



WINDCHILL

Product Lifecycle Management as the Foundation for Digital Transformation in Medical Device

A PTC eBook for Medical Device stakeholders wrestling with quality, risk, and an evolving regulatory environment.

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Continue reading to learn how peer organizations in the medical device industry ecosystem are leveraging product lifecycle management (PLM) to realize digital transformation, and thus improve speed to capability/readiness and achieve hard cost savings.

PLM's Impact for Medical Device: Trusted Data as a Driving Force

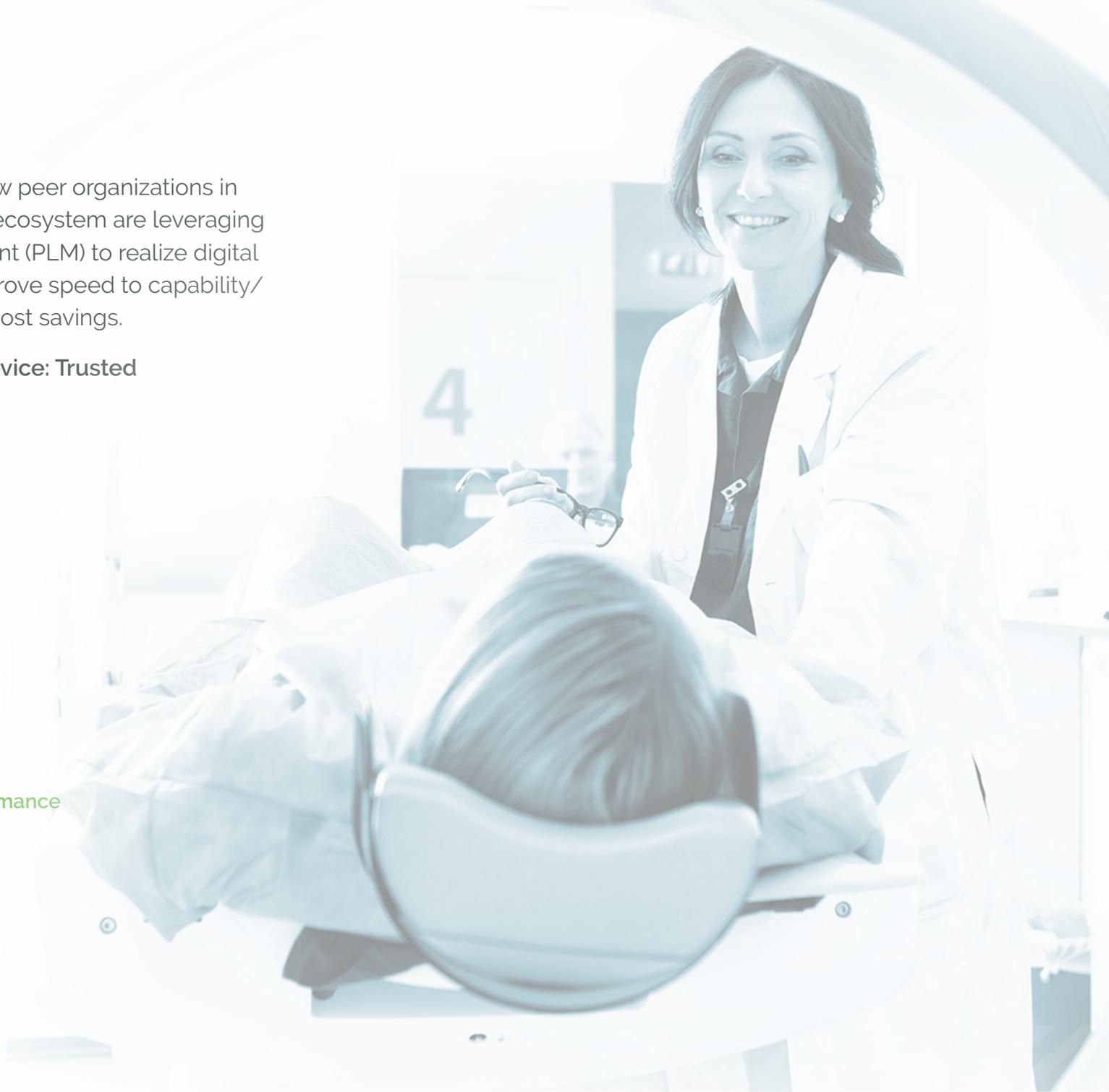
 **30%** Acceleration in time to market

 **90%** Improvement in first time right quality

 **72%** Greater CAPA effectiveness

 **95%** Lower nonconformance resolution times

 **35%** Reduction in compliance cycle time



Windchill - A Modular Approach for Fast Time to Value

PTC recognizes the need for fast, scalable tools to manage your product lifecycle and retire legacy systems that are not integrated and are costly to maintain. With Windchill, the industry-leading PLM software from PTC, medical device companies and their design/manufacturing partners can take advantage of support for enterprise and multi-enterprise secure collaboration, all in a validation ready cloud. Plus, Windchill's out-of-the-box pre-configured ISO 13485 processes can be implemented quickly.

One critical element that Windchill enables is a 3D model-based digital thread. This provides visibility into model-based detailed design data to identify CTQs for development of validation and manufacturing control plans. This, in turn, supports closed-loop feedback by collecting product failure and performance data from testing, manufacturing, and field/IoT for root cause analysis and feedback to design.

The digital thread creates "closed-loop" lifecycle system consolidation by combining regulators, manufacturers, and connected (Internet of Medical Things) product-related data. Functional system models and requirements are connected and accessible, enabling all downstream stakeholders to make informed decisions. By directly accessing requirements and functions critical to parts/products, design, manufacturing, and service; stakeholders can more efficiently meet regulations in the U.S., Europe, and Asia. One key enabler is that they can leverage product design models and their relationships to generate a visual, associative BOM (bill of materials) in place of the traditional BOM table of a 2D drawing. This helps ensure they are accessing the most up-to-date information without having to wait for updates to be made to a drawing.

With a fully integrated digital thread, medical device companies no longer need to wait as entire departments are held up from product development and production while they meet for multiple weeks for audits. That means the ability to retire legacy systems and file cabinets that contain partial information. Instead stakeholders are fully connected to the current state of the product throughout the entire lifecycle, streamlining change management and regulatory submissions. It also means data driven handovers between departments, training tracking, alarms based on adverse events (connected devices), and the capturing of FRACAS and CAPAs for correction can be provided to engineering, and updates can be made more easily in the field (i.e. software updates).

Here's the potential impact across the enterprise:

- Create a seamless data value stream for both experts and non-experts, providing full traceability from engineering through quality, manufacturing, sales, and service, all the way to end of life.
- Increase productivity and compliance by enabling product development to unite, distribute, and dynamically visualize multi-CAD models and related information with automation and provable performance in the field.

- Reduce time to industrialization by making it possible for factories to concurrently source approved parts and plan without errors.
- Drive faster response to adverse events by providing field service with access to up-to-date product information with real-time IoT visibility of connected products.

Windchill provides the foundation and continuity of product and quality information across the digital thread, whether delivered on-premises or SaaS. Our web-based tools connect physical assets with their digital twins for global, cohesive, flexible, and secure cloud delivery. With a simple link, programs are up and running.

The workforce of the future is changing; Windchill is the enterprise PLM application suite that transitions in lockstep.



A person is lying on a table inside an MRI machine, which is a large, white, cylindrical structure. The scene is dimly lit, with a bright light source from the machine's opening. The person is wearing a white shirt and dark pants. The overall image has a light blue and white color scheme.

VALUE IN ACTION

Value in Action

Smith and Nephew – Smith and Nephew, based in the U.S., is a leading portfolio medical technology company. Through their market leadership positions in sports medicine, orthopedic reconstruction, and advanced wound management, their 17,500+ employees continue to improve outcomes and expand access. Smith and Nephew’s global digital thread initiative is focused on consolidating six PLM systems for a single authoritative source of truth in support of accelerating time to market with compliance and collaboration across the value chain.

Baxter International – Based in the U.S., Baxter International's leading portfolio of medical devices, includes critical care, nutrition, renal, hospital, and surgical products available in more than 100 countries. Their digital thread initiative is focused on quality and compliance risks. With widespread inefficiency throughout the product lifecycle conception, development, and sustaining phases; they had no current method to integrate existing business units into a single collaborative platform. They are addressing business challenges of data reliability/lack of trust in data, too many systems, manual effort, redundancy, maintenance, inability to link data, and real-time reporting with a cumbersome change process. Their focus on digital thread established governance and processes to speed the onboarding of new acquisitions and ensuring EUMDR readiness.

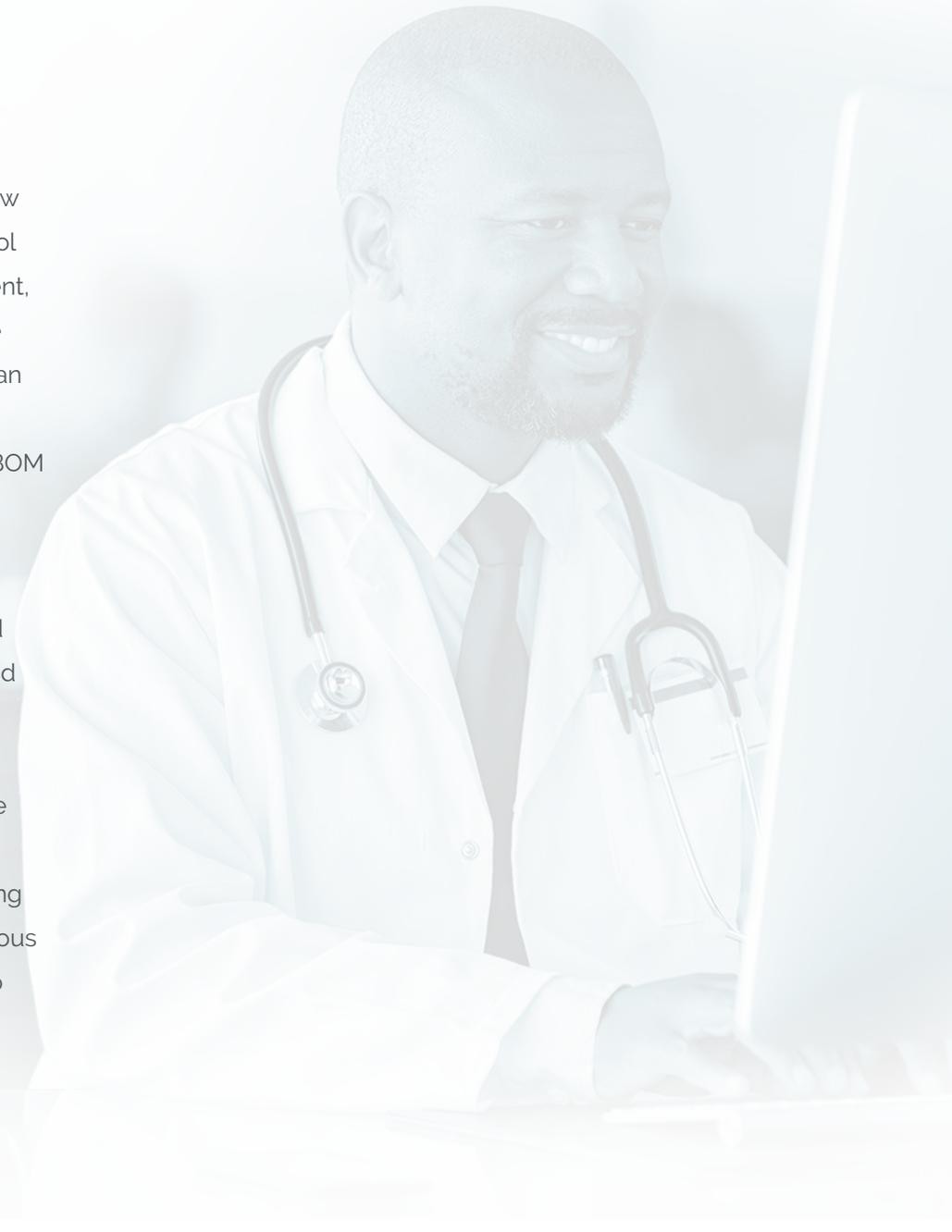
Philips – Philips, based in the Netherlands, is a leading health technology company providing diagnostic imaging, image-guided therapy, patient monitoring, and health informatics. They are also involved in consumer health and home care. Philips' digital thread initiatives are focused on collaboration, reducing time to market, and better serving global customers by harmonizing their products and processes. To drive innovation, Philips is undergoing a global transformation to put the right product information in the hands of the teams who need it, across engineering, sales, service, and marketing.

Mindray – Mindray, based in China, is one of the leading global providers of medical devices and solutions. Firmly committed to their mission of “advance medical technologies to make healthcare more accessible”, they are dedicated to innovation in the fields of patient monitoring and life support, in-vitro diagnostics, and medical imaging systems. Mindray currently ranks third in China's ultrasound marketplace by volume and second for defibrillator and blood cell analysis devices. Mindray's digital transformation initiative provides accurate and complete digital information that sales, services, and manufacturing need, all in a unified platform.

Technology to Grow with an Organization's Needs

Whether an organization is just starting a digital transformation initiative or implementing advanced PLM capabilities, Windchill offers packages to grow with the organization's needs. Windchill's core design and document control functionality – along with automated change and configuration management, business systems integration, and project execution – help establish a core product development platform. As PLM initiatives and requirements grow, an organization can expand capabilities to include variant management, parts classification, supplier management, downstream manufacturing, service BOM management, manufacturing process plans/work instructions, augmented reality (AR), IoT, and more.

Windchill's 100% web-based architecture, which is optimized for agility and flexibility, has been designed to easily integrate with existing IT, internet, and security infrastructures for remote work and multi-site collaboration. PLM deployments with PTC can be on premises, in the cloud, on a single server for a workgroup, or on a highly scalable clustered system with performance optimized for content distribution. Based on the industry standard J2EE, internet and web services interfaces, and powerful federation for maintaining data with other systems, Windchill seamlessly interoperates in heterogeneous environments with a consistent data model from CAD data management to BOM transformation.



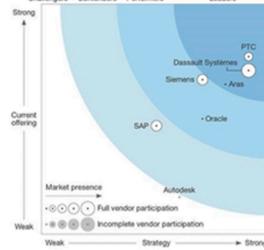
Analysts Endorse PTC's PLM Leadership

PLM Leader for Digital Transformation



FROST & SULLIVAN

Strongest PLM Solution



FORRESTER

Technology Leader in the Global PLM Market



Digital Thread Innovation Leader PLM Software



ABIresearch
for visionaries

PTC is the clear market leader in PLM for medical device manufactures with a strong heritage, expertise, and proven ability to execute. Windchill has received #1 rankings by top analysts in multiple industry reports for reasons, such as:

- **Comprehensive out-of-the-box functionality:** Customers realize value quickly through standardized functionality delivered via a comprehensive product portfolio, from core design and document control, to advanced PLM solutions.
- **Part-based design control:** End-to-end traceability of control characteristics
- **Risk-based closed-loop quality by design** PTC integrates pre-configured ISO 13485 quality processes and training tracking into product lifecycle management. This enables better management of quality, reliability, and risk through every stage of the product lifecycle.
- **Highly configurable role and task-based applications for broad enterprise collaboration:** Organizations can take advantage of apps designed for expert and non-expert users to view and format product and quality data in the context of their role via an intuitive interface for event reporting and trending.
- **SaaS leadership:** Windchill SaaS is validation-ready, enabling our customers to speed their initiatives to reduce cost of poor quality (COPQ), achieve regulatory approval, and improve new product introduction (NPI) cycles and performance.
- **Augmented reality and visual engagement:** Organizations can interact with their product development data in context with augmented reality or in 2D/3D on their device.
- **Post market surveillance:** With Windchill, organizations can extend the digital thread to enable smart connected products, people, and processes with real-time capture and communication of data with each failure, as it happens.
- **Digital product traceability:** Deep integration and interoperability ensure an unbroken data chain of custody from requirements, to system architecture, to product structures, to regulatory submission—enabling changes to be pushed to downstream consumers and deliverables with minimal effort. All while ensuring traceability.
- **Design for regulatory management:** Organizations can manage, associate, orchestrate, and flexibly deliver product data across enterprise domain systems on-premises or via SaaS, including region-specific structured documents, partner cartridges, and package submission.



WINDCHILL CAPABILITIES

Take Advantage of Comprehensive Windchill Capabilities

A Platform for Collaboration

In the context of the industrial software space, 'collaboration' is fundamental to key strategies driving medical device organizations. Medical device manufacturers must be risk averse and need to reduce the risk of non-compliance. At the same time, they are transitioning to new business models with connected products and pay-per-use business models with innovative products. PTC supports this by continually enhancing its technology platforms and alliance ecosystem, while maintaining an unrelenting focus on customer success.

PTC doesn't limit its definition of collaboration to individual members of a team working to create something or achieve a goal. Here are examples of how Windchill supports a broad array of collaboration scenarios:

- Collaborating with artificial intelligence (AI) via generative design to create a new product that is free from human constraints.
- Collaborating across multiple organizations by retiring a group of less efficient IT systems with one 'collaborative space' for Windchill governance and traceability.
- Collaborating in a temporal sense, by using the single 'collaborative space' to store product data, manage acquisitions, in turn reconciling all phases of that business unit into one view.
- Collaborating with industry partners by sharing CAD data (with IP protections) in any format of their choosing. This allows medical device manufacturers to be non-prescriptive on tools and lets design/manufacturing and supply chain partners focus on product innovation, not toolsets. It doesn't just stop at CAD data. PTC's technical data packages (TDPs), can include system requirements (if the documents are in Windchill), CAD models, drawings, schematics, system models, test procedures, required spare parts data for provisioning, training, and technical manuals.
- Collaboration with regulators. We periodically deliver TDPs through a program lifecycle. All the data is woven together through the digital thread that the Windchill platform affords.

How does COVID-19 change our definition of collaboration? It means a renewed focus on workforce safety, mobility, and resiliency. We enable teams to access the same rich functionality in Windchill from the home office, as on-premises, with integral training tracking. We also enable flexible and innovative supply chains, even supporting critical suppliers that are offline.

When it comes to options for alternate sourcing, we enable front-line worker connectivity. This includes empowering organizations with augmented reality to capture the knowledge of one worker and use it to immediately train others. It also means enabling remote monitoring of factories with IIoT to monitor equipment in real time and predict failures on machines before they happen. Those same predictive capabilities can find patterns to help medical device manufacturers improve patient outcomes and respond faster to adverse events.

The act of collaborating with regulators doesn't mean simply checking the box to attain a certification. It means leveraging the controls that drive a certification. This type of collaboration between regulators and programs benefits everyone.

Finally, for PTC, the future of collaboration is SaaS. We are investing in all our offerings (PLM, CAD, IIoT, AR) to enable even greater collaboration between internal and external stakeholders, ensure all users are on the same validated version, and drive down the total cost of ownership.



Digital Twin

As products evolve from standalone one-offs to complex product families for mass customization, Windchill's ability to control and understand the exact configuration of a product, based on effectiveness and version control (as-designed, as-built, as-maintained) is critical in delivering a digital twin. Augmented reality visualizes the digital twin in the context of the physical world.

To simulate prior to manufacturing, designers first select options and choices for the desired configuration. With Creo, they may then run real-time interactive simulations to iterate designs. Parameter inputs come from OSLC-connected requirements (such as specification limits) and ThingWorx IIoT data of similar products and/or prototypes. As the IIoT data pool grows, ThingWorx Analytics can better guide on tolerance limits, etc. Note: For the production line designs, Rockwell's Emulate3D is additionally used for simulation.

Downstream, serialized assets carry lightweight "config specs". The digital twin can combine, for example, a unique device identification (UDI), and all component changes (e.g. assembled, disassembled, maintained, etc.) with timestamps. The digital twin is used for service instruction optimization, recall and compliance support, data source for machine learning-based optimization, etc.

Role of Enterprise PLM, IIoT, and AR in Digital Twin

PLM serves as the hub for the digital product definition, maintaining a complete record for engineering specifications, service procedures, and manufacturing process definitions for each version of each component. As products evolve from standalone one-offs to complex product families, Windchill's ability to control and understand the exact configuration of a product, based on effectiveness and version control is even more critical in delivering a digital twin.

Windchill provides the traceability and governance of a product's configuration. As a result, medical device manufacturers can make dynamic, fast-paced, coordinated changes throughout the product lifecycle while ensuring that all stakeholders are accessing the most up-to date product information. Plus, unique change management notifications for CAD designers provide a link to requirements, allowing teams to make the right decisions.

Managing a product with Windchill enables medical device manufacturers to have the complete set of information required to develop a digital twin or replica of the physical piece. Employing AR to overlay the data secured through the IIoT with the digital replica makes it easier and more cost-effective for manufacturers to preview and demonstrate large, heavy, and complex built-to-order products. When coupled with new data sources from the IIoT and historic product data from CAD files, the outcome is a truly transformative experience that is driving enterprises to re-evaluate how they design, produce, sell, and support their products.

In short, Windchill ensures that the user employing the data, via AR or other downstream consumption methods, is working with the most accurate information, as well as the right version and configuration of a product.

Product Data Management and Document Control

Windchill has powerful tools for both organizing and controlling access to documentation containing critical engineering data mechanical, electrical, software, requirements, systems models, certifications, simulations and more.

Windchill further provides a pre-configured best practice quality system documentation module with training and license tracking functionality.

PDM software helps organizations connect and communicate product information across globally distributed teams, allowing the use of source CAD from different vendor formats without having to convert it (STEP, PLCS DEX, DEX1, UGNX, Catia, Creo, etc.).

Windchill can be embedded into all major mechanical CAD (ECAD and MCAD) systems so users can manage and edit CAD data and related documents (e.g., Microsoft Word, Adobe PDF) without leaving their native CAD environment.

Access to data is optimized for the remote worker by being web-based, accessible from a Windows desktop, and available in the PTC cloud.

Lightweight viewables and self-service access to role-based apps in secure project spaces enable automated sharing of more consumable data with non-CAD users.

BOM Management and Transformation

Most medical device manufacturers are grappling with speed and agility in the face of growing numbers of product options and variants.

With Windchill's BOM management and BOM transformation capabilities, product designers create and manage a part-centric digital product that can be leveraged in every step of the product lifecycle. Now mechanical, software, electronic parts and related artifacts can be integrated into the engineering BOM. This provides organizations a single interface, with which both upstream and downstream teams can collaborate on such domain systems as ECAD, MCAD, software, PLM, and ERP. Windchill ensures that everyone—from the shop floor worker and service technician to sales configuring a customer order—is using the correct product information.

Change and Configuration Management, Design History File, and Device Master Record

The various teams involved in a product's lifecycle create a range of digital data. Not only does this data span disparate functional systems, it often evolves over time—and quickly.

With Windchill, organizations deliver a real-time view of the most accurate data to all enterprise stakeholders, expanding cross-discipline involvement. Standardizing on PTC's best practices for change and configuration management drives efficiencies. Better, more informed decisions, for example impact analysis when initiating and planning a change, reduce costs associated with poor quality and enable organizations to implement changes and introduce new products faster.

A design history file (DHF) is the collection of artifacts used in the design process for a finished medical device. With Windchill, the design history file contains information related to a part structure (reference documents, change notices, change records, problem reports, variances, and so on). It contains anything that a managed baseline can contain.

A device master record (DMR) is the compilation of all the information used to produce a device. With Windchill, it contains the bill of materials (all the materials used to construct a product) and the bill of operations (all the processes used to manufacture, distribute, and service the product).

Requirements Management and Validation

Effective requirements and validation practices are more than just an integral part of developing and engineering complex products and systems. They are vital to mitigating risk and ensuring customer satisfaction.

With Windchill, organizations can centrally manage evolving requirements, test assets, and software configurations. Automating the traceability, leveraging the OSLC standard, and sharing of data enables cross-functional collaboration across applications and throughout the product lifecycle. With holistic visibility into evolving requirements, stakeholders can easily manage test sessions, determine the impact of proposed changes, and verify test results against requirements for faster and more reliable validation.

Product Architecture & Variability Management

Traditional approaches to manufacturing and sustainability make it complex to produce and support variants and configurations. Product diversity breeds higher inventories, lower economies of scale, service inefficiencies, manufacturing errors, and increased risk of non-compliance.

With the product variability management capabilities in Windchill, organizations can strategically design, create, manage, and validate product variants. Platform options, logic, and configuration rules are directly linked to BOM, 3D visualization, and CAD data to deliver a robust modular solution. Organizations can fully manage platform information across the lifecycle, making it easy to validate the product and share it with other enterprise tools, such as ERP and configure, price and quote (CPQ) software.

Design for Manufacturability

With manufacturing process management capabilities (MPM), organizations gain the collaboration tools and methodologies needed to manufacture and build products anywhere, 24x7. MPM brings design and the shop floor together with suppliers, logistics, and quality for a more connected, agile enterprise.

With the MPM capabilities available in Windchill, organizations can feed up to date information to the shop floor for greater process efficiencies. End users can access technical work instructions on demand (on a screen or with AR) before performing their own work or assisting in completing another task.

Closed-Loop Quality and Risk Management for the Entire Organization

Innovating with speed, agility, and compliance hinges on quality. Success comes down to high first-pass yields, low percentages of scrap and rework, elimination of line and field failures, and rapid response to corrective and preventative actions (CAPAs).

PTC takes a holistic approach to quality across the organization, from ideation to field service. Highly configurable out-of-the-box Windchill workflows are associated with products and parts for a complete design master record (DMR) and design history file (DHF). Key data is centrally stored and aligned with engineering, manufacturing, and service bills of materials and process plans. This includes change and configuration management, requirements, and test management, CAPAs, non-conformances, customer experience management

(CEM), audit, and document control. Calculate reliability early (prediction, RBD, Markov, lifecycle cost), plan and assess risk for service needs (FTA, FMEA/product or process, MSG-3, maintainability), and analyze failure data to improve product reliability (FRACAS, ALT, Weibull). Centralize risk and reliability support for master analysis/FMEA with direct connection to parts to get in front of failures and more easily build fault tree analysis using the data stream in the system.

With connected products, organizations can capture and transmit complete quality data on performance, operation, and environment, leveraging IoMT (internet of medical things). They can analyze conditions leading up to failure and how they could have contributed for more comprehensive, timely, and accurate failure analysis and trending (pre-production/actual failures).

By combining PLM, quality, and IoMT into a single authoritative source of truth, PTC helps organizations of all sizes accelerate the delivery of high-quality products.

Project and Design Collaboration

Design and manufacturing contracting/sub-contracting and remote work have significantly increased the complexity of product development. Internal teams—operations, engineering, manufacturing, sales, marketing, purchasing, and customer service—can be widely distributed across different locations and time zones. Suppliers and customers are even further removed. PLM project management tools enable extended product teams to securely collaborate, regardless of their location.

Organizations can track all deliverables throughout the project lifecycle with detailed status and change management for shared objects, such as CAD designs and documents. With Windchill, instead of working in silos, the organization can collaborate in a way that secures data and provides an authoritative source of truth, so teams have access to the right data at the right time.

Model-Based System Engineering (MBSE)

As products grow more complex, multiple engineering disciplines need to work together to design, build, and maintain them. Designing a system using models enables early visualization and simulation, improving stakeholder buy-in and customer satisfaction.

With Windchill's MBSE, engineering teams define systems in a modular way, with 'variability modeling' for consideration of product lines much earlier in the product lifecycle. The solution also provides traceability throughout models and with requirements, validations, and parts in BOMs. This helps prove that organizations are building the right systems and products, as well as understanding and managing the potential impact of changes. These capabilities are critical when complying with industry safety regulations. In addition, organizations can leverage powerful, visual, system-level co-simulation, along with automated system model design review to improve the quality of system designs and ultimately the systems delivered.

Design for Serviceability

PLM enables organizations to centrally manage all service information in relation to products, systems, and components. The key advantage of this product-centric approach is that it helps maximize the reuse of engineering and configuration-specific information.

Windchill leverages the engineering or manufacturing bill of materials (EBOM or MBOM) to define the parts and kits that will be used in the service environment (service bill of materials or SBOM). From the SBOM, organizations can automatically generate parts information for specific product configurations to enable consistent and accurate repairs. They can also deliver service information across a comprehensive range of languages and formats (such as service manuals, training documents, augmented reality, and more) with topic-based XML authoring.

Functional, Design, and Factory Simulation

Windchill provides integrated configuration/change management for simulation artifacts (i.e. simulation models, results, and reports), creating the relationship between products, processes, and resources. With this simulation model, there is an integration framework to leverage PTC or partner built (Ansys, IPS, Rockwell) simulation tools. PTC simulation-driven design capabilities include generative design (automatically generate optimal AI designs from a set of design requirements), real-time simulation (provide constant feedback on design decisions), and analyst level simulation (available for all engineers to provide final validation of design before production). Windchill MBSE provides early functional simulation.

Windchill MPM is used as backbone for manufacturing digital simulation and time optimization. Leveraging PTC and partner solutions, manufacturing process designs are validated:

- Cable, robotic, path planning and ergonomic (Partner: IPS)
- Virtual reality and immersive manufacturing process validations (Partner: IC.IDO)
- 3D based discrete event simulation and virtual commissioning (Partner: Rockwell Automation)
- Time estimation and line balancing (Partner: Avix)

Supply Chain Engineering

For new system introductions, design engineers might struggle when discussing and selecting the best supplier components, based on form/fit/function, compliance, available inventory, and lifecycle state. Engineering changes in supplier parts might introduce risks in areas such as compliance, inventory, and lifecycle state—a threat to their sustainment efforts.

Windchill Supplier Management enables medical device manufacturers to integrate and manage supply chain data within Windchill. In addition to helping organizations track their supplier parts, Windchill Supplier Management improves the part selection process by making manufacturer and vendor data available early in the design phase. Windchill further provides a secure collaboration space for engineering, manufacturing, suppliers, design partners, contract manufacturers, and customers.

Buyers can access Windchill via URL (no data transfer/duplication) through easy to use apps for researching component attributes (e.g. approved suppliers, data sheets, where a component is used, etc.). Buyers are notified when the BOM reaches the quote, prototype, or production state and can send the BOM to suppliers. Buyers send suppliers data and drawings, along with revisions, using Windchill project mgmt. Partner (Assent Compliance) integrations leverage Windchill APIs to enable trade and material compliance for FTAs such as USMCA and CETA as well as RoHS and ReaCH.

Windchill enables suppliers, internal users, and contract managers to collaborate on contract-driven programs. Suppliers can submit documents against a P.O. line, track the status, and resubmit non-conformant docs. Windchill facilitates the adoption, speed, and repeatability of NPI processes across organizations by leveraging a variety of comprehensive best practice project templates. It automates and facilitates Stage Gate and PACE process execution and visibility, including deliverable scheduling in the context of a plan and easy tracking of related deliverables in activities.

Analytics, Dashboards, and Reporting

Windchill provides powerful query/report builder and Jasper report capabilities. ThingWorx (PTC's IIOT platform) can be layered on top for cross system mashups/dashboards empowering organizations to make critical design, manufacturing, and service decisions from a smart, sophisticated, predictive model. These models help identify parameters that could cause incidents, and predict what part will fail, why it will fail, and when it will fail.



Windchill and ThingWorx provide closed-loop quality control of product performance and resilience by building predictive modeling that enables collection and learning from real-world performance data. Over time, AI-powered industrial systems recognize and can act upon multiple performance variables. PTC customers collect the insights from AI and machine learning to predict maintenance needs, and to improve product designs and overall manufacturing efficiency and processes.

Dashboards and reporting capabilities combine predicted and actual failure rates, risks, maintenance plans/needs/costs, etc. All organizational quality data can be funneled to a single source for trending, reporting, in context with BOM and change. "Mash up" data from other systems add valuable context to quality data.

Cloud and SaaS Delivery

Organizations interested in taking advantage of the cloud can deploy Windchill and ThingWorx Navigate with the support of PTC cloud services. Windchill is available via SaaS delivery, certified on Microsoft Azure and Amazon Web Services (AWS).

PTC also partners with USDM Life Sciences to provide validation for Windchill SaaS, enabling customers to meet the FDA's 21 CFR Part 11 and global computer system validation and computer software assurance requirements.



Regulatory Product Submission

Windchill's regulatory submission capability provides a centralized mechanism to track, manage, and maintain artefacts that are submitted to regulatory agencies. It helps organizations with a process to document their compliance and submissions. This feature provides customization capabilities that you can leverage to create and automate the submission process to meet business requirements.

Adverse Event and Malfunction Reporting

Regulatory Safety Reporting (eMDR, EU Vigilance, Canada, etc.) covers adverse events and malfunctions. Triage and adjudicate customer complaints to stop recalls and prevent occurrence (CAPA and NC).

Unique Device Identification (UDI)

UDI, within the Windchill environment, allows users to comply with the Part 830 medical device regulation for the UDI submission process. Users can electronically submit unique device identifiers for their medical devices and device packages to the Food and Drug Administration (FDA) Global Unique Device Identification Database (GUDID).

Audit Management

With Windchill, audits can be created, planned, and executed to establish a quality governance process that can be used by upper management to ensure that the key corporate processes, requirements, and directives are being followed. It is a process to gather evidence. Audit evidence can then be used to evaluate the implementation of audit criteria. Windchill ensures that audits are

objective, impartial, independent, systematic, and well documented. The audit process is both systematic and documented.

Upgrade

Windchill's centralized tool for managing upgrades allows organizations to upgrade data in place and automates the gathering of system properties, saving time and effort in the process. With an easy-to-use guided step-by-step user interface, fast time for schema upgrades, and new data loads, organizations see low user disruption and high speed to adoption.

Administration and Support

Windchill provides a robust set of business administrative and support capabilities to reduce incident rates with tools for conflict detection and resolution. Always-on system monitoring helps ensure SLAs are met on time. PTC leverages IoT to provide product telemetry insights so organizations can detect issues before they become problems. Organizations can also learn from PTC experts and drive an even faster ROI through self-paced and in-product learning resources, live classes, and custom learning programs.

ERP AND PLM SYSTEMS

ERP and PLM Systems

As the definition of PLM has broadened along with its impact, many organizations are unsure how to develop and implement a strategy that enables them to derive maximum benefit from both ERP and PLM. PTC believes both systems play critical roles, and that the proper coordination and calibration of these systems can add value beyond what either one can deliver alone.

Unfortunately, some organizations make compromises that prevent them from realizing the full benefits of these systems. This is largely due to treating them as standalone solutions that serve different needs. In many cases, organizations are forced to take this approach since these systems often capture information using different structures. Recognizing the need to ensure each of these essential systems contain the same information, manufacturers go to great lengths manually entering data to keep the systems synchronized. The potential for errors that impact time, cost, and quality can be significant.

Today, medical device manufacturers are integrating PLM and ERP to improve efficiency and quality. While these organizations may be initially motivated by a desire to eliminate the inefficiency of re-entering data and the accompanying human error, the benefits go well beyond that. Through PTC's partnerships with SAP, Oracle, and Microsoft for seamless Windchill integration, organizations can

ensure that BOM data and supporting product development data captured by PLM is made available to all functions that need it. And, because Windchill can provide routing and manufacturing process plans as well, critical upstream and downstream processes are linked and made more efficient and productive. Through the out-of-the-box integration of Windchill with ERP, organizations can develop a smooth flow of major innovations, such as new and more highly differentiated products, as well as ongoing innovations like continuous cost and quality improvements.

Additionally, for PLM/IoT data that does not require synchronization with ERP for computations, PTC offers ERP users with out-of-the-box, real-time views into PLM/IoT data. ERP users can view this PLM/IoT information to inform operational decisions. At the same time, the organization's ERP/MES doesn't need to store this content to drive workflow logic. Instead, users, such as factory and service workers needing work instructions and sensor readings, can access it directly from Windchill/ThingWorx, particularly for dynamic visualization.

In turn, Windchill users view ERP information to inform design decisions. Windchill doesn't need to store this content to drive workflow logic, but instead users, such as engineers needing part cost and quantity can access the data directly from ERP.

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What's New in Windchill 12?

Better collaboration, closed-loop quality, and concurrent manufacturing

Rapidly Develop Role- and Task-Based Apps

ThingWorx Navigate 9.0 enables organizations to build their own unique custom apps, leveraging a rapid app development environment with reusable components. Experience 8x faster time to value when building a new custom app, going from 3.5 months to under 2 weeks.

Implement Closed-Loop Quality

Application lifecycle management (ALM) and PLM integration delivers proof of traceability for finding and fixing problems early. This new capability is delivered through tight Open Services for Lifecycle Collaboration (OSLC) integration with the PTC toolchain (Windchill RV&S and Windchill Modeler) and third-party requirements management tools (e.g., IBM Doors NG).

Visually Manage Critical to Quality (CTQ) Characteristics

Creo View 7.0, embedded in Windchill, provides model-based definition (MBD) visual comparisons for better managing CTQ characteristics. Creo View 7.0 also enables users to identify changes in the view states that are captured in the CAD design.

Support Concurrent Engineering with the Factory

BOM transformation tools enable manufacturing engineers to quickly view and reconcile upstream changes with downstream manufacturing and plant-specific BOMs.



Ready to Learn More?

For a demo of any of the capabilities described in this ebook, **please contact one of our PLM specialists** to schedule an appointment. If you'd like to see what analyst firm, Tech-Clarity, recommends for the criteria to use when evaluating PLM vendors and solutions, download their buyer's guide, **Choosing the Right PLM for the Medical Device Digital Thread.**



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