



Awareness Unlocks Potential

Explore PTC Solutions for Medical Device Manufacturers

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We envision IoT enabling a hospital of the future based almost exclusively in the cloud. Digital healthcare market could see as much as \$32.4 billion in near-term revenues. ”

– Goldman Sachs, 2015

Disrupt or be disrupted

For today's health IT and medical device professionals, the choice is clear: disrupt or be disrupted. Participants in the health care industry are realigning incentives and business models, as value-based reimbursement models are expected to surpass fee-for-service by 2020.

The patient health care value chain is being reformulated to be more collaborative and outcome-based. At the same time, medical device manufacturers are rethinking their approach to risk as they transition from reactive compliance reporting to proactive quality management.

The health care revolution has only just begun. Will you lead... or follow?



To drive innovation, Philips is undergoing a global transformation to put the right product information in the hands of Engineering, Sales, Service, and Marketing teams.

PHILIPS

Build a culture of innovation and quality

Life sciences leaders seek a fresh approach to managing today's complex product engineering challenges. The ideal solution would provide the enterprise backbone for product innovation—speeding the delivery of next-generation medical devices that are secure, extensible and resilient to change. It would unify distributed teams spanning engineering, manufacturing, quality and service talent. And it would improve quality, reduce the cost of compliance, and securely manage the chain of custody of engineering decisions and deliverables.

Digital Product Definition: Design, CAD/Visualization, BoM, Parts, DHF/DMR, Change & Configuration Management

Document-Based Information: SOPs, Policies, Quality Manual, Training Tracking, Change & Configuration Management

Quality Management with Integral Change: CAPAs, NCs, Complaints, Audits, Training...



CONCEPT



DESIGN



LAUNCH



MANUFACTURING



SERVICE

For more than 30 years, PTC has been privileged to partner with life sciences leaders to help them build more innovative products that win in the marketplace. Unlike the industry's status-quo of engineering intelligence spread over multiple, disjointed systems, the PTC solution enables unified insight and oversight. All of which helps you build higher quality products that improve patient lives and outcomes.

Rapidly design and deliver next-generation products

How quickly can your company capitalize on the opportunity to deliver smarter, higher value medical products? First mover advantage is significant. Success requires the ability to rapidly develop devices that are robust, secure, and ready to participate in rapidly evolving health care networks. That's where PTC can help.

The world's leading IoT platform*

ThingWorx IoT Platform is the only enterprise-ready technology platform that enables medical innovators to rapidly develop and deploy smart, connected solutions for the Internet of Things. With the ThingWorx IoT Development Platform, teams can efficiently prototype, create, test and deploy secure, enterprise-ready connected medical engineering solutions.

ThingWorx is designed for interoperability, critical in the increasingly collaborative and networked world of health care systems. That allows you to deliver value in multi-tiered health care networks, while avoiding the disruption, risk and cost of a "rip-and-replace" approach.

The industry's leading 3D CAD software

We're proud of the fact that PTC invented and first launched parametric CAD modeling software nearly 30 years ago. Today, medical innovators worldwide rely on our flagship CAD software to accelerate design through digital prototype and delivery of breakthrough medical products.

* IOT Analytics, Experton Group, Forrester

Innovate while reducing risk

- Securely monitor, manage and control medical devices
- Rapidly prototype, design and deploy medical applications
- Collect and analyze data from connected devices and health care systems
- Interoperate with health care value chains



Learn about IoT transformation at Carestream, a worldwide provider of dental and medical imaging systems and IT solutions.



Manage the product lifecycle from idea to announcement

As a medical innovator, you operate within a regulated environment described by stage-gated engineering processes. At regular checkpoints, your organization must demonstrate adherence to structured, repeatable and controlled processes. You must also demonstrate that products comply with standards for safety, security and fitness for use.

Silo'd systems are a costly overhead expense

Many medical device manufacturers manage regulatory workflows using paper-based systems or disconnected, single-purpose software solutions. For these organizations, regulatory record-keeping amounts to an overhead activity that depletes time, money and resources.

PLM: Your engineering, quality and regulatory backbone

There is a better way. Integrating regulatory workflows into your product engineering lifecycle allows you to transform overhead into engineering intelligence. This intelligence can provide critical insights to help you continuously improve and transform both products and engineering practices.



The role PLM plays is not only to manage the lifecycle of products. It is becoming almost a hub for dealing with information around products across the entire value chain. ”

– Jeroen Tas,
Chief Innovation & Strategy Officer, Philips

What if you could:

- Manage regulatory requirements by region, product family or market?
- Trace requirements to product parts?
- Provide marketing, regulatory, quality and engineering teams with custom views of correlated engineering data, pulled from multiple systems of record?
- Enhance reuse and minimize revalidation through an online parts catalog?

Leveraging a PLM solution as the backbone of your organization's quality and regulatory framework provides immediate cost savings and long-term advantage.



Hear how the Ear, Nose & Throat (ENT) division of Medtronic uses Windchill as a backbone for both product and regulatory information.



Gain holistic insight into product quality

PTC PLM products were built on the premise that product quality requires more than late-stage testing. Rather, it requires a whole team, whole lifecycle approach. We invented the world's first Internet-based PLM solution – Windchill – partly in order to help customers govern lifecycle processes and achieve ISO 9001 certification.

From these quality-centric roots, PTC has extended its core Windchill product lifecycle management capabilities into a suite of offerings designed to help medical device manufacturers streamline, simplify and gain greater value from their quality investments.

Best practices delivered

PTC's Medical Device quality solutions deliver pre-configured, out-of-the-box best practices designed for life sciences companies. The solutions maximize patient safety while following best practices for regulated life sciences environments, and are harmonized for ISO 13485, FDA TPLC and 21 CFR Part 820 regulations.

- Get up-and-running quickly with out-of-the-box best practice configurations
- Reduce the cost of managing quality throughout your product lifecycle
- Reduce the potential impact of poor quality on revenues and reputation
- Make quality a shared lifecycle responsibility, not an afterthought
- Leverage lessons learned to continuously improve products and processes
- Document structured, controlled and repeatable quality processes
- Accelerate product introductions by qualifying for FDA Case for Quality trusted vendor status



Improve service levels while reducing costs

Emerging health care models are rapidly transitioning the cost of service from buyers, such as hospitals, to medical device manufacturers. Simply put, medical devices need to work when patients need them. With outcome-based contracts, your ability to reduce service costs will translate directly to your bottom line.

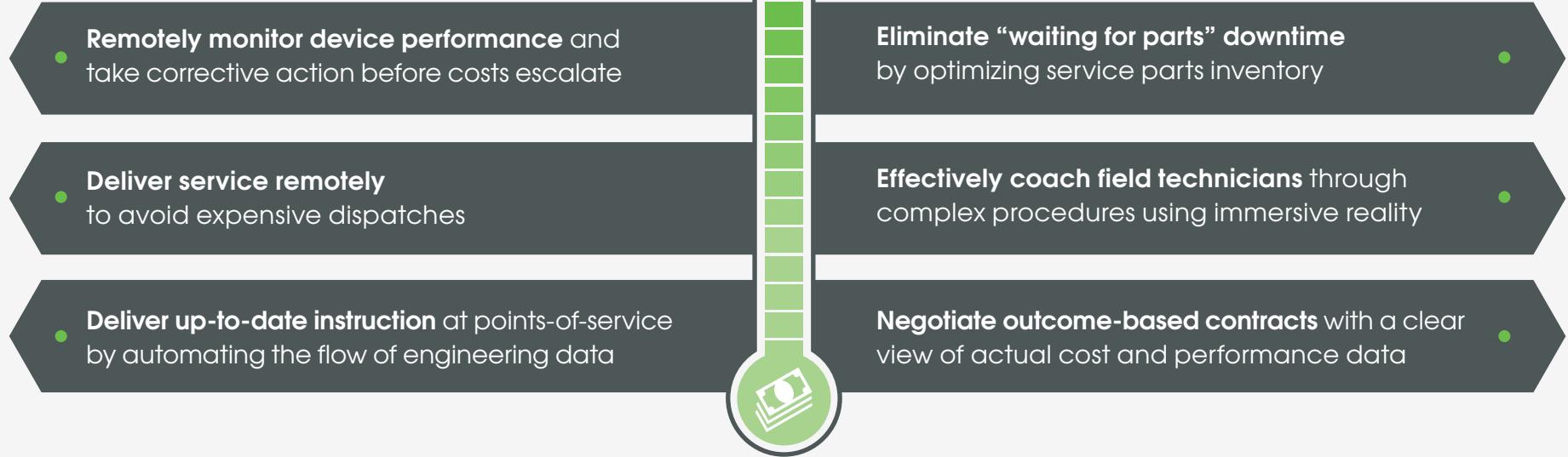
Improve service ... AND lower costs?

Yes, medical manufacturing leaders CAN achieve service responses that are both faster and cheaper! Remote service avoids dispatch costs and drive time. Predictive service avoids unplanned downtime and service effort. Service parts planning avoids downtime by ensuring the right parts are available at the right location.

Connected field service gives technicians the product- and part-specific instructions and coaching needed to improve first-time-fix rates.

For more than a decade, PTC has partnered with premiere medical device manufacturers to transform their service workflows into cost savings and revenue-generating opportunities.

How much can you save?



Interface with smart connected devices on the assembly line

Precision-engineered medical devices are only successful if manufactured with consistent quality to required specifications. Without seamless hand-off from engineering to the factory floor, details get lost – and details matter. That's why an integrated approach to medical device manufacturing is so essential to improving patient lives and outcomes.

The PTC advantage for medical device manufacturers starts with seamless eBOM to mBOM transfer. This helps ensure that manufacturing specifications are specified, verified, authorized and version-controlled.

And that's just the beginning.

With PTC manufacturing solutions, you can:

- Gain closed-loop insight and oversight into manufacturing processes, from design through manufacturing
- Get an early warning into manufacturing nonconformances
- Document and analyze CAPA (Corrective and Preventive Action) plans
- Make better factory floor decisions, based on real-world insight
- Manage independent Bills of Materials for engineering and manufacturing, to ensure that each group can access the appropriate version of product configurations
- Leverage lessons learned into the next manufacturing or engineering iteration
- Ensure SOP and process governance are harmonized; track and manage training



Digital revolution or evolution? The choice is yours

Whether you need to fill a specific technology gap or seek fundamental IT transformation – PTC can help.

Your industry is dynamic and full of challenges. Help us understand your needs and we'll help guide you through the decision process.

[To get started, contact a PTC Medical Device Solutions Expert today](#)



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