, have been used to virtually model chip functionality and performance and help design engineers to manipulate designs in the digital world since VLSI (very large-scale integration) circuits have been around. It’s not exactly groundbreaking to model a chip before producing it.

**Expanding the Semiconductor Digital Twin**

To truly realize the full benefits of a digital twin, semiconductor firms must move beyond the chip in isolation and look at how it interacts with the data, manufacturing processes, and systems that must come together to turn it from an ingot to an integrated circuit, and how that finished component interacts with the rest of the product it is used in. A comprehensive digital twin includes a full digital representation of (1) circuit performance, (2) manufacturing sensitivities and throughput, and (3) interaction of the data of all the modules in the system with other components, hardware, and software.

Understanding key interactions of the entire system up front – including electrical, thermal, mechanical, and software integrations – brings additional insights to the manufacturing process. Process engineers today are focused on process sensitivities that impact yield with
parametric measurements and functional testing. Frequently this means reacting to process excursions and parametric measurements in class probe and other test events. However, a holistic digital view of the operation of the entire fab, along with interactions between silicon and the rest of the system, can prescribe improvements to improve yields across the system – not just Silicon yields – before the chip is taped out and throughout production.

To enable a foundation for smart operations and proactive analytics-driven yield improvements, the digital twin should incorporate the performance of the component in the entire system as well as the entire fab operation. This digital view of system data provides visibility to insights at scale across platforms, process nodes and factory production lines. Engineers can leverage this data to make improvements that go well beyond traditional pre-silicon verification efforts and Monte Carlo simulations to predict yields.

For example, a fab may have yield engineers responsible for yield forecasts and trends, excursion response, root cause analysis and defect resolution. These engineers depend on parametric measurements and other yield data to make decisions. A fab will also have operation planners and maintenance personnel responsible for maximizing uptime and utilization of fab tools. They depend on planning tools, preventative maintenance, tool changeover scheduling, and process flow recipes to manage the operations. The digital twin should be able to model the interactions between these disciplines, such as wafer histories, log files, tool dependencies, production volumes, and throughput requirements. Yield engineers gain visibility into tool impact on parametrics and yields, and operations can predict production loads, tool configurations, and throughput requirements well in advance. This enables engineers to look both at output and yields to capture overall equipment effectiveness (OEE).

Four Ways to Get Started with Digital Twins

Of course, creating this system-wide digital view is a challenge. EDA and simulation data are stored in development systems that speak their own language. Production and yield data are stored in production systems that speak another language. Operational data are stored in factory scheduling systems that speak yet another language. And system engineering data that models the performance of all the components in the system is also separate.

While these systems are separate, the data can (and should) still be brought together to enable views that produce valuable insights. Here are four ways to get started:

1. **Identify the business problems that need to be solved.**

2. **Begin by connecting disparate sources of data** with a summary of results and statistics to demonstrate value through connecting information. Consolidating to a single source of truth for this data is not needed right away. Meaningful insights can be gleaned by analyzing summary-level data across domains. There are many tools that can enable views and analytics from disparate databases.

3. **Establish an intelligent data lake** that can connect more and more sources of data and bring in additional context and structure to that data. This will be an ever-evolving source of data that can be sliced and viewed in different ways to continually improve predictive and prescriptive analytics.
4. **Continually improve the accuracy and precision of your digital twin.**

One view isn’t enough. Analytical analysis will become outdated. New interactions and dependencies will surface. As you generate and connect more data to expand the view of your digital twin, continually look for additional views and insights, including design sensitivities, production yields, system performance, cycle times, and reliability standards. The more data you have, the more valuable your insights will become.

The semiconductor industry has historically been a digital twin pioneer, and semiconductor technology drives the proliferation of digital technologies in other industries. It is time for leading semiconductor firms to pave the way with the next generation of digital technologies by creating a more comprehensive digital twin.

**Learn More**

[Download our eBook](#) for full details on leveraging digital technologies in high-tech, including use cases, benefits and pragmatic starting points.
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

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.
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.

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.

More Reading

eBook: Imperative of Better RIM Download this eBook to learn about the evolution, imperative and benefits of RIM
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