Fresenius Medical Care Trades in Paper-Based Silos for Digital Product Development

Discover how this healthcare leader is using Windchill to transform its business and improve patient care.

Fresenius Medical Care is a global leader in dialysis products and services, improving the lives of more than 2.8 million people living with end-stage renal disease. Operating across 120 countries, the company's commitment to innovation spans the entire patient journey, from advanced dialysis machines to life-sustaining consumables and integrated care services.

In recent years, Fresenius Medical Care has accelerated its digital transformation strategy, transitioning from paper-based and disconnected systems to a unified product development process. Communication inefficiencies, the pace of external change, the risk for human error in manual handovers and product inconsistencies were key drivers for digitizing.

Central to this transformation is PTC Windchill, the Product Lifecycle Management (PLM) solution that underpins the company's digital thread. It creates traceability, streamlines processes, and enables audit-ready, compliant workflows across the entire value chain.

Challenge: Disconnected systems and paper-based bottlenecks

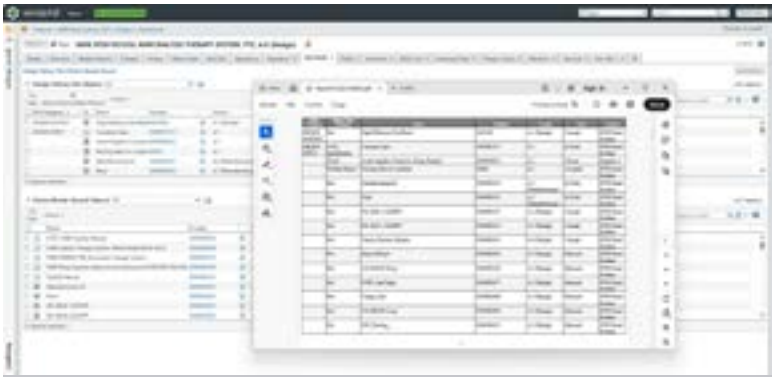
Historically, Fresenius Medical Care's product development landscape was characterized by siloed systems, independently operating sites, and a heavy reliance on manual, paper-based processes.

"In our industry, digitization was often just replacing paper with Word documents," said Christian Vogelei, Principal Capability Architect at Fresenius Medical Care.

This fragmented approach created multiple challenges. Each manufacturing site operated independently, with localized systems and quality processes. These sites were effectively siloed, meaning that Fresenius lacked global consistency and visibility, creating delays, and potential compliance risk, including the time and cost required to demonstrate compliance with paper-based, siloed systems. Likewise, traceability and configuration control were difficult to maintain across product variants without the latest manufacturing data to avoid late-stage changes and avoid loss of time and errors from manual handovers. This made it difficult for the R&D and manufacturing teams to collaborate, impeding design transfer.

> "Each site was like its own company, with its own quality system and digital thread. Harmonizing these workflows and uniting our global operations was a major priority."

Christian Vogelei, Principal Capability Architect at Fresenius Medical Care



Company Overview | Fresenius Medical Care

Headquarters	Bad Homburg, Germany
Revenue	€19.3 billion (2024)
Employees	125,000+
Industry	Medical Technology, Life Sciences
Website	freseniusmedicalcare.com

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Solution: Enterprise Industrial Connectivity with Windchill

Fresenius Medical Care adopted PTC Windchill as the foundation for its enterprise-wide digital thread Lifecycle, connecting data, people, and processes from research through to production and service.

With Windchill, the company established a single, consistent configuration management system for products across global sites and this meant that enterprise-wide change management could now extend beyond design data to include facilities and services. The system now has full traceability from requirements to implementation, supporting audit readiness and integrates with CAD and ERP tools to enable digital twins of both reusable consumables and complex dialysis machines.

The implementation also brought cultural transformation.

"The digital thread means teams that hadn't interacted in years are now proactively collaborating around the same data set," Vogelei explained, "It's completely changed how we develop, manufacture, and support our products."

> **"We can now design a product once and produce it anywhere. Our design data is transferable across manufacturing sites, with full visibility and faster, more transparent change management."**
>
> **Christian Vogelei, Principal Capability Architect at Fresenius Medical Care**

Results: A unified platform for global product development

The shift to Windchill has brought measurable benefits for Fresenius Medical Care, driving operational efficiency, improving product quality, and simplifying compliance.

Fresenius once presented the following measures in regard to the engineering-to-manufacturing handover:

- Improved traceability and audit readiness, particularly in meeting MDR and FDA requirements.
- Change cycle times reduced by up to 76%.
- Digital twins that enhance long-term product support and lifecycle management.
- Enhanced collaboration between R&D and manufacturing through shared access to product data.
- Consolidation of formerly isolated systems into a unified PLM platform.

With Windchill, teams can now generate complete Design History Files (DHF) or Device Master Records (DMR) with a single click.

"Once you've created a DHF or DMR in Windchill that easily, you never want to go back to another system," Vogelei added. "We no longer have top-down processes. The users of the digital thread - the engineers, the teams closest to the product - are the ones driving its evolution, which is how it should be."

Looking ahead

Fresenius Medical Care continues to scale its digital thread Lifecycle strategy, expanding Windchill adoption across more sites, processes, and teams. With a shared product data foundation, the company is also exploring new frontiers including AI-assisted design verification, personalized product variants, and broader ERP integration.

"Our digital foundation isn't just about replacing paper," said Vogelei. "It's about rethinking how we innovate. Windchill gives us the transparency, traceability, and confidence we need to build the next generation of patient-centric therapies."

Key Takeaways

- Digitized, end-to-end product lifecycle with traceability across all phases
- Enterprise-wide change management and configuration control
- Digital twins supporting variant management and design transfer
- Faster time to market and reduced regulatory risk
- Unified platform connecting R&D, manufacturing, and service
- Single-click generation of DHFs and DMRs for audit readiness

Fresenius Medical Care's Change Management Approach

- Shifted away from a hierarchical approach to a network approach that is less controlling and more empowering.
- Moved from resource-driven to purpose-driven with full transparency and visibility so all stakeholders can see what's happening.
- Replaced more than 15 standard operating procedures with just one.
- Built expert clusters along core activities of a product lifecycle from design, development, transfer, manufacturing and maintenance.
- Established globally harmonized engineering change management across sites and teams, including and end to end process landscape that covers all engineering and manufacturing departments.
- Today, vertical and horizontal capability clusters drive capability evolution.

PTC Products Referenced

Windchill (PLM)
Creo (CAD)
ThingWorx (IoT)