The Next Wave in Healthcare: *Improving Patient Outcomes with the Internet of Things*

Integral R&D, Manufacturing, Quality, Compliance, And Risk Management For Connected Devices

Changing Industry Trends are Impacting Medical Device Manufacturers' **Total Cost of Quality (TCoQ)**

Cost Of Poor Quality Costs Medical Device Companies Between 12%-18% Of Their Revenue

Industry Compelling Events

1

Changing Regulatory Requirements & Impact of Healthcare reform

- Recent revisions to the global medical device regulation ISO13485
- "Case for Quality" initiative by the FDA and the medical device industry
- Hospital Value-Base Purchasing -Affordable Care Act (ACA) program aimed at advancing value over volume

2

Connected Healthcare

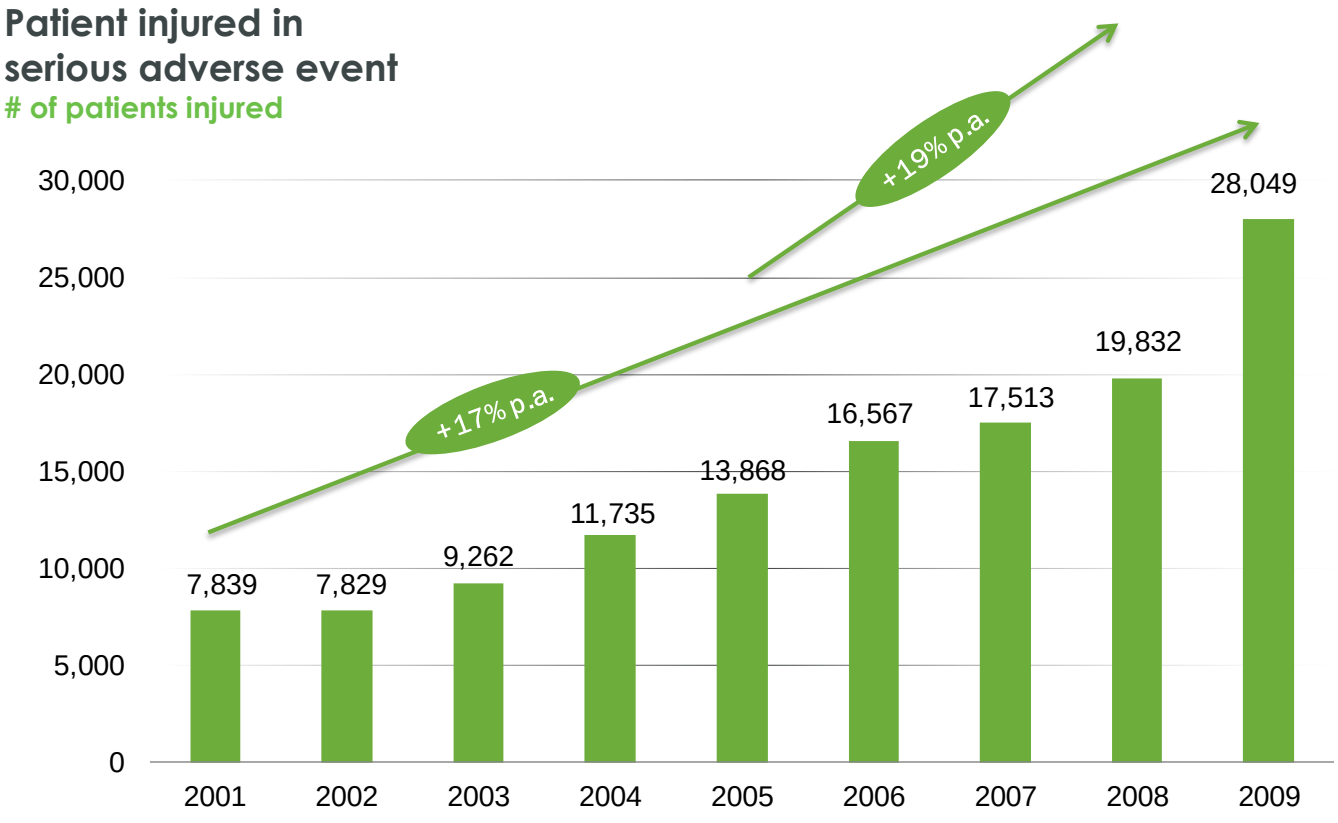
- Digital disruption in healthcare industry driven by connected devices (IoT)
- Improving Patient Outcomes with the Internet of Things (Value-based care)

"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, The Digital Revolution comes to the US Healthcare, 2015

1

Serious adverse event reports related to medical device use have outpaced industry growth by 8% per annum since 2001.



Trends In Medical Device Adverse Event Report

Source: FDA 2011 https://open.fda.gov/device/pma/

"The medical device industry is approaching a ***tipping point*** where ***the increasing likelihood of a quality event***, the rising costs of such events, and the public nature of quality performance will force companies to focus on ***quality and reliability throughout product design, manufacturing, and marketing***."

- McKinsey, The Business Case for Medical Device Quality , 2013

1

McKinsey estimates the **financial benefit** to improve quality costs in Medical Device companies is around **$4.75-$6.0B USD**.

Recall Failure Codes

	Design	Suppliers	Manufacturing	Post Production & Change Control
Hardware	15%	12%		2%
Software	8%			7%
Labeling	4%		3%	1%
Packaging	1%		3%	
Process	3%	2%	18%	1%
Total By value Stream	31%	14%	24%	12%

Source: Data from RECS database

"Data indicates an over emphasis on pure compliance versus quality outcomes."

Source: FDA 2011 - Understanding Barriers to Medical Device Quality

An analysis of root cause data reveals that **failures in product design and manufacturing process control caused more than half of all product recalls**.

"Reducing the Cost of Poor quality can convert 12%-18% of revenue into profit." - Mckinsey

2

Medical Device Companies can **spur Innovation, Transformation, and Growth** by Embracing the Potential of **Connected Devices**

Source: TI Medical

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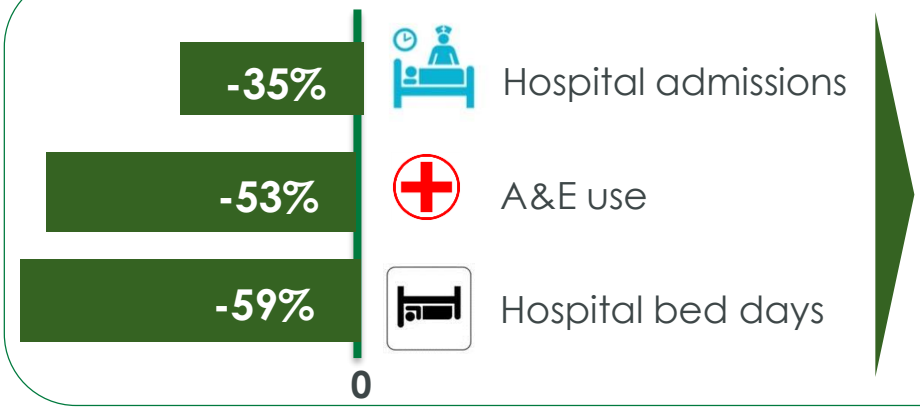


Connected healthcare can increase patient safety and cost reduction by monitoring devices used by hospitals, patients and doctors office

Source: Deloitte Center for Health Solutions, Connected Health, 2015

PTC's Medical Device Value-Ready Deployment™ (VRD) supports the FDA's "**Case for Quality**" and offers a set of **pre-configured validation ready regulatory templates**

Manage customer requirements

Integrate compliance, quality & product

Speed change requests

Manage projects and changes

Visualize new products

Manage compliance

Create trend metrics

Visualize automatic dashboards

Reduce manual reporting

Manage UDI Compliance

Reduce time for submission

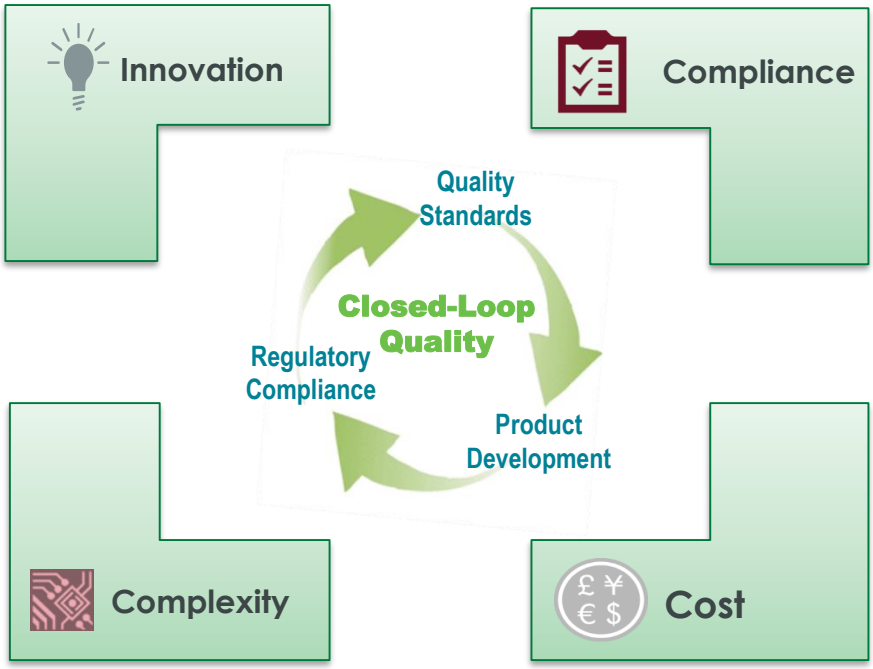
Track full audit trail

PTC Windchill VRD enables customers to improve patient safety and product efficacy while following the ISO 13485 standard, harmonized with the FDA Total Product Life Cycle (TPLC) and 21 CFR Part 820 regulations.

PTC's smart connected PLM™ solution enables companies to **design, manufacture and service connected medical device products** in a closed loop fashion

- **Speed-to-market** first-mover advantage and repeatability
- **Decisions** via access to connected product data
- **Quality** of new products and processes

- **Global** regulations to expand into more markets
- **Complete** supply chain needs to comply
- **Traceable** throughout the product lifecycle



Windchill PLM helps customer maximize profitability at each Lifecycle Phase

- **Systems** designed for software and hardware, and iOT
- **Lifecycle** collaboration across the organization
- **Strategic** new technologies

- **Efficiency** in operations and product introductions
- **Insight** into sources of issues and costs
- **Preventive Action** to reduce costs and risk

"Smart, connected products require a rethinking of design." — *Harvard Business Review*

Source: How Smart, Connected Products Are Transforming Companies, HBR

Next steps: Request a collaborative session to see how smart, connected PLM can help you **lower Total Cost of Quality (CoQ)** and **improve patient outcomes**

Document Backbone

Manage & Control all key documents / Document Control

Quality Backbone

Quality, reliability, and risk management is harmonized with engineering & suppliers, across products & processes

Product Backbone

Manage and control product information / CAD, BoM, BOO, Change Control, Processes / Workflows…

Integral Document Control, Design Control and Quality Management

"According to a study from GE, a 1 percent IoT-generated reduction in healthcare system inefficiencies could bring about savings of $63 billion over a 15-year period."

Industrial Internet: Pushing the Boundaries of Minds and Machines, GE, November 2012

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