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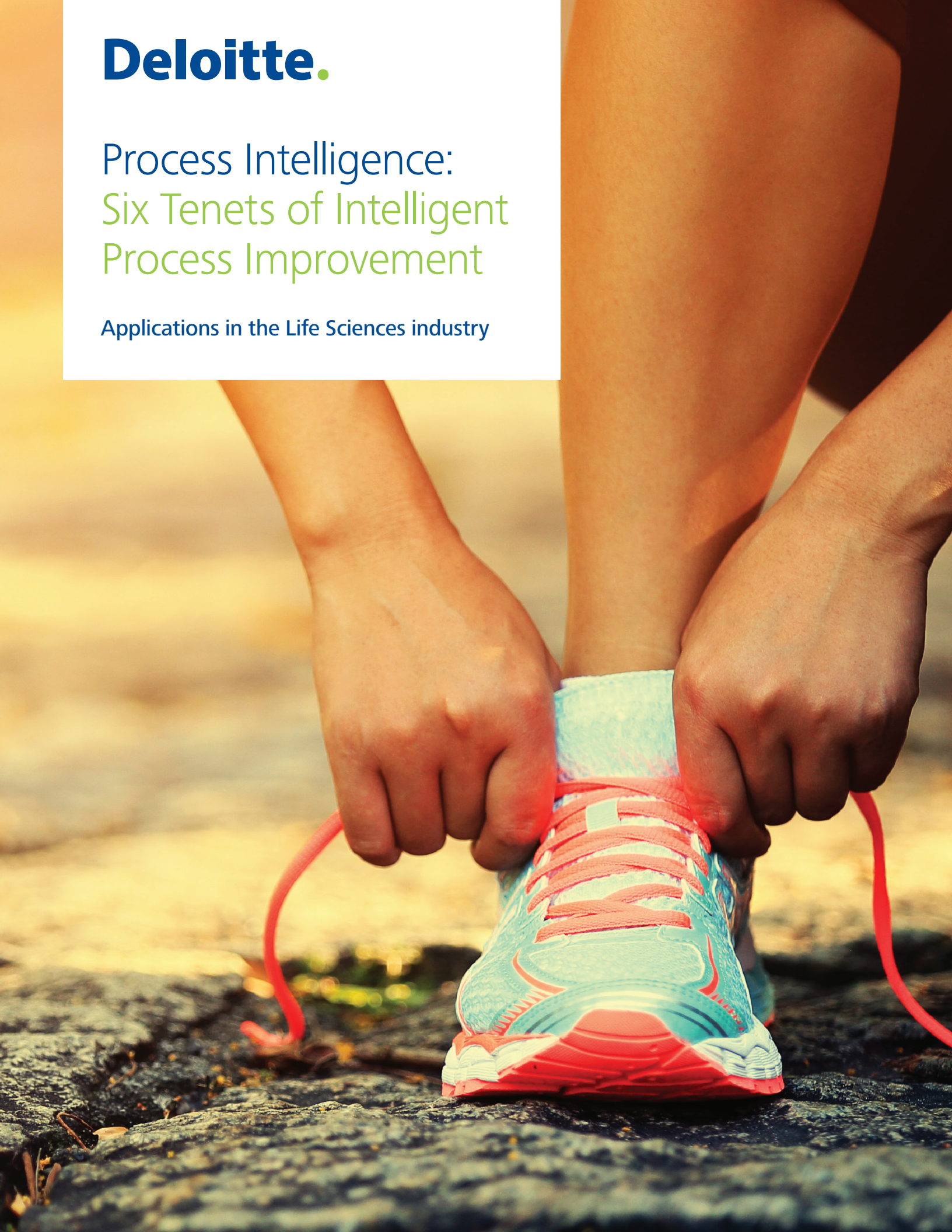
Process Intelligence: Six Tenets of Intelligent Process Improvement

Applications in the Life Sciences industry



Introduction

The Westfield Sydney to Melbourne Ultramarathon was first run in 1983. At a distance of 875 kilometers, it was going to be one of the most challenging ultramarathons in the world. Most entrants knew that to be competitive, they would need to run 18 hours each day, while sleeping only six hours.

A 61-year-old man named Cliff Young showed up to run the race wearing worn-down overalls and worn-in work boots. When asked if he had ever run in a marathon before, he replied, "See, I grew up on a farm where we couldn't afford horses or tractors, and the whole time I was growing up, whenever the storms would roll in, I'd have to go out and round up the sheep. We had 2,000 sheep on 2,000 acres. Sometimes I would have to run those sheep for two or three days." The runners all laughed. Young was clearly not up to the standard of these world-class athletes.

Amazingly, though, the 61-year-old underdog won the race, beating the record for similar races by 40 percent, or almost two full days![1] How was this possible? Young didn't "know" what everyone else knew—that he had to sleep—so he just shuffled along each night at a slower pace while all of the pro runners dreamt soundly. His win catapulted him to fame in Australia—the race thereafter was named the Cliff Young 6-Day Australia Marathon—and launched a new era of ultramarathon running. Now that world-class runners "know" that it's possible to run days at a time without sleep and that they can conserve energy by adopting an easy shuffle jog, they have a new way of approaching ultramarathons.

Business process improvement today is in a similar state as ultramarathons were before Young's feat—people often "know" which process improvement methodologies work, and they approach those methodologies the same as they have for decades. Yet despite those decades of history to learn from, companies are still struggling to realize success from their process improvement efforts.[2]

Why do some process improvement efforts succeed and others do not? This paper outlines six tenets to help companies think beyond what is currently "known" and bring more "intelligence" to process improvement.

[1] "The Legend of Cliff Young: The 61 Year Old Farmer Who Won the World's Toughest Race," Elite Feet for Runners, December 30, 2007, http://www.elitefeet.com/the-legend-of-cliff-young.

[2] "3rd Biennial PEX Network Report: State of the Industry, Trends and Success Factors in Business Process Excellence," PEX Network, Fall 2013, http://www.processexcellencenetwork.com/downloadContent.cfm?ID=1697.

Tenet #1: Challenge conventional wisdom

Many organizations are constrained by conventional wisdom, much like the world-class runners in Australia. For example, companies are moving away from Six Sigma as a methodology for Process Excellence because they feel their firm doesn't have the necessary level and quality of data to effectively support a Six Sigma based approach. This may explain why the methodology has steadily declined since 2005.[3] Instead, companies may take a flexible approach to process improvement, allowing teams to pick and choose methodologies and toolsets.

But isn't flexibility a good thing? Not necessarily. Companies that stick with a consistent approach realize an average of 40 percent more benefit than those that don't.[4] A demonstrated and time-tested approach to process improvement includes the following five steps:

- Clarify the problem and set a goal for improvement.
- Measure performance levels today.
- Uncover the root causes of the problem.
- Figure out ways to address those root causes.
- Make it stick.

These steps happen to be the same logical and time-tested approach employed by Lean Six Sigma, currently the second most widely used methodology in the process improvement tool kit, only behind Lean.[5] It's also quite flexible, as it can be applied to a variety of problems of various sizes. It's an "intelligent" approach that has been shown to be effective and efficient in problem solving, even without significant levels of data and statistical analysis.

Complexity in clinical trial design and management is driven by a number of factors and regulations that must be carefully considered and managed. More recently, the emergence of adaptive design—clinical trials that can be modified over the course of the trial based on ongoing findings—has introduced potential cost and efficiency gains.

Although adaptive design has many in the industry excited about the prospects of greater flexibility and cost savings over the course of a trial, it also creates an additional layer of complexity in trial design and decision making. To capture the benefits of adaptive trial design, traditional clinical trial processes need to be flexible yet optimized. Leveraging a consistent approach to eliminating waste and redundancies could help to reduce non-value added activities, rework, and effort. At the same time it can enable the adoption of adaptive trial design without introducing additional operational risks.

Example

A global pharmaceutical company was looking to understand opportunities to improve clinical trial productivity and drive process improvement for critical startup activities such as trial planning, protocol development and site contracting. Eliminating waste was seen as an important step towards introducing more flexible adaptive practices for trial planning and execution. Due to the complexity and uniqueness of each clinical trial design as well as the involvement of a large number of stakeholders throughout the startup process, it was widely believed that variability was unavoidable and opportunities to standardize the process would be tough. Deloitte utilized its Enterprise Lean Six Sigma approach and conducted a DMAIC (Define, Measure, Analyze, Improve, Control) exercise including value stream analysis to measure performance and evaluate key areas for improvement. A five-why analysis was then conducted to identify root causes of rework and non-value added activities. By utilizing a consistent approach to assess process improvement opportunities, the team identified solutions that could reduce process variability and improve productivity while resulting in an overall reduction of study start up by over two months. Based on the successful pilot, the approach was also applied across various key areas within study execution and close-out.

[3] "3rd Biennial PEX Network Report: State of the Industry, Trends and Success Factors in Business Process Excellence"
[4] LSS Aberdeen Six Sigma Report
[5] "3rd Biennial PEX Network Report: State of the Industry, Trends and Success Factors in Business Process Excellence"

Tenet #2: Stretch beyond process mapping

Another commonly accepted practice is to use process mapping as the core tool in process improvement. Process mapping is an important tool, but it has limitations. Process maps show how people think a process typically works or how it should work. How the process actually works is often quite different.

Various advanced analytical tools can provide much richer insights and "intelligence" related to actual process performance. For example, Deloitte's Process X-ray™ is a process analysis platform that reconstructs the actual process execution based on data from a company's underlying technology (see figure 1). It enables users to ask up to 10,000 questions to find the variants and root causes of problems in the process. Similarly, detailed value stream analysis recreates actual process performance at a handoff level of detail, enabling process improvement teams to identify which steps in the process are not adding value.

The "intelligent" insights gleaned from these analyses help generate breakthrough improvements that are hard to realize when process maps alone are used. As companies increase focus and investment on workflow automation and data analytics (big data), supplemental analytical process intelligence tools will become increasingly more important in driving toward solutions.[6] [7]

For Medical Device manufacturers, reducing the time for product development while ensuring regulatory compliance is paramount to maintaining a competitive advantage. Especially in recent years as new entrants and collaborative models have started to accelerate the pace of innovation, many traditional Medical Device companies are looking for ways to streamline and accelerate their development process while maintaining quality and compliance.

This can be an overwhelming task as the steps to meet quality and regulatory requirements can add layers of complexity and variability to the process. To capture the right insights, companies should consider leveraging data and analytical tools such as detailed value stream mapping on different variants of the process to uncover "hidden" complexity and to quickly and accurately understand where the true opportunities lie.

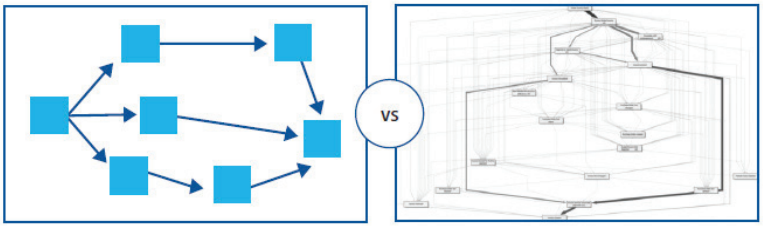


Figure 1: Traditional process mapping versus analysis of actual process using Process X-ray

Example

A leading device manufacturer faced increased market pressure and needed to dramatically improve its New Product Development (NPD) cycle time to become more responsive to the marketplace and customer needs. Instead of relying on traditional process mapping, a series of key stakeholder interviews helped to identify preliminary areas of focus and were followed by a rigorous value stream analysis. Application of Lean concepts such as the "Seven Wastes" and "Continuous Flow" to the value stream analysis uncovered multiple handoffs as well as significant rework and redesign. These non-value added activities had created bottlenecks and non-standard process steps across key areas of the entire NPD process that our client was not aware of prior to the analysis. One key finding from the analysis was that a high-priority project had bypassed a critical step and caused delays up to 1.5 months. In the current state, only 50% of the project's activities were determined to be value-added. Similar analysis in other key areas of focus resulted in identification of opportunities to reduce the NPD cycle time by 20-50% depending on product category and ease of implementation. By leveraging data and intelligent tools beyond process maps, the device manufacturer was able to spotlight and quantify what was happening behind the scenes with more precision.

[6] Ibid.
[7] Deloitte internal analysis

Tenet #3: Follow the facts

There is typically no lack of opinions when it comes to business improvement efforts. But when teams act on opinions, they often jump to the wrong conclusion. A more "intelligent" approach is to convert opinions into hypotheses and test them with data before acting on them.

"Data is what distinguishes the dilettante from the artist."[8] According to a study conducted by the University of Pennsylvania and MIT, "data-driven decision making" achieved productivity that was 5 percent to 6 percent higher than could be explained by other factors.[9]

A well-structured set of hypotheses provide an organized framework to evaluate and act on options for business improvements. Furthermore, it can help avoid common pitfalls during improvement projects such as addressing only symptoms or being swayed by the strongest or most senior person in the room. As a result, instead of basing actions on guesses or hunches, companies can have more confidence that their actions are driven by facts. Hypothesis testing also lays the foundation for controlled continuous improvement as hypotheses tested and data collected can be used for future endeavors.

Making process improvement decisions based on data-substantiated facts rather than opinions and perceptions may take a little longer, but over the course of time it helps foster alignment among people with different opinions and can lead to superior results.

Life Sciences companies generate vast amounts of data for scientific, medical, and operational activities. Quite often this information is siloed and confined to the area of the business that generates it and as a result the potential value of the data is not fully realized. Many companies are now putting greater emphasis on collaboration and leveraging data across the organization to drive faster and more accurate decisions.

In the same way data drives scientific and medical discovery, process improvement initiatives are most successful when supported by robust data. Through better access and utilization of data across the organization, companies can gain a competitive advantage on driving their process intelligence efforts.

Example

After a major product recall, a leading medical manufacturer needed to address the root causes of its poor product quality across the organization. While the company had developed several hypotheses to explain why the recall had occurred, none of these hypotheses had been validated as key reasons for poor quality. Employing a number of data collection techniques and data-driven Lean Six Sigma tools revealed some of the hypotheses that were based on qualitative observations addressed symptoms more than causes. The data-driven approach also revealed that although the company had a strong reputation among consumers to meet demand, product quality had become a secondary priority. The statistical data showed that 15% of processes analyzed demonstrated variability and lack of controls to maintaining quality. This prompted the company to think more holistically about quality and refocus its efforts to enhance its quality program. Instead of stopping at the qualitative analysis, the team "followed the facts" and used a data-driven approach to validate its findings. As a result, the manufacturer was able to confidently identify key areas to be addressed, design initiatives to sustainably improve product quality, and create a quality driven mindset across the organization.

[8] George V. Higgins, The Guardian, June 17, 1988.
[9] "When There's No Such Thing as Too Much Information," Steve Lohr, The New York Times, April 23, 2011, http://www.nytimes.com/2011/04/24/business/24unboxed.html?_r=0.

Tenet #4: Buy runs, not players

In the movie Moneyball,[10] a statistician suggests the following: "People who run ball clubs, they think in terms of buying players. Your goal shouldn't be to buy players; your goal should be to buy wins. And in order to buy wins, you need to buy runs. Baseball thinking is medieval. They are asking all the wrong questions."

TThe same is true in process improvement. Many companies ask questions and use tools that fail to address root causes of problems. They employ temporary fixes that end up being costly and unsustainable. Fixes often focus on one aspect of the issue and commonly are in the form of process tweaks such as an additional quality check, creating new roles that are potentially redundant, or implementing a new system, but these actions are equivalent to buying individual "players" to fix a process rather than understanding the process itself. Such process improvement efforts effectively put a bandage on visible symptoms of problems, thus laying the foundation for disappointment—addressing symptoms alone virtually guarantees problems will reappear.

Instead, companies can better understand how to generate "runs" when they look holistically at the process to identify root causes and systemic issues. Rather than focus on short term fixes, when problems are identified and addressed at their core, the benefits tend to be greater and longer lasting.

In the age of big data, cloud computing and analytics, Life Sciences organizations expect to resolve process issues and drive cost savings by implementing systems and technology solutions. However, these solutions often do not address the underlying root causes of the issues.

Whether it be clinical trial management, drug supply, or clinical contracts management, Life Sciences companies investing in large-scale technology solutions can also fall into the trap of buying the system while not adequately addressing the process. By addressing the whole value chain and understanding where the technology can enable the process, companies can unlock the true potential of their investments.

Example

A leading global pharmaceutical and animal health conglomerate was facing problems with its Procure to Pay (P2P) process after undergoing several organizational changes in recent years that included outsourcing its Accounts Payable (AP), creating a P2P Shared Service function, and implementing a new global P2P system. While these changes had been made in an attempt to improve the overall P2P process, the changes had caused a significant bottleneck to advancing the progress of many business operations such as launching clinical trials and supporting brand campaigns. The company decided to take a Process Intelligence approach and performed a holistic analysis of the end-to-end P2P process that included evaluating the people, technology, and cross-functional interactions. Rather than providing individual solutions to specific parts of the process ("buying players"), the Process Intelligence approach helped to address the root causes across the value chain and enabled development of a full roadmap for closing the gaps ("buying runs"), which led to a 50% reduction of P2P lead time.

[10] From Moneyball, the movie.

Tenet #5: Carry it across the goal line

In Super Bowl XXVII, the Dallas Cowboys' #78, Leon Lett, recovered a fumble on the Dallas 35-yard line and ran it toward the end zone. At the 10-yard line, approaching the end zone, Lett slowed down and held the football out in celebration, unaware that an opponent was chasing him down from behind. The opponent knocked the ball out of Lett's outstretched hand just before he crossed the goal line, sending the ball through the end zone and costing the Cowboys a touchdown.

In the absence of proactive leadership alignment and change management, process improvement teams can fumble before they cross the goal line, too. Two-thirds of executives indicated in a recent survey that competing priorities for time and resources often take precedence over process improvement efforts, resulting in an unstructured or undefined process excellence program.[11] Because of this, process improvement efforts can either have a tough time getting off the ground or can go after too much and stretch their resources too thinly. Instead, leadership can take on fewer improvement efforts and execute well against those things rather than taking on too much at once and fumbling. Process improvement efforts can have the flashiest data-driven analyses and the most insightful recommendations that get at the root causes of the problem, yet those recommendations are worthless if others in the company don't accept and act on them in a committed and coordinated manner.

For many Life Sciences organizations, document management has historically been a lower priority compared to other activities. This is particularly true for the Trial Master File (TMF), the definitive source of clinical trial documentation that retells the end-to-end story of a clinical trial. Management of these records, which can exceed millions for large studies, can be taxing as trial-related documentation are generally spread across multiple formats, repositories, and geographies.

That being said, recent regulatory scrutiny along with new requirements around data integrity has brought TMF to the forefront and has forced the industry to put greater emphasis on transforming the TMF from a residual output of clinical trial activities to a primary driver in order to demonstrate quality and compliance. This transformation can require significant leadership and buy-in from Life Sciences organizations in order to be successful.

Example

A global pharmaceutical company was faced with growing quality and compliance concerns due to mounting regulatory pressures as well as inspection findings. As part of the company's Correction Action Preventive Action (CAPA) plan, Deloitte was engaged to help improve the company's global Trial Master File (TMF) management processes. Through use of quality by design (QbD) principles, the team identified critical-to-quality (CTQ) requirements organized around three dimensions – completeness, document quality and timeliness. In order to ensure that the redesigned process satisfied the CTQ requirements and to mitigate potential process failures, Deloitte utilized a variety of tools such as fish-bone diagrams, Pareto charts and failure modes and effects analysis (FMEA). To measure the effectiveness of the new processes and to provide transparency across the organization, several key performance indicators were developed around the three CTQ dimensions. A key success factor was senior leadership playing an important role in helping to drive change and adoption of the new process across the organization. From a change management perspective, trial teams were also empowered to actively own and manage their TMFs in order to drive greater accountability across all stakeholders on each study. As a result of on-going leadership support and proactive change management, the TMF completeness metric improved by 50% after the first year of implementation.

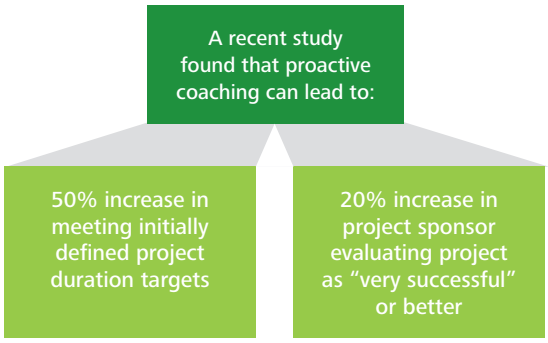
[11] "3rd Biennial PEX Network Report: State of the Industry, Trends and Success Factors in Business Process Excellence"

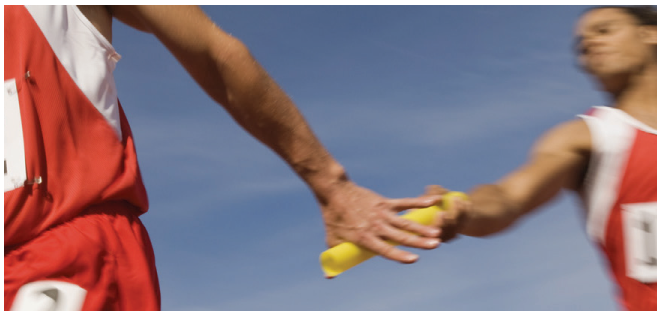
Tenet #6: Two heads are better than one

While training is essential for obtaining skills and knowledge, coaching and mentorship help people apply learning in the real world. Research of coaching effectiveness shows that a structured, proactive coaching approach where a schedule is followed leads to more successful project completion in comparison to an ad-hoc coaching approach (see figure 2).[12]

Such a mentorship model is necessary for effective implementation of Lean Six Sigma; it can keep teams motivated, foster continuous learning, and, most importantly, maintain improvement gains. One such model, the "belt" method, has been successful in helping teams draw from the wisdom of those who have walked the path before.

Figure 2: Coaching improves outcomes





In a data intensive industry, one of the greatest challenges for Life Sciences companies is the management of knowledge and the sharing of knowledge effectively across the organization.

Many companies have invested in systems and repositories for the storage and dissemination of these valuable knowledge assets and while these tools lay the foundation for knowledge sharing, they often fall short of establishing a knowledge sharing culture.

Establishing a mentorship model that includes identification of key knowledge owners, processes to connect owners and seekers, and a continuous learning program that combines classroom and on-the-job opportunities can improve the likelihood that the true value of the knowledge can be unlocked.

Example

A leading pharmaceutical company launched an initiative to build and operationalize a process excellence (PE) organization. While the company had numerous initiatives, there was limited infrastructure for identifying and managing the initiatives and the "one-time only" mentality towards projects limited long term sustainability, effectiveness and ownership by the business. Deloitte worked with the company to build out the internal capabilities of the process excellence team and key business stakeholders. In order to transform the mindset of the organization, the team collaboratively developed and delivered instructor led training. In addition, live coaching and on-the-job training was provided as part of a comprehensive enhanced Process Intelligence training program. The new knowledge was institutionalized through the execution of a series of process excellence initiatives with active coaching and mentorship along the way. Through the implementation of a structured capability building and apprenticeship model, the company was able to realize stronger adoption of the "process excellence" mentality.

[12] http://www.isixsigma.com/implementation/teams/how-effectively-coach-green-belts-and-black-belts/

Intelligent process improvement: Back to the future

In an age of intense and evolving competition, along with regulatory and pricing pressures, Life Sciences companies increasingly need to sprint in new directions. To meet these immediate challenges, process improvement efforts can be deployed quickly and return results in the near term. However, companies that do this well also take a long term view and recognize the need for continual process improvement efforts over time.

If ever there was an ultramarathon in business, process improvement is likely it. It requires discipline, patience, consistency, and lots of hard work, and the mindset is foundational to any level of change an organization needs to make. When process improvement methodologies first came into vogue in the 1980s and '90s, they challenged 50 or more years of conventional manufacturing wisdom, enabling companies to improve manufacturing quality, reduce production waste, eliminate bottlenecks, streamline processes, and cut costs. Twenty or more years down the path, many variations of standard process improvement techniques and tools have been introduced. Along with them have come many opinions about which techniques and tools are most effective. However, one incontrovertible fact remains: Lean Six Sigma continues to be one of the most prevalent and consistently productive approaches to process improvement. By following the six tenets described in the paper, companies can continue to leverage Lean Six Sigma for solid results in the modern ultramarathon that process improvement represents.

Case Study
Batch record review process harmonization

A major biopharmaceutical company wanted to examine process harmonization across their biologics manufacturing supply chain. In particular, they were looking to improve their batch record review process, the review process that occurs during manufacturing and evaluates factors related to compliance, safety, quality, and other key inputs. This process was not standardized across the organization and was perceived as a bottleneck at certain sites.

The Deloitte team investigated the variation in review time and processes across the client's more than 10 manufacturing sites. Due to the highly automated nature of the manufacturing process at some sites, a wealth of data was recorded before, during, and after the batch record review. This enabled the team to take a rigorous data-driven approach rather than relying solely on qualitative site interviews, and they were able to identify several root causes for the variation that existed across sites. Particular areas of focus were the timing of batch record review and the number of reviews required. The team was able to make data-driven recommendations to harmonize the process and reduce cycle time while improving overall quality control practices.

Ultimately, the team benchmarked the review process at each manufacturing site and identified other leading practices. The team implemented process standardization across the manufacturing sites, resulting in an estimated 40 percent reduction in overall batch record review time.

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