ACHIEVING LONG TERM TRANSFORMATIONAL PLM IN LIFE SCIENCES

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PLM, the Great Missed Opportunity in Life Sciences

In the life sciences industry, the opportunity to use Product Lifecycle Management (PLM) for complete “game-changing” transformation is very real. The many processes that comprise research, engineering, quality, regulatory, supply chain readiness and operations can be automated and integrated together to provide one streamlined flow. This is used to convert knowledge and innovative ideas into high-value products.

In the 16 years of working in this industry across dozens of organizations, from small companies with a single product, to the largest medical device companies in the world, I’ve seen a lack of automated and integrated process capabilities in every single organization I have visited. It’s not uncommon to see countless separate databases involved in the product lifecycle. Not to mention the many processes managed in e-mail and Excel.

At one client, my colleague, Graciella Beyers, and I, identified dozens of unique processes that were executed each time a new product was developed and released to the market. Some of these processes were repeatedly executed. Based on our analysis, we identified well over a thousand points where data had the potential to be duplicated or worked on by numerous people without clear communication from one process to the next.

We found that many of these processes were supported by stand-alone tools, and very few were integrated using automated approaches. Data integration was either a manual task or was never actually transferred as it should have been resulting in inconsistent data.

Although this particular client was actually more mature in terms of automated processes, they still faced inefficiencies in managing their processes.

While many life sciences companies have implemented PLM, they commonly use it to automate only between one and five business processes, leaving most still manual, with only paper-based traceability and history. Automating and integrating these other areas can streamline the entire new product introduction process while providing significant improvements in product and regulatory cost and reduction in risk.

This specific business issue is a continued missed opportunity to accelerate the pace of innovation. While some pioneer organizations understand the transformational opportunity of PLM, most are still struggling to achieve it.

Having seen first-hand the power that medical technology has to transform lives (I’ll touch on some personal experiences later), I believe in transforming medical companies to achieve their highest potential by optimizing their innovation and delivery capabilities.

In this blog series, I will provide some insights to why PLM has true potential to be so transformational and consider some of the obstacles that companies in the life sciences industry encounter.
PLM Pioneers

In this blog series, I will provide some insights to why PLM has true potential to be so transformational and consider some of the obstacles that companies in the life sciences industry encounter.

In my first post of this series, I talked about the most common missed opportunity for life sciences companies as they implement PLM. Now I’ll cover one of the reasons behind this, as well as what it takes to be a true PLM pioneer.

Based on my observations, companies within the life sciences industry will buy or build countless point systems. A point system helps to automate one or a few processes, most often with minimal consideration to the broader need for integration. The various departments typically use their budgets to meet their unique set of needs. This results in islands of automation that solve isolated problems. For example, many of the organizations I have worked with rampantly purchase standalone purchasing control tools, quality solutions that manage CAPAs and complaints, and requirements and risk analysis programs.

With these point solutions, individuals or individual groups may be able to do their job somewhat better than before, but at an enterprise level, costs skyrocket and there is no visibility to data across the business. The departments will continue to waste time trying to manage quality data coming in and out. I have interviewed hundreds, if not thousands, of life science engineers over the course of my career, and so often they all say the same thing: “We had some problems with our product, but I didn’t hear about them for six months.”

I believe that the first organizations to truly achieve smart processes - fully integrated and automated - will have an opportunity to turn their best ideas into high quality, effective products, moving them more quickly and more efficiently into the market. This will enable them to respond to customer insights and product issues at a faster rate. They will do this at a fraction of the traditional cost and be first to market when compared to competitors.

I am not just talking about those that implement PLM to automate 3 or 5 or 7 processes, but for the 75-150 processes that affect all aspects of the product concept, design, delivery, marketing, distribution, globalization and post-market quality improvement. These companies will use a PLM solution and tightly couple it with ERP and MES. They will not tolerate standalone tools, or limited multi-point solutions. Their mantra will be seamless process and data flow. Although I have not seen any company come close to achieving this level of solution yet, certainly not across the entire product lifecycle, conversations and discussions have begun regarding how to architect a truly enterprise-wide solution.

I think these companies will be like the first settlers in America; the pioneers. While their journeys will be fraught with challenges and untold hurdles, their opportunities will be massive. Those that make this journey will outpace their competitors at every turn.
Adoption Obstacles

In this blog series, I provide some insights as to why PLM could be so transformational.

I don’t believe any company is there yet, or at least that I have seen. If you believe I am wrong in this respect, I would love to hear about it.

So why is there a struggle to achieve PLM transformation in the life sciences industry?

The reasons can be summarized into three categories:

Lack of Awareness…:

- … of the Opportunity - There is a broad lack of understanding of the opportunity at almost all levels, and I would argue that even many practitioners of PLM (consultants) fail to understand the real opportunity
- … of the Scope - Many people think of PLM in terms of conventional out-of-the-box capabilities (Bill of Materials, Change Control, Document Management, etc.)
- … of the Effort - Even when opportunity is more fully understood, the difficulty of implementing is over-simplified, leading to initial excitement followed by disillusion and even program abandonment
- … of the Cost - The opportunity is understood with high ROI estimates, but the complexity, cost, time and efforts appears to be overwhelming, for large companies with big expansive agendas, it’s possible that costs run into the 10s or 100s of millions (big PLM is catching up with big ERP in this respect)

Technology Issues:

- Historic lack of PLM technology maturity (breadth and/or depth of capabilities)
- Usability problems (for many reasons)
- Many of the platforms were initially architected decades ago
- Most of today’s PLM platform vendors have acquired other PLM companies and the resulting solutions are either integrated from a marketing perspective only (they have the same platform name, but separate technology stacks), or must maintain backward compatibility
- Overly expensive upgrades
- Expense and upgradability issues if you extend or customize the solution
- PerformanceSCALE problems
- Data migration challenges

Execution Challenges:

- Ineffective program leadership and governance
- Ineffective organizational change management
- Ineffective implementation methodology
- Changes in leadership over the lifespan of the program
While I have never seen any one company overcome all these issues on a sustained basis, I have seen each of these issues overcome individually. The first successful pioneers will overcome all or most of the challenges well enough to cross the chasm. The good news for everyone is that the technology is finally getting better, especially in areas like usability and industry focus. No doubt cloud will become increasingly relevant in PLM and help us overcome the traditional architectural problems we often see.

If the best solutions are in place, companies can achieve truly transformational PLM. A visionary goal might be to automate 70-80-100 processes, but even getting to 10-15 of the most critical pieces of the product lifecycle would be a tremendous advantage over the majority of the industry.

In the remainder of this series will focus on what works well to overcome these challenges, and how to manage the program so it’s self-funding.
It’s Time to Get Excited About PLM in Life Sciences

In this blog series, I provide insights as to why PLM could be so transformational. In the previous post to this series, I summarized why there is a struggle to achieve PLM transformation in the life sciences industry.

In this entry we will start to look at why PLM is such a great opportunity and, if you are not already, get you as excited as I am about PLM and what it means for product innovation.

PLM can have many impactful business benefits:

- Safer and better products
- Greatly reduced organizational risk (fewer recalls, litigation and compliance issues)
- Improved product throughput
- Reduced operational / manufacturing costs
- Consolidation of unnecessary inventory
- Leaner production
- Cleaner, more environmentally friendly products
- Less stressful work environments
- Improved market share
- Simplified audits with regulatory bodies
- Operational quality consistency

There truly is solid rationale to believe in all these benefits, and we’ll touch on some of these later, but I ask that before we do, you to consider this a little more abstractly. Let’s put the business justifications aside for a second, and instead let’s think more like the innovator or the dreamer.

It all comes down to broad adoption of smart (automated) and seamlessly integrated, fully traceable processes across the entire product lifecycle.

My colleague Graciella Beyers and I confirmed what we instinctively knew: the number of interchanges between processes in a typical product lifecycle is staggering. In one company there were thousands of places where we identified data changing hands between one process and the next, which means it probably takes 10X that number of data exchanges to get a product to market.

What if those interactions happen in real time, without delay or uncertainty, and based on the correct data?

As my colleague, Chris Kay, suggested to me many years ago, the potential for PLM is not in the automation of any given process but in the interconnectivity of all the processes smartly working together across the enterprise.

Imagine if every process was leaned out to just the steps needed to deliver high quality outcomes consistently every time (think six sigma but automated), affording flexibility in the right places to encourage innovation.

Next, imagine that each process receives and serves up data to all the other processes that are related. Data is never duplicated, but always available. Data is always searchable and reportable in any way imaginable, and analytics can predict outcomes with scary levels of reliability.
In such a world, you log-in to work, regardless of how you contribute to the product lifecycle, and you always have what you need to contribute to the best of your potential. You have all the information in the right place and when you miss something, the system has a decent chance of detecting it and letting you know.

This is the potential for PLM. Not just the parts, BOMs and documents (as much as I love helping clients with those things), but all things across the lifecycle of the product, from the ideas, to the design, the supply chain, and consumer experience supercharged with 2015 or 2020 automation (like big data, cloud, augmented reality and mobile). We will consider some tangible examples in the next few entries.
Business Benefits: Risk Reduction

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 safeguards 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.
Business Benefits: Cost Reduction

If you have been keeping up with this series, you know I have a thing for the potential for PLM in life sciences. If you haven’t, well go back to the beginning, do not pass go, and do not collect $200.

In the last part of this series I started to explore the first of three potential business benefits through the transformational opportunity with PLM in life sciences. I considered how PLM has the potential to transform risk and product safety. With that, we also need to make medical product innovation economically feasible. This brings me to the second important business benefit: cost reduction.

Cost Reduction

I believe companies are missing out on millions, if not billions, of dollars in potential cost savings by ignoring the fact that their processes are disconnected in inefficient ways (there’s an equal opportunity for cost savings by migrating to standard parts, but that’s for another blog).

The answer lies in putting the right capabilities in our innovators’ hands. Not only the engineers and product designers, but those who must be creative in developing the supply chain logistics. These capabilities are based on broadly implemented, tightly integrated, smartly automated processes.

There are at least two chief ways this kind of capability can save massive amounts money. The first lies in information and knowledge reuse. The second is avoiding mistakes and waste. Several years back, I worked with a client who had confessed to me that they had developed many unique methods to extract DNA from a cell. They admitted that one method would have been sufficient. But because they couldn’t leverage their information, it was “easier” in the moment to create an additional method. This is an example of a common problem that I have witnessed throughout my career – lack of information and knowledge reuse.

By providing product development teams the data necessary to make designs manufacturable and by seamlessly transferring data from one process to the next, we can avoid unnecessary scrap and waste. When data is copied – which is a common practice and an issue not limited to life sciences companies – the risk of mistakes increases. At one client, data was transferred incorrectly between two process capabilities (automated without integration), causing an expensive plant shut down that lasted for several weeks.

Part reuse and mistake avoidance have been key benefits of PLM from the beginning, even for simple Product Data Management (PDM) systems, a predecessor to PLM. However, it’s worth reconsidering these classic benefits from the expanded context of smartly integrated processes.

As we correctly interconnect each additional automated processes, the cost benefits are magnified, possibly exponentially.
We can quickly establish if we have done something before, and more importantly, whether that approach was effective. For example, we can reuse validation protocols, understand which suppliers are best and what risks exist with some real (vs. hypothetical) understanding of severity, occurrence, and detection.

Once data is entered and verified (perhaps with the facilitation of automation), that data can be propagated throughout all the interconnected processes. Depending on the level of integration, the implications can be vast – from pre and post market quality, regulatory filings, supplier communication, and many others.
Innovation Enablement

I recently had the privilege to help facilitate an innovation workshop for one of our clients. Seeing the innovation process first hand is truly exciting. The overpowering excitement it brings, the endless amount of possibilities it provides, and the opportunity to make new and better products are the compelling aspects of innovation that draws us to it. Let’s face it, innovation can be fun, but it can also be hard to find the time and data to do it well.

Sometimes people say “Dave, I get that PLM is helpful at organizing information, but can it really help with innovation? Isn’t innovation about ideas? Computers can’t have ideas, can they?”

The reality is that today’s computers aren’t coming up with ideas. We are making some in-roads with artificial intelligence as a society - think of IBM’s Watson that won jeopardy and has been promised to soon be integrated into our medical diagnosis. Perhaps one day Watson could actually formulate new ideas. But for now, what we can do is help our innovators practice their art better.

How does PLM help with this?

First, to recap, what I am talking about is a lot of smart (automated) and interconnected processes that the innovator has available to them. Not just a few things that track parts and documents, but all the information that explains the product’s journey through its invention, design, testing, commercialization and post-market performance.

Once we have this, PLM does several things for the innovator:

- **It gives the innovators time back to innovate.** Instead of spending the time trying to find data (something I hear that a lot of companies do), they have time to focus on what they love: imagining and designing great products and developing the supply chain, assets and processes to realize those products.

- **It gives them data to feed ideas.** Imagine that all customer feedback data (results of marketing studies, complaint information, CAPAs, social feedback, etc.) was always made available to our engineers and marketers. This data would be integrated directly at the part, process and product level in real time.
• **It allows them to leverage past ideas for future work.** Much of innovation is about enhancing what we know. But so often knowledge is lost from one project to the next and it becomes a tribal art-form to carry that knowledge forward. What if when we try things we can more reliably carry those lessons forward to the next team with relevant and related ideas?

• **It provides an innovation framework for our innovators,** such as phase gate to efficiently capture data to help us get organized for gate reviews.

I am quite sure there are many other ways that smart, connected processes enabled with PLM could help drive innovation. These are just a few examples that come to mind. By recycling our knowledge, we can solve new problems at speeds previously unimaginable and inform our stakeholders (at stages and gates) with solid rationale based on trusted data.
In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies. Working across many companies in this industry, my observation is that many have toyed with PLM, at least through traditional PDM (Product Data Management). Now it’s time to get serious! Companies that truly embrace PLM over the next five to ten years have an amazing opportunity to leapfrog much of the industry and achieve many and impactful business benefits.

PLM Technology Choices

In the past, many out-of-the-box (OOTB) PLM solutions lacked support for critical life sciences areas such as research, marketing, quality and regulatory affairs management. So for many years, we would build a custom solution for each client directly on top of the PLM platform. These solutions could be anything from ideation filtering to quality issue tracking to operations planning and management.

For the PLM vendors that have maintained a focus on the life sciences industry, the OOTB solutions they offer continue to expand with smart integrations at the process level. This is true for everything from entry-level cloud PLM solutions that have added quality processes, to traditional engineering PLM solutions and high-end PLM platforms that continue to put serious investment into industry-specific products. High-end PLM platforms can now support biologic, chemical, and materials modeling. They support formulation management, integrate discrete manufacturing and design, and then link regulatory, quality, manufacturing, and supplier information. It’s truly outstanding what the possibilities are for our pioneers. The road, my pioneering friends, is finally opening up!

Others vendors in the industry who have only recently embraced a life sciences market strategy are playing catch up or sticking with a horizontal strategy. Nevertheless, PLM vendors should continue to focus on industry-specific capabilities and life sciences is a great candidate to continue to mature, largely because a lot of what is expected in the product lifecycle is defined by FDA regulations and ISO standards. This provides a standard base for vendors to work from.

None of the vendors, to my knowledge, have conquered all common aspects of the product lifecycle. For this reason, it’s very important to compare vendors - not just across the process and capability areas you’re considering in the short-term, but to consider the long term PLM strategy. This means you must compare module by module and understand what each vendor offers.

It’s important to accept that no one vendor is going to match all of your needs, nor your potential appetite for end-to-end product management. If you think otherwise (and many do), you will be disappointed. Instead, consider how many capabilities are offered out-of-the-box and whether those capabilities meet your needs. Then consider how extensible and configurable the platform is to meet your unique and evolving needs to fill in gaps.
If you are a real pioneer looking to leap-frog competition, don’t bother with platforms that aren’t easily configurable and extensible; at best you will get a me-too capability set.

One thing I will admit I am concerned about is pushing everything to the cloud and oversimplifying for the sake of easy deployment. If vendors stop providing flexibility at the platform level, companies are stuck with what the vendor offers and nothing more. This will be a setback.

I can understand vendors being enticed by the commercial advantages of simple cloud solutions that are limited and don’t encourage extension, but this has limited benefit to our pioneers that recognize they will need to fill in some blanks themselves by extending into areas the vendor hasn’t focused on. Cloud approaches can be enormously useful for PLM, but vendors should not give up flexibility when doing so. Even if some vendors move to an oversimplified (non-flexible) cloud model, not all will take that path. I believe that those who keep their platforms open will win by supplying our real pioneers with the capabilities to make it out west.
Enterprise Architecture Considerations

So far, we have established that the opportunity for PLM is enormous for pioneering life sciences companies. We know now that technology capabilities are generally improving. But selecting a platform is just one part of the journey.

Before we choose a PLM platform, it’s essential to have an enterprise architecture (this blog only deals with one aspect of enterprise architecture) that identifies the system of record (the system that usually creates, and certainly maintains edits to the data) versus the systems of access (systems that need to only read the data, but not create/edit the data). We need to define these for each capability. This will help identify the PLM capabilities your solution needs to have, both out-of-the-box and configured.

There are several technology categories, or enterprise applications, that have a material impact on a product’s journey. These include:

1. Project and Portfolio Management (PPM): To help manage the business process around a catalog of new innovation

2. Product Lifecycle Management (PLM): To manage all aspects of product definition from cradle to grave

3. Enterprise Resource Planning (ERP): To manage product transactions and production logistics

4. Manufacturing Execution System (MES): To manage building a product through the manufacturing process

5. Analytics and Business Intelligence (BI): To analyze product information and gain meaningful insights in order to inform decisions

Designing the Enterprise Architecture

Ideally, we first catalog every process in the product lifecycle and determine what capabilities are needed to support it. Next, we make a decision about which enterprise application is the system of record (or owner) for each capability. There can only be one application that is the system of record, but there can be many, many systems that are systems of access.

Most likely we already have dozens, if not hundreds or even thousands of systems that are involved in the product lifecycle. We can eliminate many of these with an IT strategy focused on integrated processes built on enterprise application platforms. This eliminates information roadblocks and complexity (and certainly cost) that impedes throughput of the product’s lifecycle and responsiveness to new opportunities.

There are many advantages to this elimination and consolidation process. There are fewer security models to keep in sync, fewer integrations between systems, and fewer software applications and hardware to buy and maintain. We can also focus resources on making a few systems better vs. maintaining many systems (probably poorly). There are also fewer points of entry for potential security threats.

While each company is different, I recommend using this simplified view as a starting point when making decisions around division of labor.
Common Missteps to Avoid

When making decisions about your enterprise architecture, it’s important to have a long term view that informs the technology selection. We need to know that we aren’t putting in capabilities into PLM that will fail to span into the other areas as we progress through our journey. For example, if a client asks me to make PLM the system of record for Device History Record capabilities, I will generally divert them to MES solutions. I had an example of this where the client followed exactly that advice and thanked me for it several years later. I’ve also seen many companies make ERP the system of record for change control around the BOM. In this case, ERP should be a system of access, because anything that has to do with change control belongs in PLM, including the definition of the BOM and the manufacturing BOM.

When developing a plan around the catalog list of capabilities, only consider bringing point (or dedicated) solutions into the mix with very strong justification that’s better than “the users like it,” or “the department head wants it.”

For example, when selecting PLM in the life sciences industry, a separate Quality Management System (QMS), database or solution is not only unnecessary, but will be destructive to the potential flow of information. These solutions can manage change, CAPA, complaints, etc. But making a QMS the system of record for this information will disconnect the flow of information that should exist between the design, DMR, the router, risk, and many others. PLM should be the system of record for all of these.
The “PLM Program” is Where We Went Wrong

While many consultants (and admittedly myself earlier in my career) have approached PLM programs without a clear and compelling business case, our job is to help our clients draw a clear line from their overall business drivers to specific quantitative and qualitative metrics where PLM can make a material impact on the business.

Let’s go back to our pioneer metaphor. Think of PLM like the wagon (our enabling vehicle). The pioneer is probably very interested in their wagon; the quality and sturdiness, the capabilities and features. But what they really care about is getting out West. This means they also need to understand how to survive in the elements. They need to know how to defend themselves if attacked. They probably need to know how to hunt and fish. They probably could use a map and an understanding of what places to avoid and which towns might be friendly to the weary traveler. Only when we bring all the right pieces together do our pioneers stand a real chance of making a successful journey. Poor planning and execution, without considering all these aspects, most likely equals failure, even death.

Instead of forming a PLM team (which is often IT focused), form a business transformation team (which is business focused) dedicated to results. This team can look at adopting PLM (with capabilities deployed in phases) as part of their integrated business transformation plan. This team should start by understanding what business transformations are needed. When I study 10-K reports, I can almost always find ways that we can meaningfully impact many (say 75%) of the drivers cited in the “risks” section with PLM as part of the equation. Not too shabby! We can’t help much with currency fluctuations, but we can meaningfully enable time-to-market, cost, quality, compliance, risk, ROA, improved access to global markets, strategic growth, innovation and many other things.

Framing the initiative as a business transformation means selecting which one to three drivers provide the greatest impact for a specific client, and then ensuring that every project delivers measurable benefits to those specific drivers. Only when companies understand the value they will realize from every PLM project do they overcome many of obstacles I’ve covered in this series.

In order for companies to realize the business results from their PLM project, they must follow a well-defined phase gate methodology, and gate reviews must have teeth and proper metrics. PLM can help facilitate much of this, but a tool (no matter how smart and integrated might be) is not the only aspect of the equation. It’s a combination of strategy, people, process and tools.
No matter where you are in your PLM transformation journey, it’s not too late to step back and reframe your initiative on business results. It’s okay to have a PLM team, but that team must report into a business transformation team.

In the next entry we will consider how we reframe our program and start by developing a business transformation strategy. Then we will see how a web of smartly integrated PLM processes can be truly differentiating (compared to the competition) as an enabler of that strategy.
Getting to a Business Transformation Strategy (with an Emphasis on Product Innovation)

In this series, we have considered why life sciences companies aren’t achieving the full value of PLM. We have looked at common problems, considered the enormous value of the opportunity, and recognized that the technology is maturing to the point of being truly viable to pioneers looking to make a real transformational leap.

Now we’re talking about practical starting points. In the last entry, I introduced the notion of starting by building a business transformation team. This team is focused on business outcomes, not technological implementation outcomes. They are not afraid to look holistically at the problem. In addition, while they understand that PLM provides an amazing opportunity to integrate many currently disparate, stand-alone processes across the full set of good manufacturing practices into a web of smart and integrated capabilities, they recognize that this must be done in the context of a larger business transformation strategy.

The foundation of this strategy should be built on a solid understanding of the product delivery engine. Ideally, this includes performing the following steps:

1. **Strategic Initiatives Assessment:** Understand the strategic initiatives that have been defined for the business by the executive team and why. Respect their wisdom and provide feedback during development of the business transformation strategy.

2. **Innovation Results Analysis:** Study past product development projects to find what worked well and what failed. When did we get the in-market results we expected and when did we fall short and why?

3. **Product Lifecycle Cartography:** Map how products are made from concept through obsolescence and what tools (technologies/databases) are used to get there. Catalog all processes for conceiving, designing, developing, testing, manufacturing and servicing a product. Characterize each one and consider how they fit together. Build an interface chart that shows which processes interact with each other and how strong those connection points are (how often they are hit throughout the lifecycle). This map clarifies the context by which business decisions should be made.

4. **Organizational Assessment:** Implementing a business transformation strategy - and in turn PLM - requires considerable organizational upheaval. Ensure the right skills within product delivery project teams to achieve the desired results. In this early stage, it’s critical to understand who the key stakeholders are and how supportive they are for a transformation. Do they want to do everything the old way, or are they ready to embrace improved processes and tools?
5. **Technology Assessment:** Catalog the entire list of automation tools (much of this will happen in step two), with the help of IT to understand what tools are used to manage product or product related information. A full technology assessment will identify hundreds, sometimes thousands of tools – ranging from spreadsheets to simple databases to very sophisticated implementations – and the integrations between them. This assessment shows how the information flow is fragmented.

With these steps complete, we can talk seriously about business transformation (and eventually transformation with PLM) in the context of product innovation. We now have a good understanding of the strategic landscape, people, processes and tools that drive innovation and what results we achieved or how we failed. Now we can strategically recommend multiple projects or actions to transform the business. One of those programs most likely will include using PLM and this can often start immediately. Others could be people-focused (training or coaching), or process-focused (re-engineering). Often these initiatives can be woven together, with PLM adoption as a catalyst to drive more fundamental change.

In the next few entries, we will cover the development of the PLM strategy.
PLM Strategy: Setting the Stage and First Release

In the last entry, we gave practical tips for developing a business transformation strategy that prepares the business to transform results through PLM. In this entry we’ll set the stage for a PLM strategy and look at what phase one should look like.

For pioneers that want to use PLM to transform the product lifecycle and not just automate traditional features, they need a vision that ties all elements of the product lifecycle together into a matrix of smart and integrated processes. If your business does not need that level of change, there are many, good, entry level PLM systems on the market that provide basic features with minimal fuss on a modest budget. Companies that want to make a transformational impact in product leadership (examples were covered earlier in this series) can use an extensible, scalable PLM platform to bring a whole new dimension of excellence with only a small to moderate increase in risk.

Setting the Stage for PLM Strategy

With a solid business transformation strategy in hand, we know much more about what we must do to affect change. We understand our product development process and cultural readiness for change. We are finally qualified to start talking about how we can apply PLM most effectively to the organization.

To set the stage for a PLM strategy, first consider which implementation roadmap approach is best for your company. With a phased approach, one group of capabilities are implemented, followed by another. A slightly different incremental approach entails annual or even twice yearly releases. Think of this more like a train, which makes scheduled stops that deliver incremental capabilities.

I favor this approach because it keeps the team accountable for delivering value on a schedule and ties better to annual budget and return calculations. I will cover more detail on how to develop this roadmap in the next entry of this series.

Release One for PLM

Almost all companies need the same set of fundamental capabilities that are core to just about every PLM project. These include document management (product documentation and quality documentation), bill of material (BOM) management, and managing the broader Device Master Record (DMR), which integrates product and quality documents into the BOM. These fundamental capabilities create a comprehensive product recipe and work in concert with change management tools, typically broken into change request/assessment and change order workflows. Stack up the benefits of these fundamental automations against other possible starting points and they’ll win every time. It’s hard to derive much value from PLM without these elements, but they still must still be implemented with a strong link to the business transformation strategy and goals.

In the next entry we look at steps beyond phase one, which depend more on unique business challenges.
PLM Strategy: Beyond the First Release

In the previous two parts of this series, we consider how business strategy and PLM strategy are important starting points that play a key role in helping life sciences companies get the most value from their PLM solutions.

A viable PLM strategy must support an overall business strategy, defining how PLM links to and enables overall business drivers that deliver better results from innovation. In a previous post, I recommended doing a cartography exercise that catalogs the entire product lifecycle and clarifies the context by which business decisions should be made.

When setting out on a PLM journey, companies must think through if a phased or incremental approach is best. Phase one of any implementation should start with the fundamentals; putting in a PLM backbone and a foundation to build from. Now it’s time to go beyond the foundation and consider more exciting possibilities for the roadmap beyond the first release.

With PLM, there are literally hundreds of things we can automate across the product lifecycle, so it’s important to select the things that will provide the most business value. The cartography exercise provides a strong characterization of each product development process and how they tie together.

These results, plus our understanding of business drivers and challenges that we need to address, allow us to consider how our processes might be automated and integrated. The next step is to imagine automation initiatives, where each initiative is a component of a PLM release cycle. The list would include automating processes, framed as capabilities like DHF management, regulatory management, CAPA, and market analysis.

True PLM pioneers know that automation can be achieved in at different levels. Several years ago, my colleague Graciella Beyers and I developed three automation maturity levels for any given process. The first level is basic data management where PLM is used almost like a virtual filing cabinet for storing documents, with no smart links between the documents or the data in them. The second level introduces liberated data, stored so it can be acted upon, and includes more advanced workflow capabilities. The third level brings in predictive analytics and tools that think with you to solve problems (we called them helpers – similar to how Siri works). Graciella has an imagination for this stuff like no one I have ever worked with. She can take what seems to be the most basic or boring business processes and find ways to make them extremely useful to real people and real product teams through automation.

It’s probably overkill to identify three automation maturity levels for each capability, but it’s important to figure out what maturity level provides the optimal value for your business. My next entry will cover the process of prioritizing and grouping capabilities into individual releases to formulate a roadmap that is both defensible and addresses the business challenges in our overall business transformation strategy.
PLM Strategy: Automation Initiative
Prioritization and Grouping

In this series, we are looking at why life sciences companies aren’t achieving full value from PLM. In the last few entries, we considered how developing strategy is key, and we identified that we must start to convert the product’s lifecycle into a set of potential automation initiatives. Now we’ll look at how to prioritize those initiatives to develop a roadmap.

Companies should not try to implement too much change at any given time. There will be multiple constraints from preventing us from doing so: budget, business driver priority, resource availability, ability to manage change, and considerations related to incumbent tools (like point solution capital investment schedules), not to mention some inevitable politics.

Prioritizing with a Quality Functional Diagram

My colleagues and I have found it useful to use a Quality Functional Diagram (QFD), which we learned from someone who was is a Six Sigma Master Black Belt. A QFD is a prioritization tool that stacks options against a set of variables. Each initiative option is scored across each variable (I like to use a 9/3/1 scale where 9 is “high impact,” 3 is “moderate,” and 1 is “low”). Variables should include things that matter to the strategy, such as the ability to impact business drivers and support for an innovation-focused business strategy. While there is no set-in-stone formula here, variables I find useful include: organizational readiness for change; PLM architecture contribution (like building a house, we give priority to foundational components); and the ability to positively influence results from innovation (if not already covered by other drivers).

For each initiative, ask yourself, “By executing this initiative, what will be the impact to each variable?” Once we have scored each initiative across each variable we have an objective basis for comparing relative priority.

If done well, a QFD can be a lot of work. Teams should provide solid rationale for every score. But numbers and QFDs alone can be misleading, so beyond the quantitative comparison, a good dose of qualitative comparison should be added. Consider system usability and other harder to quantify rationale.

Developing a Release Roadmap

Once key stakeholders have agreed on the prioritization of automation initiatives, we can start grouping them into releases.

How do you group initiatives into a set of releases? Look at dependencies and synergies. Initiative X may be a really high priority, but perhaps it doesn’t make sense unless we also do initiative Y and Z (for example, to do regulatory automation well, it’s helpful to have the Design History File or DHF, since the data is often the same). Also look at synergies. For example, when implementing CAPA, it’s also useful to look at risk management since the two are highly correlated.
Don’t be afraid to spend time analyzing the various options; these are really big decisions around which business drivers are most important to your business. Those are the basics to prioritizing and grouping the initiatives you’ll automate with PLM. In the next entry we will consider how to solve common strategy problems you are likely to encounter.
How should we handle processes slated for far out releases?

Most likely, the PLM roadmap will indicate some capabilities that are years away, and some process owners may feel short changed by this. They will likely want to go buy a dedicated solution that automates just their process. We know that pioneering life sciences companies should generally avoid dedicated or point solutions, because these usually impede the cleanest possible flow of product data throughout the lifecycle (not to mention lower complexity and cost). But we must also be pragmatic.

Some processes need at least some basic automation and while they may exist separately from the system of record, isolated automation can often be much better than a manual approach, even though it’s still inferior to integrated automation. My recommendation is that if the PLM roadmap suggests something is more than three years out, it’s probably worth considering point solutions very selectively and carefully. In many cases, the best point solutions might be simple cloud software and using office applications like Microsoft Excel, Word and Project.

What if the roadmap seems too long?

I recommend not trying to implement more than five to seven capabilities at any given time, but there are many variables that can influence this threshold. This would be a good number for a division that has a single, standardized quality system. When bringing multiple quality systems together from multiple divisions, the number may be lower. Two or three capabilities would be a lot to harmonize at once.

One approach would be to segregate the product lifecycle into groups where coupling is rather loose between the groups and runs in parallel. This is challenging but I have seen it done. Otherwise, patience will have to be the price of attaining greatness. Measure your success by extracting business value at each release, using the prioritization methods previously described, instead of the quantity of features you implement.
So just how much is this going to cost?

I see PLM investment heading in two seemingly disparate directions. On one hand, I know of PLM programs for a few very large companies that start to rival ERP in terms of cost. On the other hand, I see a growing number of PLM implementations delivered with much lower cost and time required than in the past.

Regardless, I have always been a believer in pay as you go. In other words, don’t ask for the big budget all up front. Plan for and acquire enough to cover what’s needed for the next release or two (one year out plus likely support and maintenance). Then, in your implementation, please have a relentless focus on meaningful business metrics (something that is sadly overlooked in many projects). Use the business metrics as a way to demonstrate success at each phase. The resulting returns from well executed early phase PLM efforts should be more than enough to cover subsequent year investments.

In many ways, PLM is becoming more cost-effective. But to make it out west with PLM (and to reach the potential I have formerly discussed), it still requires a significant investment in people and process change. If done right, every penny invested will be returned multiple times over.
In this series, we have considered why life sciences companies aren’t achieving the full value of PLM. So far, we’ve covered building the business and PLM strategies, and we’ve considered the hurdles companies are likely to face while building the strategy. In the last entry we looked at the common issues of time and cost. Are we past those yet? Okay cool! Next we’ll consider a particularly tricky strategy question; how to plan for upgrades.

Upgrades update the software with the latest offering. Companies upgrade for many reasons, but the most common reason is to maintain support from the vendor.

Don’t underestimate the risk and cost of upgrades; they are often quite painful and can degrade internal support and potential value over the long term. Sadly, I have seen this happen firsthand after companies have invested tens of millions into PLM, only to be stumped by a painful upgrade and subsequently turned off. The program dies under its own weight. For our pioneers heading out west, they reached the Mississippi but didn’t get across.

There are a few techniques I can recommend.

First, consider how to reduce upgrade frequency over the long term. One of the big drivers for upgrades is when PLM systems are coupled with authoring tools, especially CAD. To get the new CAD program many still believe we have to bring along all of PLM. This is both the tail wagging the dog and a throwback to old school product data management (PDM) thinking. PLM outgrew its CAD/PDM roots many years ago, yet may still think of it this way. My recommendation is to consider carefully separating the PDM tool from the PLM tool, so that we can be more agile with CAD upgrades and let CAD/PDM tools do its job. This may sound counter to an integrated strategy, but in this case I think it’s an acceptable compromise. Instead, integrate the PDM tool with the PLM tool (potentially very loosely). If your vendor doesn’t have a separate PLM tool, there probably is little stopping you from having two instances.

My colleague John Hubert, a PLM veteran of nearly 30 years, takes this point further. His recommendation is to consider keeping upgrade cycles to five years or longer. Some people might disagree, but John and I have seen companies be successful running the same instance for as many as ten years. Yes, the eventual upgrade will be painful and companies may face support problems, but the alternative - upgrading every two to three years - can be detrimental to progression of the overall roadmap. Base PLM packages don’t evolve as quickly as you might expect; it’s taken years to get to the kind of advancements I spoke of previously. Pick a point in time, where the version has stability, and consider the pros and cons of staying with it for a longer period of time. Even if direct vendor support lapses, you may be able to get by with other methods, so it’s a matter of evaluating the risk.

Select PLM vendors address the upgrade issue head-on, and will upgrade your solution (including all your customizations) as part of your subscription. In fact, they may even guarantee your solution will upgrade so you never have to worry about configuring and customizing the system to work exactly as your business needs.
Look for this kind of guarantee before you buy, and contact me if you’d like to know which vendors offer this. If your vendor doesn’t - and most don’t - they still may be the best fit for many other reasons, but you will pay a much bigger price for upgrades at some point.

Finally, consider how to build out or implement end-user automation capabilities within the product lifecycle. We have or will select our core platform, but that doesn’t force us to buy every add-on module that automates individual processes. This is the topic for my next entry (to build or to buy automation capabilities). Answering this question will have a profound impact on the eventual cost of upgrades, usability, organizational change and other variables.
Solving Common PLM Strategy Problems: To Build or To Buy?

In this series, we have considered why life sciences companies aren’t achieving full value from their PLM implementations. If you’ve been following along to this point, you know you need to have a roadmap. Perhaps you have planned to automate a dozen or so process areas over the first five years. Now you need to decide if you will buy the process-focused add-on-module (capability) offered by your vendor, or if you will build it yourself on top of the PLM platform.

Even asking this question is controversial. It reminds me of how people daren’t speak Voldemort’s name in Harry Potter. It really annoys and surprises some people to even consider strategies that might bypass vendor capabilities. Common arguments center around support and cost – that there won’t be adequate support or upgrades, and that it will cost a lot more in the long run. A majority of time, these concerns are valid; however, there are cases where the benefits of building your own can outweigh the downside. There are also two middle ground options: you can partner with the vendor to build out the capability you need, or you can start with what they have and heavily extend it.

When Should you Build Your Own Capability?

First, you must have a flexible and extensible PLM platform (some are built to only work as the vendor recommends), and at least one of the following situations must apply:

- The capability is not offered, is not on the vendor’s roadmap, or is in a distant release.
- The capability provided is superficial, or not aligned with your requirements.
- The capability exists, but your vendor doesn’t emphasize it. Ask your vendor tough questions about the number of clients who’ve installed this capability in production. If the vendor has low demand, the capability probably won’t have the features you want and you will end up extending it anyway. Why waste time changing your process if the vendor approach is going to be abandoned?
- The capability is not easy to use, poorly designed, designed in a lab with no real world experience, or exceptionally unfriendly, clicky, or impractical to use.
- The vendor has the capability, but it was based on an acquisition and isn’t properly integrated into the core platform (or the vendor doesn’t provide clear guidance on when they will integrate this capability into the core platform).

None of these conditions are sufficient to immediately conclude you need to build this capability on your own. Meet with the vendor. Help them understand your business need and their opportunity to capture a greater share of your business. If they’re willing to reprioritize their offerings to meet your business needs, and your industry (you don’t want them to write a solution just for you, even if you are big enough) then go with them. Otherwise, you’ll need to think carefully about building it on your own.
For example, just because your vendor has a CAPA capability, it might not meet all your CAPA needs. I reviewed such a module from a vendor a few years back. It was designed as a standalone point solution and lacked integration to other processes. The capability was immature and demonstrated an amateur understanding of CAPA. This doesn’t mean I wouldn’t have recommended it to my client, but I know we would have had to do extensive work building what we needed on top. This brings me to another point; don’t just look at bells and whistles within the capability.

This is a common mistake made by departmental buyers who are given decision authority from a PLM champion with little understanding of process integration and enterprise architecture constraints. You must consider the process-to-process integration requirements as well as your company’s enterprise architecture principles around complexity, change, and cost.

The life sciences industry (including medical device manufacturers) is still not a core industry for most PLM vendors. They’ve implemented some capabilities very well, but many times lack both depth and breadth of their offerings. So in all reality, some build-out is needed if you want to get the full value of smart, integrated processes. Conducting an objective assessment of each vendor’s capabilities requires deep implementation experience with each platform you’re considering, or a partner that has successfully implemented each of the platforms you’re considering in large life sciences companies and can provide an objective view of each platform. Don’t rely on just a vendor demo and RFP response.
Solving Common PLM Strategy Problems: Vendor First or Strategy First?

In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies, but many aren’t getting there. In this entry, I’ll revisit the topic of PLM vendor selection, diving deeper into how PLM vendor selection and PLM strategy should tie together.

Sometimes I see companies make the mistake of picking a vendor and then developing a PLM strategy.

Here’s what I have seen happen, much too often.

Some crisis has occurred. For example, lagging sales, margins trending lower, missed opportunities in emerging markets, an FDA-issued 483 form or warning letter, expensive recalls, or declining market share. The knee jerk reaction is, “We need better systems to improve innovation/quality/fill-in-the-blank business driver.”

A well-intended, enthusiastic executive recommends that PLM is the new answer. I love those people of course; it’s that energy that provides the spark. But here is what happens so often: the idea gains traction, excitement builds and a sponsor is appointed and given some budget. Sometimes, this champion doesn’t have adequate qualifications in the processes that will be automated in the near term, or has little understanding of PLM technology. Vendors are invited in and conduct scripted demonstrations. After a lot of time and effort, a favorite begins to emerge.

Next, purchasing gets involved and insists an RFP is issued. The champion does his or her best to write the RFP, but it’s filled with idealist or highly specific concepts that may be unrealistic. Often the requirements aren’t well constructed, are too vague or are impossible to address. The vendors do their best to respond, despite their frustration. Vendor sales reps do their utmost to develop a relationship with the champion; all well intended, all good. Hungry for a deal, vendors compete furiously and ultimately a system selection is rewarded.

Throughout this entire process, the focus is not on the business transformation required to solve the crisis or compelling need. Instead, the focus is on buying a PLM system. Because there is a weak link to the problem the company is trying to solve, the selection is misguided, and lacks a PLM strategy based on business needs.

In these cases, even after the vendor has been selected, the problems continue. Suddenly the company realizes that PLM is complex, so an integrator is hired to configure and install the solution. At this stage, the company may still have inflated expectations, and at the same time, an unrealistic budget and schedule.

A good integrator will seek to better understand the history and possibly push back on the assumed roadmap, recommending the company develop a strategy. But with licenses already purchased, they may be still stuck with a potentially mismatched solution.
If this scenario sounds anything like the journey you are on, please reconsider!

You should always develop your business strategy focused on solving product leadership and innovation challenges, and then develop a PLM strategy before selecting a vendor. Remember that the first release is likely focused on core product data (something most the vendors can do quite well), but all releases beyond that are where the real differentiators between the vendors come to light.

You should know what PLM platform capabilities will best achieve the business outcomes your organization needs in both the short and long term. You will be operating from a much better, more informed position (reread entry 9 for specific steps to get prepared). Only then should you go through a vendor selection process. You will be able to find a vendor that best fits your needs, and you will be set up for a future that allows you to achieve the full value of PLM in life sciences, while being able to meet and exceed near term business goals.

Dive deeper into the debate on software or strategy first: Which Came First, the Innovation Process or the Software Tool?
Transformational PLM is Hard – It’s Time to Rally the Troops

In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies, but many aren’t getting there. We have covered adoption obstacles and turned our attention to developing a business strategy focused on innovation and then a subsequent PLM strategy. We have talked a lot about picking a vendor and getting prepared. Next, we need to consider creating the necessary ground swell, excitement, and momentum to ensure adoption.

This is going to be big – really big – which means we’ll be fundamentally changing how we work every day for the better. And not just for engineers, but just about everyone who touches the product in any way. If we do PLM right, it should affect 90+% of the organization.

But this enterprise nature also means PLM will be hard, and every phase will be challenging. Data migration alone is enough to make you want to quit. So developing and nurturing buy-in from the organization is essential to longevity. Here are some practical things you can do to rally the troops.

Socialize Your Roadmap

Socialize the roadmap with the right stakeholders, in the right order, at the right time. The roadmap should paint a vision for the organization that is truly inspiring, especially for companies that are replacing very dated tools or point solutions that are focused on very limited set of processes with no integration to other internal systems.

As the roadmap is communicated, it’s helpful to build a stakeholder assessment, tracking them with an organizational structure (showing reporting lines), and indicating who is resistant, neutral, positive, etc.

The roadmap should be painted from two angles to provide different perspectives:

1. It must address how PLM impacts business drivers (compliance readiness, time to market, global access, market share, etc.)

2. It should consider the day-in-the-life of a typical engineer, quality manager, regulatory lead, sales executive or operations worker

Most often I see companies over-emphasize the business angle (you win the mind of the business) but not think about the people (you don’t win the heart). In this scenario, executives have high expectations, but people don’t embrace the system, and the business results that we got so excited about aren’t achieved.
Brand PLM

To really get the excitement going, develop a change campaign and a brand for your PLM program. A brand is much more than just a cool sounding name and logo; it needs to speak to people on an emotional level.

As you build your brand, consider questions like:

· With this new capability, how much more effective and better will daily work be?
· What tasks can people skip now, allowing them to focus on more interesting work?
· How much more informed will any individual be if the data is smartly integrated?
· How much faster can you make a decision and move forward?
· How much more confident can you be in decisions that are made?

Next, use the stakeholder assessment to build a change campaign. This is a comprehensive sequence of events that involves talking to the right people (yes there will be an element of selling), conference room pilots, lunch-and-learns, and of course classroom/computer based training and coaching.

Innovate Coaching and Training

One of my favorite ideas is to keep classroom training to a minimum (formal classroom training is only so-so effective in my view) and instead, interject coaches (or Support Ninjas as we sometimes refer to them) throughout the organization. These folks do real work alongside people as they use the system, ensuring proper use and giving the initiative a more personal touch.

If you really want to step up the results, train the coaches in not only the tool but the process area they help with. This will drive results beyond what the PLM tool can provide and instead drive new behaviors.

If implemented well, PLM can be so meaningful to people that do the day-to-day work. Get them on your side by winning the emotional battle. This will help develop sustained adoption, ensuring the longevity of the program.

A Note of Caution

In some cases, a big, high-impact change campaign done at the wrong time can actually be damaging, so timing is everything. Step forward carefully and intentionally, and ensure you understand the political landscape. It may even be prudent to get something small implemented successfully before going big.
Amazing PLM Governance

In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies, but many aren’t getting there. We have come a long way – we have developed a defensible strategy, picked technology, and developed a change campaign. Now we need effective governance models in place to help mitigate risk, remove obstacles and assign accountability.

In my experience, to ensure long term success, there should be at least two governance models in play.

The Program Governance Model

The first is a program governance model that considers the long term interest of the program. This model transcends any given phase and is focused on the long term vision of success and the true transformational capabilities required to smartly integrate our processes.

The program governance model should be sponsored at the most stable and highest level of the organization, and should be as impervious as possible to major organizational shifts, including:

- Restructuring (new acquisition, divestiture, and merger): When possible, the PLM strategy must be adapted to the changing environment. This is possible when the PLM strategy is linked to a broader business strategy and focused on business results that cannot easily be upended or removed from the three year plan. Regrettably, I have seen organizational restructuring kill otherwise fantastic PLM programs because there was a failure to adequately create this linkage. Instead, there was a reliance on the previous organizational leaders to shoulder the risk.
- Change to key leadership positions: The PLM strategy must live beyond a single enthusiastic leader. A tight-knit group of senior sponsors can be helpful when changes occur in individual leadership roles, and when major organizational restructuring or strategic growth changes occur.

The program governance team should be instrumental in removing obstacles like financing or differences between departments. Strong leaders with vision and tenacity can hold the project teams accountable.

It’s very important that the sponsors are educated on what an optimized product lifecycle could look like and that they understand the context of a broader enterprise strategy. I have been surprised by how hard it can be to educate senior leaders on these concepts. Be prepared to explain things very differently; these are very smart people but you must be able to define impacts to business results (reduced risk of recalls, reduced cost and impact of regulatory compliance, improvements in top line revenues, improved staff productivity, etc.). Remember, senior leaders don’t speak the same language as those you deal with daily about PLM.
The Project Governance Model

The second governance model is a project governance model. This must fit perfectly with the broader program governance model and reporting should be defined between the two. Project metrics should feed into the program metrics and program governance guides the requirements for project governance (for example, if we agree to certain outputs, it will be down to individual projects to generate the raw data).

At a minimum, the project governance model must address the following:

- **Team management**: Team roles and responsibilities, providing role clarity on who is responsible and accountable for what
- **Methodology expectations**: Ideally, your implementation is based on a delivery methodology that has been tried and tested. It’s unlikely we will do everything the methodology calls for because not every project is the same. But we need to agree on the principles we will apply when determining what aspects must be covered to ensure appropriate level of quality. In life sciences, the standard is generally very high
- **Deliverable process**: Define the process to align on deliverable expectations, review with the client, and ensure consistently high quality work
- **Meeting process**: Document what meetings will we have, who must attend, and the process for each
- **Reporting expectations**: Reporting and project governance artifacts (what reports must exist, who owns them, frequency of updates)

In subsequent entries we will dig deeper into some of these areas and look closer at what it takes to deliver them in practice, especially in the areas of teaming and methodology, which are difficult to do well.
Ten Traits any PLM Team Must Have

In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies, but many aren’t getting there. We have come such a long way with our journey. If you haven’t had a chance to read the previous entries, you have some catching up to do.

We have moved into the part of our story where we are executing on the strategy and doing actual implementation projects. Maybe we are on our first phase where we likely will establish a Device Master Record (DMR), a strong change control process, and we’ll bring control and automation to the bill of materials (BOM) and documents. In this entry I pay homage to the importance of what makes a good PLM team.

Everyone knows that having a highly functional team is paramount to success. But what does that really mean, especially in the context of PLM? Any team must have at least these ten traits to be successful.

1. **Trust**: The team must trust each other and be comfortable being vulnerable with each other. They should be comfortable explaining where they have blind spots and areas for improvement. Without trust, the team is not a team; it’s a collection of individuals doing work and probably hating life. Trust will build over time when people act with integrity, especially in more difficult situations (all PLM journeys will likely present many of those).

2. **Fun**: One of the most successful PLM Program managers and architects I have ever had the privilege of working with is Jon Nelson, a PLM veteran of 15+ years. Years ago, I asked Jon the secret to his leadership success. His reply was simple, “If your team is having fun together, they’re setup for success.” This sounds easy, but it doesn’t come for free. It takes discipline and planning to ensure that fun things happen, especially during the course of a demanding PLM program.

3. **Decision Empowerment**: I can’t tell you how many times I see PLM programs suffer slow deaths because the team is not empowered to make decisions. I believe that PLM programs are especially sensitive to this. The team must be carefully selected so they can represent the organization and understand the impact of their decisions, especially if existing processes are being redesigned. I had the privilege to be a part of a PLM program very recently where the decision authority was given to a very small handful of extremely skilled individuals, which helped the program move at lightning speed. The first real test came on the day of the conference room pilot; a time when the broader enterprise would get a peek at what had been designed. The team had done their job admirably, and it was clear that the appointed team had the right skills both politically and technically to make good decisions for the organization (these items are covered in subsequent points in more detail). I have also seen just the opposite, where perfectly great PLM programs were killed by committees.
4. Access to the Right Tools: The team must be armed with the right tools. Programs suffer tremendously if this is skipped, and sadly, it often is. Give the team the time to set those tools up in a way that helps them be most productive. For example, a developer might decide they want an integrated development environment (that’s their programming environment) and they want this directly linked into the PLM platform. This way when they tailor the system they can quickly test if their changes are effective. Without this link, the process can be really slow and burn through a lot of time and money. Not all developers work this way, but those that want to should be allowed to. It might take a day or two to set this up, but it can save masses of time and frustration later on. Project managers should not deny these kinds of requests due to time pressures, and project leadership should constantly ask and re-ask the team if they have what they need to do their job. So often, people feel their requests are ignored and they hobble along unnecessarily. If leadership isn’t listening to the troops, then you have a problem.

5. The Right Mix of Skills: PLM programs are not just technology projects, especially if the program is going to be transformational. We must not only have good technical experts (many PLM platforms can take years to learn well), but we must have individuals that can lead process redesign, those that know how to drive organizational change, those that can articulate business benefits, and those that can lead a team. This takes a variety of backgrounds and experiences and it’s truly hard at times to find the right blend, especially when time is short. The most successful programs I have lead or been a part of have at minimum: a program manager, a program architect, a business process analyst team (one BPA for each major workstream), an organizational change team, and of course engineering and testing staff.

6. Leading Practices from Deep PLM Knowledge and Experience: Team members in any role must be armed with PLM leading practice-knowledge. PLM is really hard. When team members don’t know what works best in what circumstance, or don’t have real-life experiences to pull from, it gets really tricky. PLM is flexible, so one common mistake occurs when people make up answers and then tailor the solution to fit those answers. It’s easy to do this if you have good technical talent. But it’s hard to know if those made-up answers are going to ultimately box you into a corner or lead you to a place that isn’t right. I have seen many examples of companies that spent a lot on a PLM implementation, but their programs are led by individuals that lack real insights into the platform. This inevitably leads to lack of adoption, inability to maintain the solution over time, and underwhelming results at a business level.

7. Discipline and Experience in PLM Solution Methodology: With PLM implementations, it’s very important to follow a proven methodology. Technical proficiency in the solution is not enough. Those that want to work really hard at playing and hacking will ultimately fail to deliver. An established implementation methodology (even ones that enable an agile methodology) helps avoid common post-launch issues like frequent bugs, poor documentation and uncoordinated roll out. Team members must first understand the PLM implementation methodology being used (some experience helps, as does a well-defined and documented methodology containing templates and examples). Next, they must respect it enough to follow it and take the time to do the stuff that might not seem natural to them (developers often hate to write documents). If team members are committed to quality outcomes, they will respect the methodology and use it, and the program architect and manager will enforce it.

8. Involvement and Accountability: The entire team must be involved in planning (my colleagues and I refer to this as integrated planning). The plan cannot be built by the program leadership in a conference room away from everyone else. During execution, team members must be held accountable for earned value on a daily or weekly basis. When people fall short of their commitments, we need to understand why and help them overcome and possibly reset. We also need tools that help the team manage project execution, calculate dependencies, and critical path.

9. Sense of Purpose: It’s very important that each member understand the magnitude of what we are trying to accomplish and know they are part of something big and exciting. Each team member must feel it on an individual level, communicate it constantly to stakeholders and be motivated by the notion that we are doing something special.
If your goal is to really leverage PLM to the max, and if you want to go big and get to the true opportunity by integrating the 50 to 100 to 150 processes that comprise the product lifecycle, it should be easier to attain a sense of purpose. The team is doing something special, something really transformational. If they don’t understand this, take time out to educate them on why this program is special, how it will transform your business and drive their careers to new heights.

10. **Belief:** The best team in the world can only be as effective as their belief in the program governance model and trust in the commitment of the executive committee and sponsors. If the team lacks trust in the governance model, motivation will surely wane and if they sense the executive sponsors are less committed than they are, this will become a problem. See my last entry for more about program and project governance.

In the next entry we will think about deployment methodology in much more detail (building on point 7 above).
Three Characteristics of a Successful Implementation Methodology

In this blog series, I provide insights as to why PLM has true potential to be so transformational for life sciences companies, but many aren’t getting there. We have come a long way, established the right technology, developed a defensible roadmap and socialized it, created excitement and ground swell. We put in place a governance model that will help the program last and overcome the many obstacles that commonly slow or dismantle these kinds of programs. Finally, we have selected or built a great team.

Next we need to consider a most important question; how do we actually get this done? This is a question of methodology.

Two Successful Implementation Methodologies

In my career as a consultant, I have seen two successful PLM implementation methodologies.

The first is a descriptive methodology. With a descriptive methodology, the team defines requirements for the solution, perhaps based on optimized business processes. The advantage of this approach is that the business gets exactly what it wants (and possibly what it needs) to optimize the product lifecycle. The downside is typically cost. While one phase alone might seem okay, when this cost is multiplied over three or five or seven phases (not counting upgrades), cost adds up fast. With a descriptive approach, be prepared to spend a significant amount (although still less than an ERP implementation) on a roadmap that spans the entire product lifecycle. This is not necessarily bad as long as we can prove—at every step—that PLM makes more money and provides more value to the business than it costs.

The second approach is a prescriptive methodology. With a prescriptive methodology, you lean entirely on the vendor and implementation partner to bring leading practice approaches for a specific industry. Note that this is not the same thing as out-of-the-box, which may not be based on leading practices as much as one would hope. With a prescriptive approach, the team supplies basic setup information that is unique to the business (e.g. lists of sites and users), but has almost no say in the functionality, business process or data structures. If done well, this approach can be very quick to implement and cost a fraction of the price.

These two approaches represent the extremes on a spectrum and both can be perfectly valid for some companies. Most companies should select a middle ground along this spectrum that best fits the organization. Discuss this heavily with your implementation team or partner. It’s also important to be realistic about where you are on this spectrum. Many companies make the mistake of saying “we want leading practices,” but then are unwilling to change processes (or undertake the organizational change) required to implement them, leading to significant cost overruns.
Three Characteristics of a Successful Implementation Methodology

Regardless of the chosen approach, the methodology should have at least the following three characteristics:

1. It should be holistic (People, Process, Tools): People (often executives) make the mistake of thinking of PLM as a technology project. PLM should be a practice and a way of thinking. This means we not only need to put in technology, but we need to think about the organization and the processes. We have all heard the mantra “don’t implement a bad process.” The methodology should be designed to cover all three of these components, ideally with entire swim lanes dedicated to each.

2. It should be quality-focused: When implementing PLM, I find the V model to be a very reliable approach for driving quality. With a V model, we build a series of documentation that ties together with a trace matrix. The V model helps link business needs to technical solutions by establishing a firm set of unambiguous requirements and use cases, and assures high quality with multiple types of testing (verification, validation and user acceptance). The trace matrix ensures that all requirements are covered as use and test cases, and that the system has been validated. Finally, the PLM solution provides reports to illustrate the actual costs, so we know if the results from PLM outweigh the cost to build it. In the descriptive model, much of this documentation is built during the implementation, and in the prescriptive model, much of it is templated ahead of time.

It would probably require a white paper to describe all of the components, but the essential elements of a V model are shown in the figure below.

3. It should embrace uncertainty: I have said it before in this series and I will say it again: while the benefits of PLM can be very high, implementing PLM correctly can be really hard! The design is rarely right the first time, especially with a descriptive methodology. Therefore, it’s essential to build in system reviews (often referred to as conference room pilots) throughout a project. This gives the users a chance to walk through the system (often following a script based on use cases), and these sessions can last hours or even days if done well. Users should be quizzed and challenged for their insights, and discussion should be encouraged.

After each review, the team should be allowed to make adjustments to the requirements. The first session will allow for the most change and then the amount of changes allowed can be tapered at subsequent sessions. The number of review sessions needed to be effective will vary widely depending on the complexity of the organization and project phase, but three review sessions is a good rule of thumb, especially if the PLM strategy has been developed with well balanced phases.
On a Personal Note

If you’ve been following this blog series, you already know that I am passionate about PLM. But I also am passionate about medical innovation and safety.

I would like to wrap up this series on a personal note. At the age of eighteen months, we discovered that my son had a hole in his heart. To correct this problem, he went through open heart surgery, and as a result was cured of heart disease. Before his surgery he was in the 23rd percentile for height and as of his most recent doctor’s visit he was in the 76th percentile (a tall kid).

This is why it’s easy for me to get interested in helping make medical devices safer and better to use. I will always be grateful to Children’s Hospital of Denver and their excellent medical staff, and to Terumo Medical Systems, who made a very safe and effective bypass machine. I have always believed that PLM can make a big impact, helping companies create more effective medical products that save more lives, and I have been frustrated to see companies failing to achieve the potential that it brings.

I hope I have shared some of this passion with you. I hope that this series has generated excitement around the potential benefits of smartly integrated and automated PLM processes and technology. I hope it has inspired you to consider going big and broad with PLM.

At some point, a life sciences company is bound to successfully complete their PLM journey with a very tight set of smart and integrated processes across the entire product lifecycle. If you are that company or you think you are on the way, please let me know; I would love to learn about your journey. If you are considering a PLM transformation, you’re not alone. There are many organizations trying to make it out west with PLM. Many are tripping and falling, some have tried, failed and are now restarting, and others have lost their way, but it’s entirely inevitable that someone will get there sooner rather than later. Let’s hope it isn’t your competitor.

Author’s Note

Each of the entries in this series have been tirelessly reviewed and edited by close colleagues Chris Kay and Amy Kenly. I cannot tell you how much I have appreciated their help along the way. They never interfered with what I wanted to say and let me do it my way, but always made the content much more professional. Thanks for all the support guys!
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