

# CLOSED LOOP PRODUCT LIFECYCLE MANAGEMENT: WHAT DOES IT BRING TO MEDICAL DEVICE MANUFACTURERS?

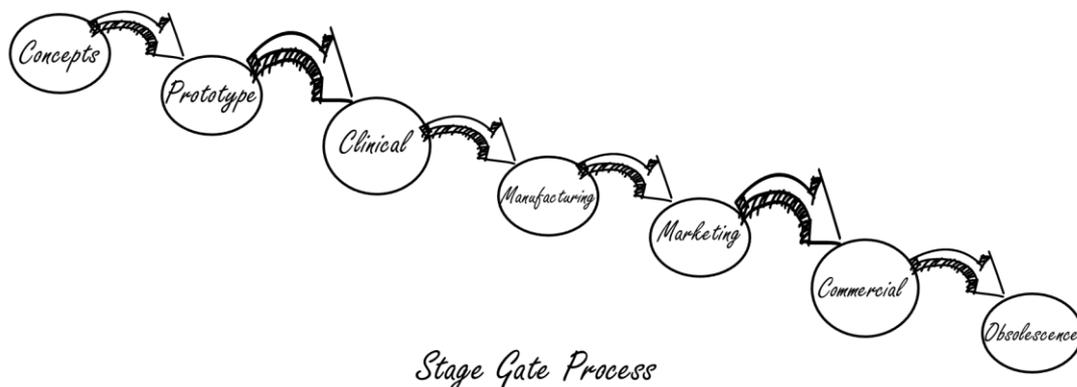
By: Eric M. Luyer, Market Research Analyst & Daniel R. Matlis, President

Digital Transformation was the key topic at the PTC European Forum, held November 15<sup>th</sup> in Stuttgart, Germany. Part of the day was devoted to clarifying how the Internet of Things (IoT) and Augmented Reality (AR), in relation to digital transformation, benefit decision-making processes.

We are living in a time where it seems like everyone and everything is getting connected using technology concepts such as IoT. At the same time, there is a strong focus on improving product quality and value. However, the products or related services are getting more complex and the market requires product delivery be on request.

It is interesting to hear and learn how new concepts and technologies such as IoT and augmented reality (AR) can be used specifically in the medical device industry: to drive success with the ability to create, produce and market innovative and value driven products to market quickly. Certainly, in a global market, proactive strategies are needed to support improved product quality and patient outcomes while supporting compliance with applicable regulatory requirements.

As the Food and Drug Administration (FDA) and other regulatory bodies have embraced the concept of managing the total product life cycle (TPLC), Product Lifecycle Management (PLM) has become an important pillar for the medical device industry, supporting the device lifecycle.



Today many medical device manufacturers have implemented PLM systems. However, in most cases these systems are often used only during the design and engineering phase, and not extended across the total product lifecycle. PLM systems provide the ability to connect

and integrate product information throughout the different stages of its lifecycle: from its design to production & testing, to post-market maintenance to retirement.

The benefits of introducing the concept of (total) product lifecycle management to medical device manufacturers are huge but in practice, unfortunately, under-estimated. Benefits include:

- ▲ Improve product quality
- ▲ Increase productivity overall
- ▲ Faster time-to-market
- ▲ Single source of truth across the complete supply chain
- ▲ Maximize supply chain collaboration
- ▲ Manage configurations and version control
- ▲ Reduce prototyping costs
- ▲ Lower cost of new product introduction
- ▲ Lower field maintenance and warranty costs
- ▲ Simulate field maintenance processes to optimize real sequences and reduce down-time
- ▲ Streamline regulatory compliance and audits and monitor safety procedures
- ▲ Insight into critical business processes
- ▲ Real-time reporting and analytics

Medical Device manufacturers will need to include and implement PLM features in all aspects of manufacturing including:

- ▲ Nonconformance Management
- ▲ Customer Experience Management (CEM)
- ▲ Corrective and Preventive Action (CAPA)
- ▲ Risk and Reliability / Service Management
- ▲ Audit Management
- ▲ Unique Device Identification (UDI)

Certainly, as the regulatory focus shifts from compliance to quality, the reduction of corrective actions in favor of preventative actions is essential to building in quality at the early design stages of the product lifecycle. Failures and root causes must be evaluated to prevent reoccurrences.

In the design and development of medical devices, the FDA's "Case for Quality"<sup>1</sup> initiative calls for manufacturers to ensure the highest levels of device quality and safety throughout product design, manufacture and service. The complex and advanced technology inherent in today's medical devices and their production means that all aspects of the system—including

---

1

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm>

mechanical, electrical, software, and hardware—must be carefully controlled throughout the product development lifecycle in accordance with strict worldwide regulations and standards.

A major software vendor in the area of PLM is PTC. PTC has an array of solutions in PLM / Manufacturing, Digital Transformation, IoT and AR. PTC's PLM solution is combined with Quality Management System (QMS) capabilities to accelerate product innovation and to maximize product profitability and reduce compliance cost. It delivers a “single source of truth” for business processes, product data and content across enterprise functions and locations. Best practice processes specifically for medical device manufacturers are pre-configured in the solution. PTC also has a Validation Accelerator Pack to assist in the software's compliance with FDA regulations for the design and development of safe, effective medical devices.

The value of these type of systems is most effective with closed-loop lifecycle management of the product or the medical device. Research from medical device manufacturers that are using closed-loop processes shows that there is approximately a 75% time-savings in release management. Apart from the benefits mentioned above, such as cost reduction and quality improvement, it is in the end the patient that benefits from better outcomes.

Another important element is that the number of recalls per year can be significantly reduced by using a closed-loop PLM solution to introduce new or updated medical devices into the market. A closed loop solution provides full visibility including quality control and product service components from design to operations.

### Conclusion

Medical device manufacturers are focused on developing high quality products and services aimed at improving patient outcomes. By adopting and successfully implementing a PLM system, companies can make faster and better decisions while accelerating innovation, which in turn can result in faster time to market. Due to increased product sophistication and complexity of medical devices, closing the loop throughout the product lifecycle has become critical for medical device manufacturers.

Using better medical devices that fulfill the requirements of hospitals with increasing demands on quality, ultimately benefits the patients!

PTC ([www.ptc.com/plm](http://www.ptc.com/plm)) is one of the leading software vendors providing integrated, internet-based solutions around product lifecycle management and digital 3D design. They provide field-proven IoT and AR solutions which are bringing together the physical and digital worlds to “reinvent” the way businesses create, manufacture, operate, and service products. PTC has created a new way of deploying Digital Engineering Transformation for more insight into the product lifecycle and better overall outcomes.

For more information on this topic see: [Managing Medical Devices Across the Total Lifecycle](#).

**About Axendia:**

Axendia, Inc. is a leading trusted advisor to the Life-Science and Healthcare industries. We provide trusted counsel to industry stakeholders on Business, Regulatory and Technology issues.

For more information, visit [www.axendia.com](http://www.axendia.com) or contact us at [info@axendia.com](mailto:info@axendia.com)

Read Axendia's blog: *Life-Science Panorama* at <http://LSP.axendia.com>

Follow us on Twitter at [twitter.com/axendia](https://twitter.com/axendia) and LinkedIn at [linkedin.com/company/axendia-inc](https://linkedin.com/company/axendia-inc).

© 2017 Axendia, Inc. All Rights Reserved. This publication is copyrighted by Axendia Inc. and protected by United States copyright laws and international treaties. This document may not be reproduced or posted on another web site beyond the sponsors' without prior written consent from Axendia. Unauthorized reproduction of this publication or any portion of it by other parties may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent necessary to protect the rights of the publisher.

Published April 2017