Risk Reduction

Achieving Long Term Transformational Success with PLM in Life Sciences: Part 5

by Dave Hadfield

When I get out of bed each day I think PLM, PLM, PLM! While yes I am a nerd, that's not why I get excited. Okay, maybe a little. Let's go a little deeper in understanding my enthusiasm. In the last entry of this series, I started to explore why PLM has a massive benefit for life sciences companies. It comes down to a simple theme: smartly integrated, fully traceable processes that give our innovators the information they need to make the best decisions at the right time. In the next three parts of this series I will explore three important business benefits that could be realized through this truly transformational opportunity - risk reduction, cost reduction and innovation enablement.

Risk Reduction

Risk reduction is about minimizing, monitoring, and controlling the probability and/or impact of unfortunate events that can happen at any phase of the product lifecycle, particularly when the product is in the hands of the user.

No matter how many talented quality, safety and reliability engineers you have in your organization, without access to all relevant product information from research, development, production, quality, and management, risks that could have been prevented are not. Companies are left with customer complaints, unacceptable levels of product non-conformance, recalls, issues identified during an audit, or adverse or unstable trends in product and process monitoring.

Instead, we must rely on smart and integrated processes that feed on rich and probably big data sets. This is not intended to replace our innovators' ability to think, but to help provide insights that would otherwise be unattainable.

With such a capability that spans across product development and sustaining processes, we can put in safe-guards around unexpected failures or failure rates, feeding the data to innovators in real time as adverse events come in. More importantly, we can move from corrective actions to preventive actions. With smartly integrated, fully traceable processes and information, we now have the ability to proactively see potential discrepancies before they occur.

When making design improvements or changes to our products, we can make more informed judgments. During a change, the system runs a holistic analysis of everything else that is affected. It analyzes not only the Bill-of-Material (BOM) or formulation or both, but the entire ecosystem of processes and information that surround the affected item, its parent and even child BOMs (one, two or n levels removed). This includes labeling, validation, claims, comparison to consumer studies, regulatory submissions, supplier information, or risk and requirements data. This automated analysis can be further examined by the change initiator (the innovator) and secondarily change analysts, impact assessors and reviewers. The latter group can ask, "If our innovator makes this change, what might break or what might be the safety implication?" The system could even automatically make updates based on the results of an impact assessment. Without a system to bring data and processes together, this information isn't readily available, so innovators must spend time digging and make judgements based solely on gut feel vs. facts. The more disconnected the data, the greater the risk that something is missed.

Smartly interconnected processes enable real-time comparison of predicted failure rates with actual incidents in the field. While some failures won't get reported or reported correctly, companies can at least understand if actual complaint levels exceed anticipated failure modes and they should know this as soon as possible. And with analytics tools, we can start to make sense of all this big interconnected data and what it might mean for product safety.

What could be more meaningful than improving patient outcomes and value?

I have witnessed all of these capabilities implemented in one form or another. Rarely, if ever, have I seen them implemented together. I look to pioneering companies that will take the steps to tie proven techniques together into a single answer. Why not super-charge the tools, integrate these capabilities under one roof, and empower our innovators by giving them smart systems that reduce risk and facilitate discovery?

We have the know-how and technology available to make products safer with smart integrated processes. PLM can be a big part of this, and that's at least one big reason why I get so excited about the potential.

More In This Series

The Missed Opportunity and How We Can Overcome It

- PLM, the Great Missed Opportunity in Life Sciences
- PLM Pioneers
- Adoption Obstacles
- It's Time to Get Excited About PLM in Life Sciences

The Business Benefits

- Risk Reduction
- Cost Reduction
- Innovation Enablement

The Basics of Technology and Strategy

- Technology Choices
- The "PLM Program" is Where We Went Wrong
- Getting to a Business Transformation Strategy (with an Emphasis on Product Innovation)

PLM Strategy

- Setting the Stage and First Release
- Beyond the First Release
- Automation Initiative Prioritization and Grouping

Solving Coming PLM Strategy Problems

- Time and Cost
- Upgrades
- To Build or To Buy?
- Vendor First or Strategy First?

Making it Real – People, Governance and Methodology

- Transformational PLM is Hard – It's Time to Rally the Troops
- Amazing PLM Governance
- Ten Traits any PLM Team Must Have
- Three Characteristics of a Successful Implementation Methodology

Originally published on May 20th, 2015

What's your view? Add your question or comment

About the Author

Dave Hadfield

dave.hadfield@kalypso.com

Dave brings over 17 years of experience in product lifecycle management (PLM) to Kalypso's clients, with deep expertise in the medical device industry.