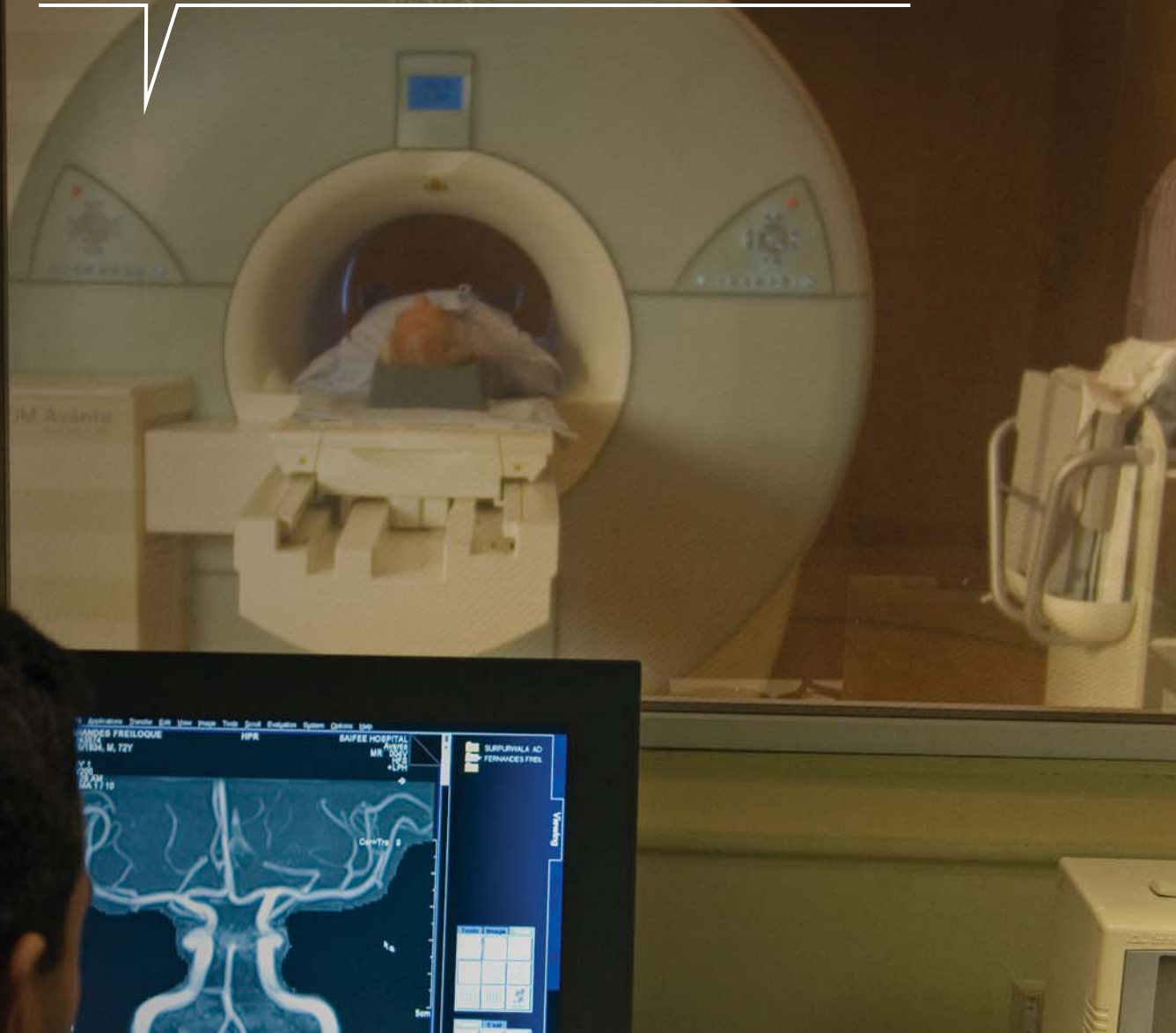


# How do we transform the process of innovation for medical devices and diagnostic instruments?



Siemens PLM Software offers product lifecycle management (PLM) solutions to build the right product and build the product right

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# Today's life sciences industry



Many manufacturers of life science products use enterprise resource planning (ERP) software to support transactional business processes, such as ordering, cash collection and the general ledger. But leading manufacturers realize that their innovation processes will not be adequately supported by using software designed for transaction management.

A recent survey conducted by AMR Research revealed that 31 percent of manufacturers in the life sciences industry are already using product lifecycle management (PLM) software to accelerate innovation and to design products that better meet market needs. Another 55 percent say they are now evaluating PLM software<sup>1</sup>. These companies recognize the need for a PLM platform to answer the toughest challenges facing their innovation process today.

Siemens PLM Software is ready to help provide proven solutions that speed innovation, reduce costs and improve regulatory compliance.

<sup>1</sup>2009 research study conducted by AMR Research and Siemens PLM Software.

# Business challenges



Delivering profitability and improved patient outcomes in today's dynamic environment is increasingly difficult. Manufacturers are under intense pressure to:

- Accelerate the innovation process
- Increase global reach
- Make better up-front risk decisions
- Ensure quality and regulatory compliance with traceability through manufacture and back to design
- Reduce costs everywhere

The ability to meet these challenges in a volatile economy is especially daunting – requiring new approaches and new tools. PLM software has been proven to help life science product manufacturers make fast and measurable progress towards these and other objectives.



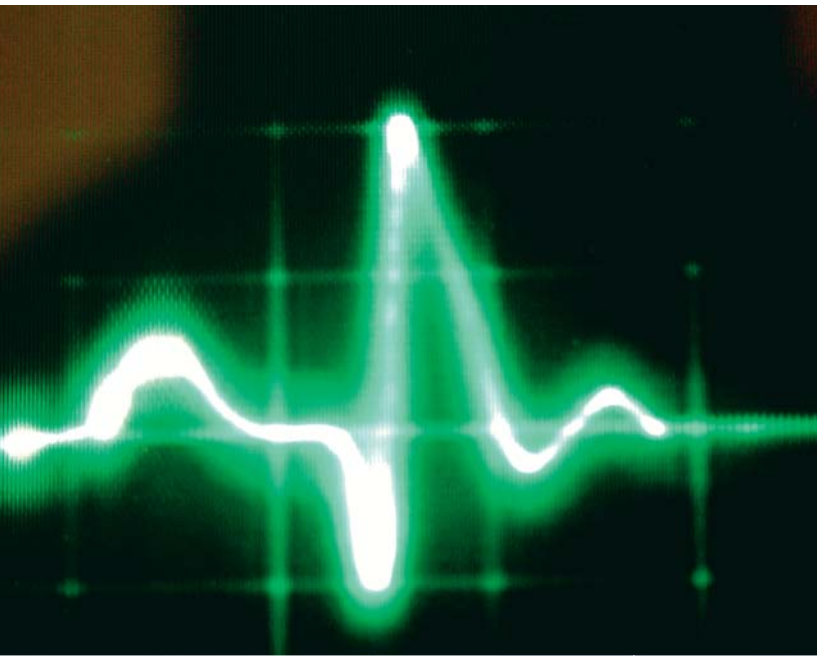
## Mastering complexity

### Globalization

Emerging markets offer new opportunities for growth. However, varying demographics give rise to new product requirements. In addition, individual countries have their own sets of regulations, which introduce further complexity. This increased complexity builds a strong case for a PLM software platform, including process automation capabilities that facilitate process repeatability and traceability, consolidated data management and IT applications standardization.

### Optimization

Product innovation involves the participation of multiple disciplines that cross functional and corporate boundaries. Optimal product launch choices, successful designs and on-time execution depend upon accurate market and business requirements, visibility and collaboration during product engineering. They also require effective information transfer to manufacturing and ongoing tracking and analysis of performance throughout the entire process. A PLM software platform helps orchestrate and optimize this continuous flow of interrelated activity, while capturing corporate knowledge for re-use to support validation, audits, change processes and new product development.



### Speed

A recent AMR Research study indicates that “the main driver of new product innovation strategies in 2011 will be decreasing overall cycle time of the design process.”<sup>2</sup> As this study implies, financial success increasingly will be based on the ability to rapidly bring new technology or improved designs to market. This imperative is often driven by expiring patents or the presence of competitors who can deliver viable substitutes. However, speed to market should not be achieved by sacrificing cost, quality or compliance. By providing a globally accessible repository of product and process knowledge, PLM platforms preserve relational linkages that ensure product innovation speed, as well as process accuracy.

<sup>2</sup>Ibid.

### Sustainability

Life science manufacturers are committed to ensuring environmental sustainability, as well as improving and clearly documenting related corporate performance. Sustainment initiatives that minimize solid waste emission and water/energy consumption are managed alongside product development and manufacturing improvement initiatives, such as the use of digital design/validation to reduce physical prototyping and manufacturing execution systems that target manufacturing inefficiency. A PLM platform enables manufacturers to achieve and measure progress towards these goals by tracking material usage and facilitating sustainable decision-making at key points in the product lifecycle.

# Product lifecycle management for the life sciences industry

Innovation is challenging. With proven solutions from Siemens PLM Software, your company can begin the PLM journey in a single process area. You can address a current pain point today while building a complete innovation platform step-by-step, delivering increased value at each step along the way.

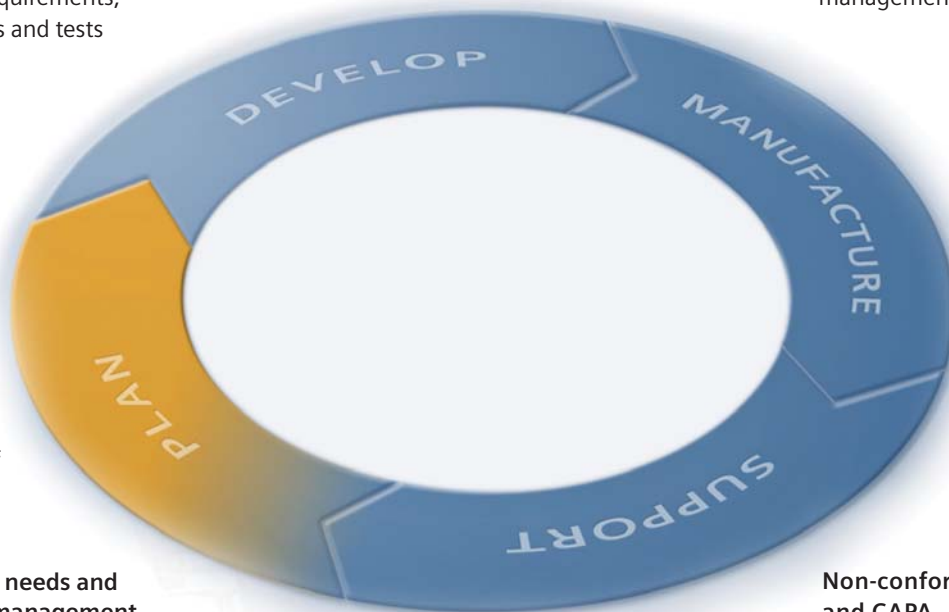
**Risk and requirements management**  
Create and track detailed requirements based on patient/clinical needs and regulatory requirements; validate plans and tests

**Collaborative product and manufacturing process design**  
Design/specify products and manufacturing processes on a global platform that enables image/data sharing with internal and external stakeholders

**Verification using digital simulation**  
Verify product performance and optimize manufacturing processes in a digital environment

**Regulatory and environment compliance**  
Track and report material usage, regulatory records and key quality management processes

**Portfolio management**  
Align product development portfolio to overall business strategy within context of in-flight projects and available resources for a steady stream of successful innovation



**Supplier relationship management**  
Identify and validate suppliers, collaborating globally in a safe, secure, and authorized manner

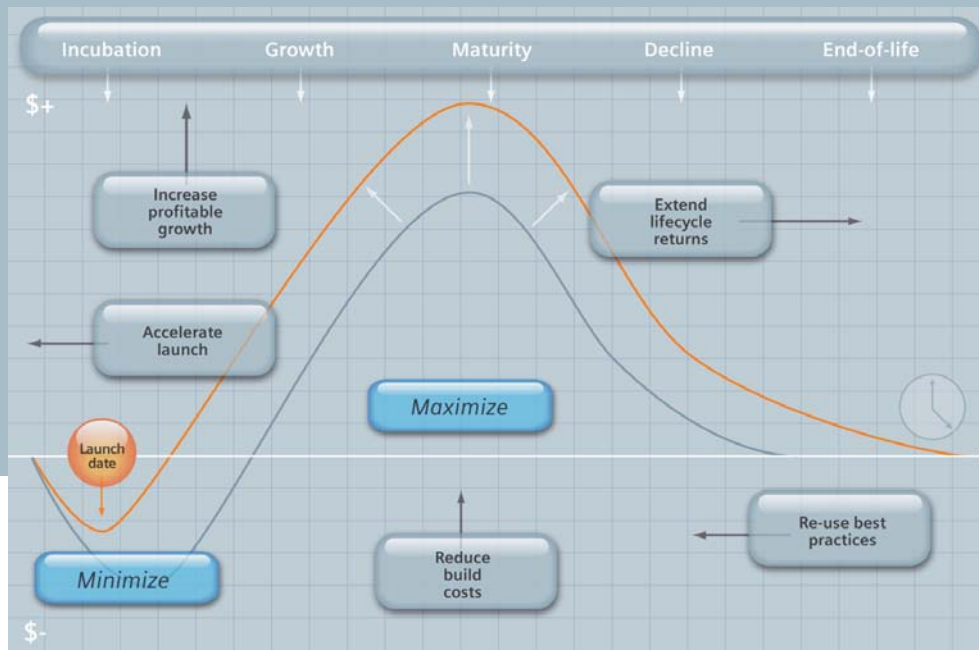
**Manufacturing execution and intelligence**  
Integrate manufacturing execution systems to download process plans and upload as-manufactured product records

**Customer needs and ideation management**  
Capture and classify patient/clinical needs; develop ideas into concepts

**Product maintenance and service**  
Maintain integrity and quality of configurations and service operations for installed products

**Customer complaint handling**  
Track, link, report and resolve customer complaints in same system used for non-conformance, CAPA, change management and quality management

**Non-conformance and CAPA**  
Identify, track and resolve quality issues, aggregating information from multiple inputs; link to resultant product and process changes, creating a closed loop quality process



## PLM benefits for consumer life sciences

### Accelerate launch

Bringing innovations rapidly to market enables you to establish leadership and a higher initial margin.

*Siemens PLM Software solutions enabled a global orthopedic products company to be more competitive in the marketplace by allowing manufacturing, engineering, quality and marketing all to work in parallel with one another. According to the company's lead design engineer, "That means saving time, getting our product on the market in a faster manner and beating the competition more often than not."*

### Increase profitable growth

PLM facilitates mass customization by enabling companies to deliver patient-specific medical products built on a product platform strategy. This breakthrough process indefinitely extends a product's growth curve.

*One of our customers used PLM to establish a re-usable product platform,*

*saying "As far as different sizes for implants or something the doctor wants changed, it's easy to do because everything updates succinctly."*

### Extend lifecycle returns

A single source of product and process knowledge enables you to better evolve products within their market space, extending their life and maintaining their margins.

*One of our customers used our PLM solution to establish continuity and good housekeeping. Our solution always delivered the latest information, making it instantly available and error-free. This saved time, avoided frustration and speeded up communications between team members.*

### Re-use best practices

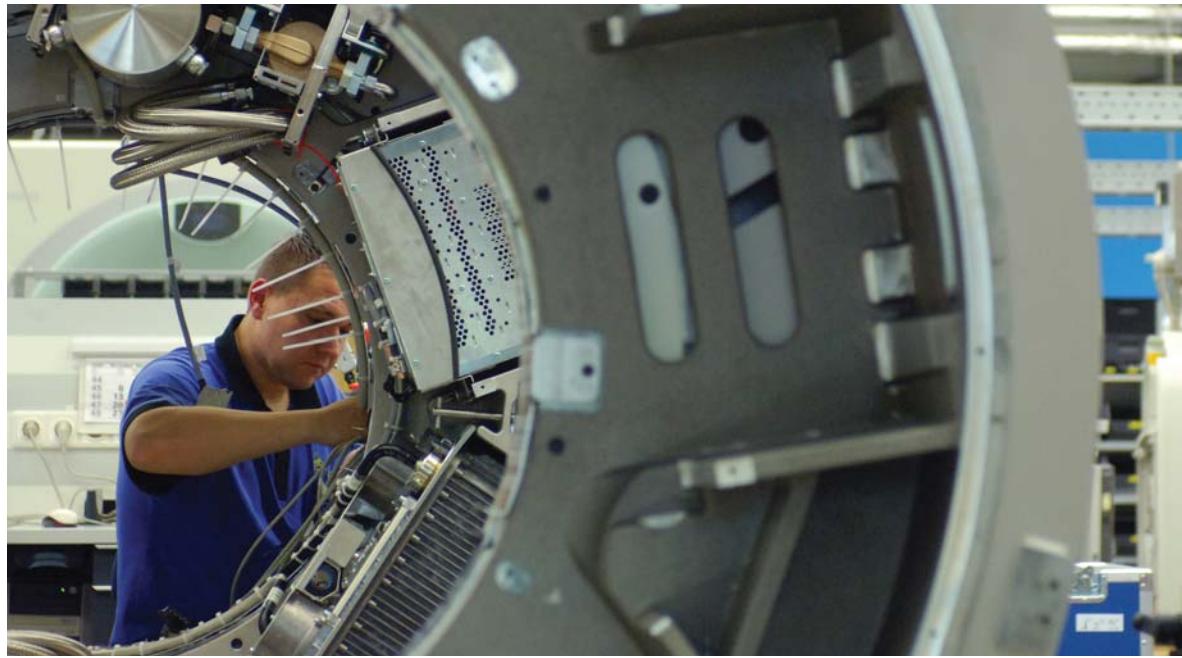
You can leverage PLM's digital deployment capabilities to more efficiently and rapidly replicate successful business processes across your company's disparate geographies and business units.

*The largest supplier of custom nucleic acids in the United States accelerated its machine design process by increasing the re-use of its existing design data. This approach enabled the company's designers to leverage their existing design work instead of starting from scratch.*

### Reduce build costs

Designing products for efficient production leads to lower material and operating costs.

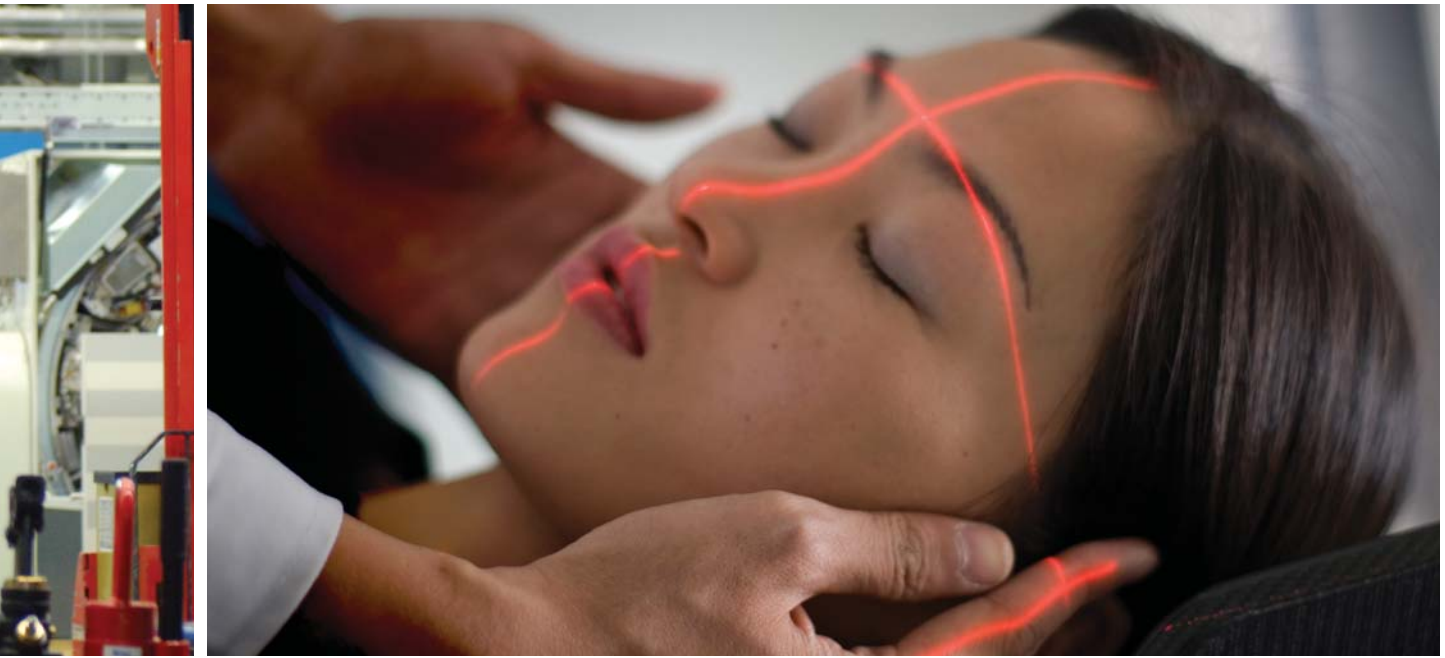
*By leveraging our PLM software to quickly access its product data, a manufacturer of ultra-precision molds expects to achieve an additional 16 percent workforce resource saving. Management also expects our software to reduce its turnaround time by four to six weeks.*



## Build the right product and build the product right

There rarely is a shortage of good ideas in any organization. But how do you make sure that the right ideas – ideas that create the most value – actually make it to market? Siemens PLM Software provides industry-specific solutions on a PLM platform with the technology you need to build the right product and build the product right.

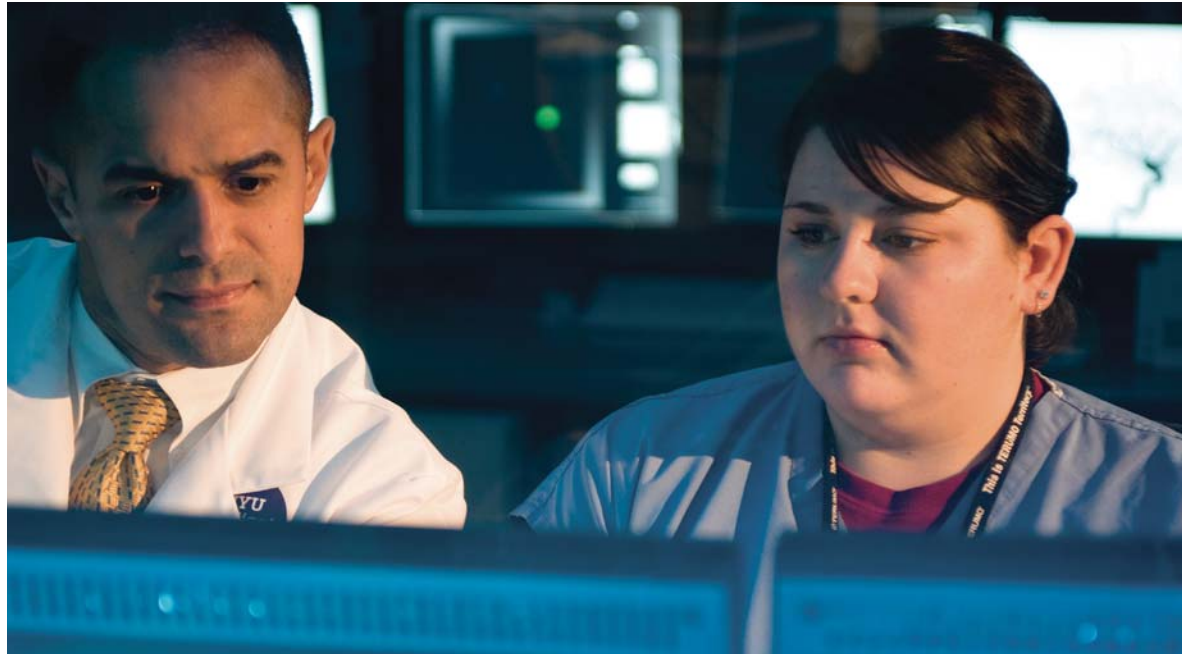
You can capture ideas from any source and give structure to these concepts, resulting in better product portfolio decisions that facilitate a steady stream of successful innovation. PLM solutions enable you to execute these ideas more efficiently. They make product requirements visible to every stakeholder in your innovation process, helping to instill the discipline needed to build the product right the first time.



## Transforming your process of innovation

For most companies, examination of the innovation process quickly determines the need for transformation. Successful innovation requires companies to build product and process knowledge, enable collaboration both inside and outside their organizational borders and instill discipline across their development process. Siemens PLM Software can help you turn more ideas into successful products and bring the right products to market in accordance with your strategic objectives.

Siemens PLM Software provides an innovation platform especially designed for life science manufacturers. Our industry-specific solutions transform your process of innovation across an enterprise footprint that minimizes total cost of ownership while ensuring a rapid path to full deployment.



## Solutions for life sciences

### **Integrated product planning**

The integrated product planning process begins with capturing ideas and managing the requirements that will be used as the basis for evolving these ideas into new products. The solution facilitates integrated risk analysis by continuously balancing known failure modes with business and product requirements. Integrated project planning capabilities allow specific plan elements to be built-in up front based on this early-stage analysis. The planning process continues as the product portfolio is evaluated, portfolio-related decisions are made and project plans for managing and deploying the product are created and disseminated. Our PLM solution accelerates the integrated planning process, supports better decision-making and eliminates planning errors.

### **Collaborative design and simulation**

Geographically distributed product teams enable companies to leverage diverse competencies. However, a new set of IT capabilities is needed to properly control information, workflow and task execution across multiple time zones and organizational borders. Siemens PLM Software provides a PLM platform to facilitate global collaboration and enable entitled stakeholders, both inside or outside your enterprise, to work together effectively. Our platform also provides the ability to share 3D simulation, and other supporting data, on-demand, thereby improving the speed and accuracy of your design process.



### **Integrated quality management**

Closed loop quality management is essential in helping companies manage the risk of non-compliance and litigation. By capturing tightly aligned product, package and label information during product design and development, PLM enables you to track and trace compliance decisions in a single environment. In turn, you can leverage this environment to globally manage non-conformance, complaints and corrective and preventive action (CAPA) processes.

### **Patient-specific medical products**

Medical device manufacturers can leverage Siemens PLM Software solutions to improve patient outcomes by enabling surgeons to accurately and pre-operatively model surgeries based on individual patient anatomy and other conditions. You can leverage our solutions to securely transfer patient scans over the web and digitally create pre-operative cutting guides that match a patient's anatomy to a standard, off-the-shelf, total knee replacement kit. All of these tasks can be performed without expensive and time-consuming customization of individual implants and instrumentation.



# Industry advantages with Siemens PLM Software

## Scalable

Large global companies need a collaborative platform that can scale to thousands of users in a single software instance without sacrificing performance. Siemens PLM Software provides an enterprise PLM platform designed for security, scale and speed in a variety of enterprise deployment models.

*One of our long-time, large-scale customers deployed a comprehensive document and change management solution on our PLM platform for more than 20,000 employees. Now they are preparing to transform their operations from a document-centric to data-centric process, powered entirely by our PLM software.*

## Proven

A new therapy is almost always successful when it is able to leverage proven technology, as well as reduce provider costs and improve patient outcomes. Our solutions create an environment that facilitates product and process innovation, enabling promising new ideas to reach the market quickly and deliver lasting impact.

*Two large, global orthopedic customers used our technology to introduce patient-specific versions of their proven arthroplasty products to the market. Each company was able to take a great idea and get it to market in less than a year. These experiences more than validated their initial expectations of the potential of PLM to transform the market; they also resulted in new plans to rapidly expand the scope of these programs.*

## Open

Siemens PLM Software's service oriented architecture (SOA) is the technology foundation that improves flexibility and optimizes your existing IT investments. By applying an effective SOA to PLM, companies can support more business capabilities, reduce IT complexity and accelerate IT implementation. It also enables them to re-use more applications via web services and better align their PLM initiatives with other business activity.

*With over 300 integrations to leading ERP systems, Siemens PLM Software's SOA services provide an open, high-performance, coarse-grained interface for the easy flow of financial, forecast and other transactional data that enhances the PLM process.*

## Flexible

By working more effectively in the virtual world, life sciences manufacturers can design products more rapidly to meet documented market needs. In addition, by testing new designs virtually, costly design and assembly errors can be identified and avoided before money and time is unnecessarily wasted.

*A well known company uses our variation analysis solution to virtually test its pacemaker designs. Our technology has enabled this customer to reduce total design time by 10 percent and improve product performance by simulating the interaction of its assembled components as they vary naturally and identifying related issues early.*

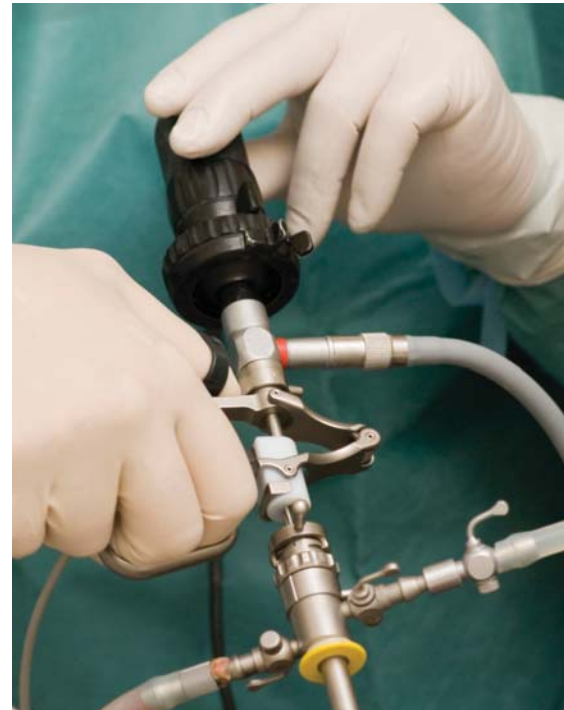


# Answers for life sciences manufacturers

Siemens is one of the world's largest and most respected companies, operating in more than 190 countries and employing over 400,000 people. This scope and experience affords Siemens a unique understanding of global business requirements. Siemens technologies help bring together product and production lifecycles, facilitating unprecedented speed to market for industry leading companies around the world.

Siemens PLM Software is helping its customers accelerate launches, increase brand growth, build corporate knowledge and extend the value of their product lifecycles in today's global market. A unified software platform delivers these strategic advantages by providing innovation capabilities especially tailored for life sciences companies. This virtual world significantly improves collaboration, accuracy and time to market at a lower total cost of ownership while facilitating faster time to full deployment.

Let Siemens PLM Software transform your process of innovation.





## About Siemens PLM Software

Siemens PLM Software, a business unit of the Siemens Industry Automation Division, is a leading global provider of product lifecycle management (PLM) software and services with nearly 6.7 million licensed seats and 63,000 customers worldwide. Headquartered in Plano, Texas, Siemens PLM Software works collaboratively with companies to deliver open solutions that help them turn more ideas into successful products. For more information on Siemens PLM Software products and services, visit [www.siemens.com/plm](http://www.siemens.com/plm).

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