

# Apply Machine Learning to PLM with Product Lifecycle Intelligence: A Medical Device Use Case

by David Wolf, Jordan Reynolds and Sajid Patel

Worldwide regulations are changing at an alarming rate. One way for global medical device manufacturers to remain competitive is by optimizing change notice lead times. Today, the ability to apply machine learning to Product Lifecycle Management (PLM) systems can help them better understand and drive insights from product data that has been collected over many years.

[Product lifecycle intelligence \(PLI\)](#) is an evolution of PLM that applies artificial intelligence and automation to help PLM users extract meaningful insights from product data, formulate predictions, recommend improvements, and automate actions within systems and processes.

The potential value is immense because with PLI and machine learning, medical device manufacturers can proactively prevent delays and failures.

This article details how one manufacturer addressed their global challenges with a unique three-phase approach, driving measurable business results.

## The Company and the Business Challenge

A top medical device manufacturer wanted to enhance transparency of the change control data stored in their PLM system. The process required a transformation to how they aggregated and displayed data such as aging and cycle time throughput. The organization used PLM dashboards, spreadsheets and shared hard drives to analyze their change control data; a process plagued with common data replication issues. The problem was intensified by the fact that there was no easy way to perform analytics on data without a massive effort and an extensive approval process - which is typical with traditional Master Data Management (MDM) and Business Intelligence (BI) solutions.

Although PLM systems store change data that may be used for auditing purposes, the core platform does not provide advanced analytics capabilities – like machine learning – that can aid in predictive analytics, root cause analysis and discovery activities.

The company decided to execute a proof of value with a role-based application that used a state-of-the-art app to aggregate data and optimize change notice lead times. Just like many medical device manufacturers, the company hoped to optimize their change management process and predict the likelihood that a product would fail or succeed in production.

## A Strategic Three-Phase Approach

To address the challenge, the company used a strategic approach based on Kalypso's hands-on experience helping global medical device organizations benefit from emerging technologies. The three-phase approach is designed to drive maximum value from digital initiatives both in the near-term and for future growth, with an iterative crawl-walk-run cycle.

### **Phase 1: Start with a Proof of Value Workshop**

This phase starts by defining a small scope of business objectives (engineering change cycle time, rejection/rework rate, etc.) The company provides data extract from PLM and Kalypso demonstrates a high-value use case leveraging PLI to drive insights from the data. With a clear link to a strategic business objective, it's easier to show results that help obtain executive sponsorship for the next phases.

### **Phase 2: Test a Minimum Viable Product (MVP) Pilot in Production**

This phase builds on insights generated from connected systems, leveraging machine learning and artificial intelligence to proactively predict and prescribe actions that prevent future crises.

### **Phase 3: Scale Pilot to other Business Units and Manufacturing Sites**

In this phase, knowledge is transferred from the first two phases, enabling multiple use cases, while leveraging medical device connectors, role-based apps and advanced analytics. It is the phase at which the enterprise-wide business value is realized, and the benefits of a strategic digital program start to accrue.

## Phase 1 Results

In less than six weeks, Kalypso addressed phase 1 with a medical device role-based app solution using the ThingWorx platform to capture and aggregate real-time data related to the change management process. An analytics engine was used to create a change management algorithm, providing immediate insight into lead time variation within the product and proof of value for leadership support.

This is just the start. In addition to optimizing cycle time, PLI can predict the rate of approval from the implementation board based on the tasks and rework cycles within the change implementation plan. The company could reduce costs from poor quality through the ability to simultaneously optimize cycle time, streamline the change process and remove bottlenecks before they occur. As a result, the company could expect to provide consumers with a safer and more effective products, resulting in positive brand reputation and increase in market share.

It's important to recognize that using machine learning with artificial intelligence allows an effortless change management process, significant error-reduction and protection of data integrity.

Mergers and acquisitions are commonplace in the medical device industry. For this company, ThingWorx smart connected systems and PLI can eliminate siloed environments, secure data and help prevent quality events.

## Maximizing the Value of PLM

PLM can do a great job of managing product data through rapid change, but it's not perfect at putting that data to work through datamining and analytics. For many discrete manufacturers, this means they are sitting on months or even years of untapped R&D product data. By combining PLM with product lifecycle intelligence, companies can bridge the gap in PLM analytics capability today, allowing them to understand current performance, historical averages, and the variances across different business units and functions.

These insights can help them develop more meaningful customer experiences, while driving business and product value. As an organization iterates through product development efforts, their database grows to be robust and the value of PLI grows accordingly.

Companies that continuously strive to maximize the value of PLM – by pursuing PLM system consolidation, looking for more opportunities to leverage insights from data using [PLI](#), and expanding the use of apps to augment consolidation strategies – will continue to expand the return on investment.

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