MEDICAL DEVICE PLM®

Powered by Minerva & Aras

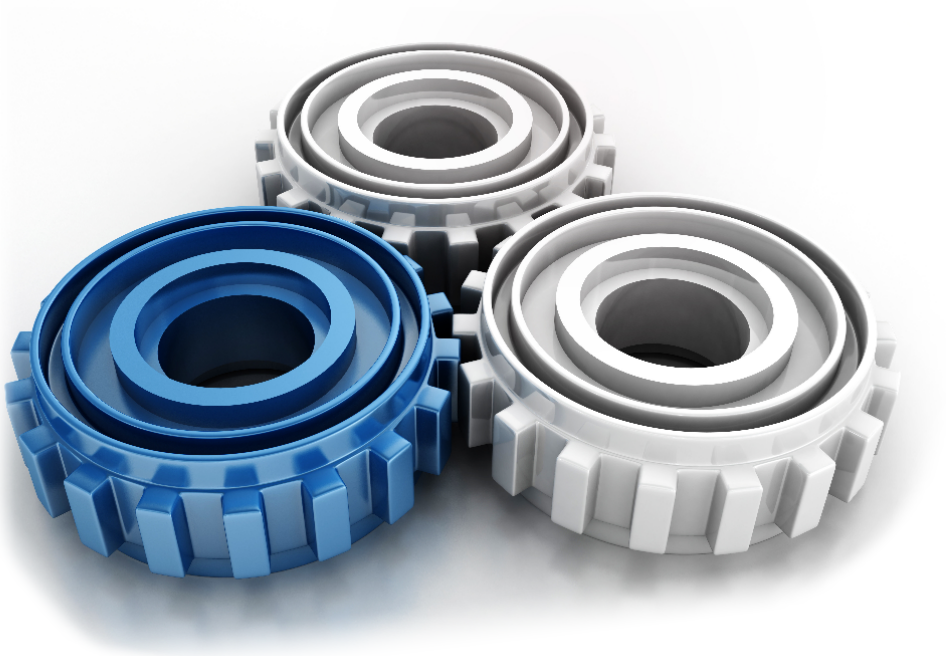
The Business of Engineering in Medical Device

The case for Integrating MBSE and PLM for medical device manufacturers

Here's why you should read this white paper:

As medical device products get increasingly complex, combining interdisciplinary approaches that span the product lifecycle into one system are a must. Disparate systems like spreadsheets, documents and databases fail to meet evolving business needs - they are too focused on the Science of Engineering. In order to keep the pace and stay profitable, manufacturers must develop a broader vision - the Business of Engineering - and implement a resilient PLM system to tackle the challenges of today's volatile and fast-paced business environment.

To succeed and win against sophisticated competitors, companies must excel at verifying the behavior and design of their systems.



A real life example...

One of our customers is a global leading innovator and manufacturer of advanced measurement technology systems with over 50.000 installations worldwide. Their solutions is considered best-in-class when it comes to accuracy and reliability and is used in many applications, ranging from aeronautics, quality assurance, image-guided surgery to biomechanics research.

The company's products are a combination of optical, electromagnetic, and increasingly, software components creating a complex and high-pressured environment for product design, engineering, and manufacturing. Additional complexity and pressure come from creating products in a highly regulated industry, such as medical device development, which carries a heavy obligation for regulatory compliance.

Medical device manufacturers are struggling to manage the ever-increasing complexity of modern products. They have become systems – sometimes even systems of systems – whose product designs require a mix of hardware, software, electronics and/or firmware.

Managing the system view of a product has traditionally been done with relatively simple tools, such as Excel, Visio, PowerPoint, etc. That simplicity disappears when managing the behavior of "systems of systems".

To succeed and win against sophisticated competitors, **companies must excel at verifying their system's behavior – find better wording** - and design as products progress through definition, development and the complete post-manufacturing product life cycle. Otherwise, product quality issues will emerge, putting brands, companies, and stakeholders at risk.

This paper addresses the way in which robust system behavioral modeling can be integrated with downstream design practices to produce better, safer products. It is intended, through discussion of the latest advancements in system-level thinking, to help inform senior engineering professionals responsible for the cross-discipline life cycle of their products.

No more simple products - complexity increases

Product complexity is not the only challenge that faces our customer company example. Additional complexity and pressure come from creating products in a highly regulated industry, such as medical device development, which carries a heavy obligation for regulatory compliance. Specifically, regulations for electronic records, governed by the United States Food and Drug Administration, as contained in **Title 21 CFR Part 11** of the **Federal Code of Regulations**. Finally, design teams, manufacturing and fulfillment are all geographically separate, in different cities and continents.

In an increasingly networked and mobile world, the complexity of medical device products has increased exponentially. The historically well-defined description of a medical device has evolved from unconnected equipment, through to wirelessly, reprogrammable implantable devices where software has become an increasing factor and controls everything.

This development confronts manufacturers with a new range of challenges. Traditionally, only very few disciplines within the engineering departments were involved in the development of a given device. Today, mechanical, software and electronics or electrical engineers must work on the same product, in many cases not even in one location, but distributed around the globe. This means that all of these disciplines have to be coordinated, which makes projects and processes much more sophisticated than they used to be.

Complex products also contain subsystems of various kinds, which in most cases are provided by suppliers. Over time, these suppliers have gained more authority for their own designs, and today, control many critical technologies. This impact on the production process is that these suppliers must be managed and orchestrated.

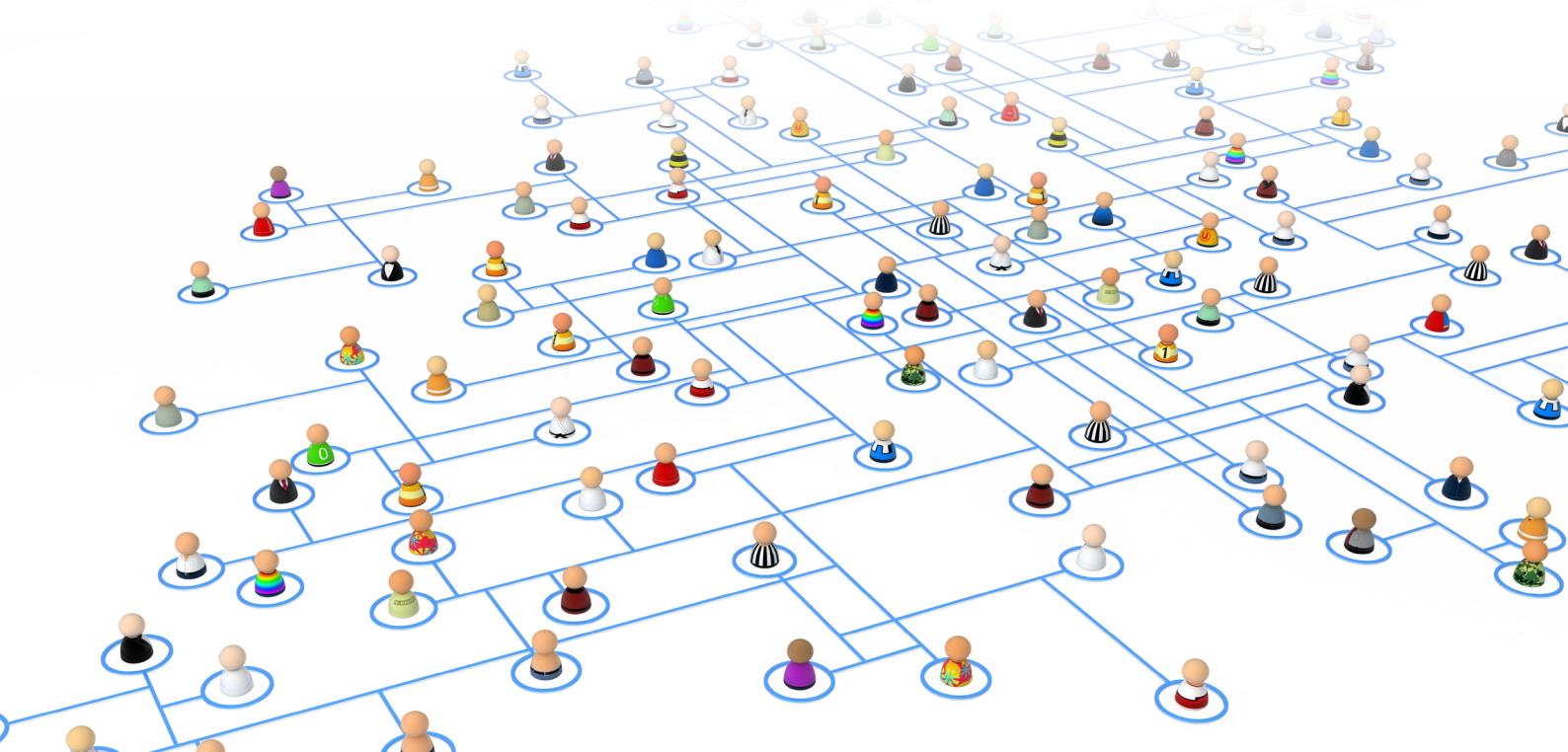
Product safety is also impacted. Needless to say, medical device manufacturers have to guarantee the safety of their products at all times - the lives of the end user can be at stake. Ensuring safety is critical - but tricky - when the product is still in the making. But it can become even more tricky when field updates are necessary, especially for software.

And last, but not least, products are not the only thing growing in complexity. Medical device manufacturers today must literally negotiate their way through a maze of laws and regulations to stay in compliance and avoid business-critical risks. With new regulatory updates such as the EU MDR and IVDR for the European market as well as the MDSAP for the rest of the world, global organizations recognize that they must undergo a transformation of every aspect of their business. Manual processes have to be replaced and legacy systems retired to maintain and strengthen both competitive advantage and the power to innovate.

The customer company began to feel the pain and started searching for a system to alleviate the constant pressures on general product development. Their search led them to explore many different options, without making a final selection, or getting approvals to proceed with an acquisition. In the meantime, they continued to acquire legacy design tools such as Creo for CAD and Polarian for Application Lifecycle Management (ALM), that settled into multiple repositories of largely unstructured and unrelated data. As a result, finding information became a daily difficulty. Simply creating a part number required a request to a separate tool outside of the normal design process.

Product management out of balance

PLM systems started out with no smaller promise than to revolutionize industrial production. When Computer Aided Design (CAD) spread widely in companies during the 1980s, it gave rise to Product Data Management (PDM) solutions, as the mass of digital data created by engineering applications had to be managed. As a significant next step, PLM was meant to go further. It involved a broader approach in deployment and a much higher level of integration across every phase of the product lifecycle, cutting across all disciplines, national and international locations, and the complete supply chain. The PLM process was meant to lower error rates and accelerate development, design, and manufacturing. A single, common source of data for all processes and departments (including suppliers and other partners) was the goal wherein the complete lifecycle would be mapped.



PLM was to centrally manage not only CAD data but also track requirements, product specifications, project plans and manage the quality of the product - literally every department from design through regulatory and quality to field support was to become linked to the central information backbone. **Faster time-to-market, reduced waste, and more efficient use of budgets were the targeted benefits.** This vision, however, has failed to materialize into reality.

Today, the reality of many PLM projects can best be described with the **10-10-100 formula**. 10 percent of the planned functionality is available, 10 percent of the users have access to the system, but 100 percent of the planned budgets are gone. This is extremely frustrating for everyone involved. Many medical device executives who have been involved in PLM projects see high risks and tend to shun PLM in general.

The state of PLM can partly be attributed to the notoriously long time it takes to implement and deploy legacy PLM systems. According to industry analysts CIMdata, more than one-third of PLM installations surveyed in a recent study still have more than three years of development time remaining. In today's fast-paced product world, that is a lifetime. Due to their inherently rigid structure, implementing these systems always means hardcoding changes and individual features. Already difficult to adjust to individual needs in the first place, these systems establish themselves in companies as behemoths that are too complex to be updated.

And, we haven't even scraped the surface and discussed the need for fast and flexible reactions to evolving market trends.

The need to respond fast leads another PLM dead end:

> Should a version upgrade of the PLM software cease to support individual features, everything done to the system to date becomes lost, along with all the investments made up until that point.

This makes companies extremely wary when considering upgrades. That's why **CIMdata** also found that:

> One-third of all PLM installations they reviewed haven't been upgraded in more than five years.

But the major reason why the whole concept of PLM has failed to achieve the original vision is that legacy PLM systems are too focused on 3D mechanical CAD, simulation and digital mock-up - which we call the science of engineering. Because the legacy providers come from the mechanical CAD world, their PLM systems were never optimized for the other processes critical to developing, manufacturing and supporting profitable medical device products - which we call the Business of Engineering - leaving them disconnected and underserved. With the 10-10-100 rule in mind, this creates a huge gap in availability - **90 percent of the users don't even have access to their PLM solution.** This leaves a gaping hole in processes that usually get filled with a patchwork of sub-par tools like Excel spreadsheets, shared drives, e-mail or Dropbox. None of these connect to the PLM system or each other, leaving critical processes poorly supported.

> Legacy PLM systems are overly focused on the Science of Engineering, making them little more than PDM systems for mechanical CAD data, neglecting the bigger picture, namely the Business of Engineering.

Preparing for the Internet of Things (IoT)

Such a PLM imbalance is a major inconvenience for the majority of users within a company. The executive level should also be aware of these limitations for several reasons. First, **as different departments are not properly connected, poor communication between hardware engineers and software developers becomes a constant source for errors and can easily result in a variety of safety problems.** This opens companies up to liability risk - looking into the recent past, this is not a theoretical possibility and can directly harm product quality, patient safety, and business results.

The lack of an integrated product configuration causes problems at the hands-offs between engineering, manufacturing, suppliers and field support. Wrong information gets shared, while different versions of bills of material (BOMs) and documentation circulate. Simply put, processes do not access a single, common source of data, resulting in delays, cost overruns, and safety issues due to faulty products. This again can have severe consequences. Something seemingly small, such as an error in software configuration, can have disastrous results.

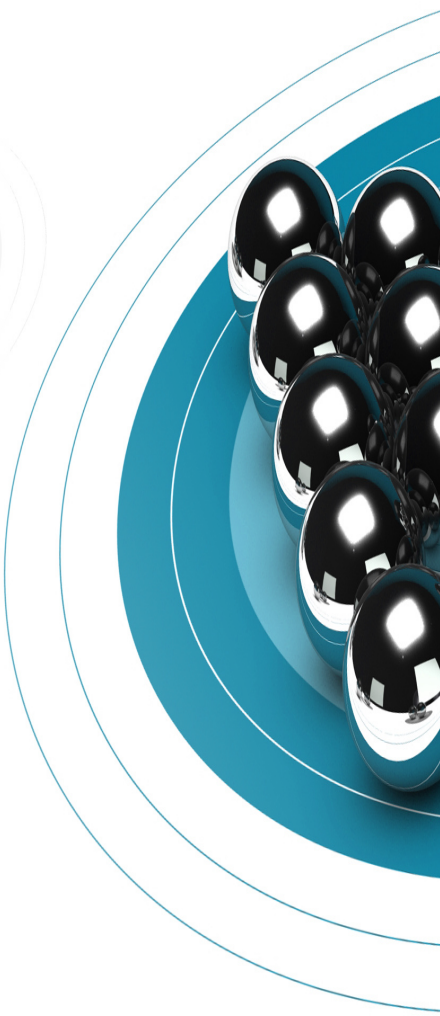
In times, where companies are being held increasingly responsible for the full life of their products, the consequences of allowing key parts of the product development and production processes to be only loosely connected are risky at best. Suffice to say, that the negative consequences are many and very costly. Moreover, fragmented data and processes bring negative consequences beyond existing products. They affect the ability of companies to react to upcoming trends and new business needs.

Consider connected devices. The Internet of Things will hardly leave any technical device unconnected, rendering everything "smart". While medical device companies are busy solving yesterday's problems, they are not able to tackle tomorrow's challenges with legacy PDM.

A truly connected workflow - as it should be:

In light of all these PLM problems, companies see a pressing need for change. Global organizations recognize that they must undergo a transformation of every aspect of their business. Manual processes have to be replaced and legacy systems have to be retired to maintain and strengthen both competitive advantage and the power to innovate.

First and foremost, **the enterprise must become more resilient and adapt to change faster.** That is the only way they can keep up with the rapid development of merging products and technology. A crucial step is to integrate mechanical, electrical and software components to establish truly cross-discipline processes. To get there, it is necessary to connect the tools used for these different components - either directly or as an overlay to existing systems for PDM and ALM (software application lifecycle management). This is the basis for an integrated product configuration that provides sufficient context to understand how each product behaves in the field and to interpret data that smart, connected devices send within the Internet of Things.



It's important to recognize that the focus cannot be placed on only the product and its behavior. Organizations also need to extend configuration management from design through manufacturing to field support. The result is a complete, transparent workflow that allows organizations to trace every decision made throughout the complete product lifecycle and connect this data back to the information the digital workflow provides. **Only then can an organization optimize processes, configurations and related cross-functional methods of working.** Along these lines, connections beyond core design processes must be made. Teams must connect critical, non-design processes, such as requirements capture, project management, quality management, process planning and technical documentation. All these processes are business-critical and contribute greatly to the success (or failure) of a product. Unfortunately, as we have seen, PDM systems are largely failing to support these processes.

The solution:

A resilient PLM for medical device manufacturers

Today, many medical device organizations are learning the hard way that they can't tackle these challenges:

- Manual handling of processes and data which creates an inefficient workflow
- Because of a complex system landscape, companies have issues with traceability and audit trails, and It is very difficult to get true traceability
- When data is stored in separate systems, and there is no visibility in data and processes.

They have to take a new approach. What they need is a new, resilient PLM solution, shaped to tackle the challenges found in the medical device industry, to make them successful in their product innovation and manufacturing. One that is Flexible, Scalable and Upgradeable.

Flexible

Every business is different and evolves continuously so a flexible PLM solution for medical device companies is critical.

But the approach used in legacy PDM system fails here - data model, business logic, services and database structures are firmly embedded in the source code. The result is a monolithic block of software that only an expert developer can access. So, for any significant change needed by the business, the code has to be rewritten. Minerva takes a different approach, an approach we call model-based, providing the flexibility to fit your business now and in the future with adaptive data models, process models and business rules. This means that business needs can be met exactly: either by using out-of-the-box applications which can be easily adapted, or customer-specific applications which can be rapidly developed.

Going back to the 10-10-100 rule, enough budget dollars have already gone into legacy PDM projects. It would be extremely painful to lose those, so the new PLM solution would ideally be able to layer-over and make use of the existing systems. Not only those this avoid a high risk “rip and replace”-implementation, it also maintains support for existing tools that engineers desire to use, making implementation run far more smoothly. As a result, such a platform is far more sustainable and reduces both risk and cost. Minerva is providing this option with the Medical Device PLM solution, built on top of Aras Innovator. The solution can be either laid over existing deployments, providing exactly the connection organizations need, or as a stand-alone solution for a completely new deployment. This approach provides the flexibility to focus on your most critical needs and keep legacy PDM systems in place as long as needed.

For organizations to realize the true benefits of PLM, implementations must be completed quickly and be able to keep up with the latest, fast-changing business requirements. In other words, they must become agile. Yet, an agile-style implementation can only happen when the underlying PLM platform technology is as adaptable as the methodology itself. Legacy PDM systems simply cannot provide the flexibility required to do "agile" properly. Aras architecture enables a flexible, agile implementation approach that demonstrates tangible business results quickly. Implementation cycle times are much shorter than they would be with a legacy PDM solution, lowering costs and risks.

CIO's are looking for the flexibility to deploy critical systems in the cloud, either today or in the near future. Legacy PDM solutions, with their outdated architectures, remain firmly locked in the data center. But Aras, with its modern, web-based technology has the flexibility to be deployed on-site, in a public or private cloud, or in hybrid configurations.

Scalable

A PLM solution that supports the Business of Engineering has to be able to grow in line with the needs of the business.

Legacy PDM systems can be hard to scale as the applications are typically built on different platforms. This complicates support for collaborative business processes as individual applications may operate in a silo or be poorly integrated with one another. But with integrated applications running on a single platform, the Medical Device PLM solution running on the Aras Innovator platform makes it easy to scale your PLM implementation when adding support for new processes, disciplines, and functions.

Scaling is further enhanced by the cross-application Visual Collaboration capability in the Aras solution which allows users to review, mark-up and comment on 3D models, documents and other kinds of data in a browser environment without requiring access to the original authoring tool. Seamless collaboration in a secure environment within a global context and across the supply chain is possible without any hurdles. That enables companies to finally break the 10-10-100 rule.

Upgradeable

Software upgrades can turn into a nightmare for organizations. The problem lies in the monolithic structure of legacy PDM systems, making it impossible to complete an upgrade without extensive updates to the custom code followed by testing and recertification. The Minerva Medical Device PLM solution, on top of the Aras Innovator platform, can easily be upgraded without any downtime and risk of losing important features and changes made by the customer. Only the service layer, which is never changed during implementation, is impacted during an upgrade. Applications, whether from Minerva or developed by the company, remain completely intact. What is more, upgrade services are included in the Medical Device PLM subscription, making it easy to stay on the latest version.

Conclusion:

Designing, manufacturing and supporting complex, connected devices are major challenges for medical device manufacturers today. And things are not going to be simpler any time soon. On the contrary: besides the Internet of Things and smart devices, medical device manufacturers also need to tackle the increased regulatory requirements.

To enable this, even more, disciplines beyond mechanical 3D CAD engineering will be involved throughout the lifecycle and will have to work together in a much more integrated fashion than they currently do. Manufacturers will have to focus on more on orchestrating their suppliers, as they provide parts or whole assemblies with all the technology in them. They will have to ensure they have sufficient insight into all of these parts and modules by connecting their suppliers to their PLM system. Being able to manage a connected, digital workflow is increasingly important and will be a must in the future.

Many medical device manufacturers - both world-leading enterprises as well as midsize manufacturers - have already realized these challenges and have taken the first steps to drive the transformation in product development. They realize that to achieve their long-sought, but yet unfulfilled PLM visions, their PLM deployments have to be fast and transparent, highly flexible and scalable, easy to upgrade and cost-efficient. A resilient Medical Device PLM platform will enable them to fully support the Business of Engineering.

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Optimizing business

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