

# **Laboratory Excellence**

## **Proven Approaches to Achieving and Sustaining Operational Excellence in the Laboratory Environment**

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## Summary

Like many industries, laboratories find themselves in an increasingly competitive and uncertain environment where margins experience significant pressure. A range of operational excellence strategies have been established across industry to provide an answer to these challenges. Key to achieving success is selecting the right strategy, best fit for your laboratory's individual needs.

Laboratories find themselves in a position where they can draw on other industries' experience and develop their own flexible improvement strategy. The best results are achieved by choosing a holistic approach to process improvement, stretching along the entire extended value chain and combining the best of the established approaches: Theory of Constraints, Six Sigma and Lean.

**Laboratories can achieve transformational change drawing on the Operational Excellence experience from other industries.**

To ensure that the improvements are sustainable in the long-term, definition of measurable targets and KPI frameworks is a basic requirement. In addition the business excellence approach should be extended to other areas, such as IT projects (e.g., LIMS, ELN deployments), for which improvement strategies need to be an intrinsic part of the project implementation.

Finally, tools and strategies will only get you so far – it takes people to make it happen. To achieve a cultural change and to embed operational excellence as a way of thinking in the organization, it is crucial to have the involvement of the people at every step of the way. Getting people on board at all levels of your organization, from the boardroom to the lab bench, is the only way to set off on a successful improvement journey and achieve the benefits of your transformational change.

## Established Improvement Methodologies

A range of improvement strategies and methodologies have been tested over the years across different industries. Below is a brief overview of the three most successful methodologies:

Theory of Constraints (TOC)	Six Sigma	Lean
<ul style="list-style-type: none"> <li>Identifies and manages conflicts between important business needs</li> <li>Focused on constraints limiting the overall process performance</li> <li>Designs policies, measures, behaviors and work-flow around the identified constraints</li> <li>Eliminates waste throughout the entire business process framework</li> </ul>	<ul style="list-style-type: none"> <li>Identifies and isolates sources of process deviations and enables a systematic removal of those variations</li> <li>Requires data-driven decisions and incorporates a comprehensive set of quality tools</li> <li>Provides a highly prescriptive cultural infrastructure which effectively obtains sustainable results</li> </ul>	<ul style="list-style-type: none"> <li>Focuses on separating “value-added” from “non-value-added” activities, with tools to eliminate the root causes of non-value-added activities and their costs</li> <li>Eliminates waste and focuses on maximizing process velocity</li> <li>Tools for analyzing process flow and delay times for each activity in a process</li> </ul>

Figure 1: An overview of the most commonly used improvement methods

Each methodology aims at a cross-functional and system-wide approach for maximum benefit but typically they each have their individual limitations. Our experience shows that these methodologies are often misunderstood and misapplied, with the result that expected process improvements are not fully achieved. In order to reap the full benefit of your improvement program, we recommend that you use the strong points from each of the methodologies according to your needs, so as to get the best of the three worlds.

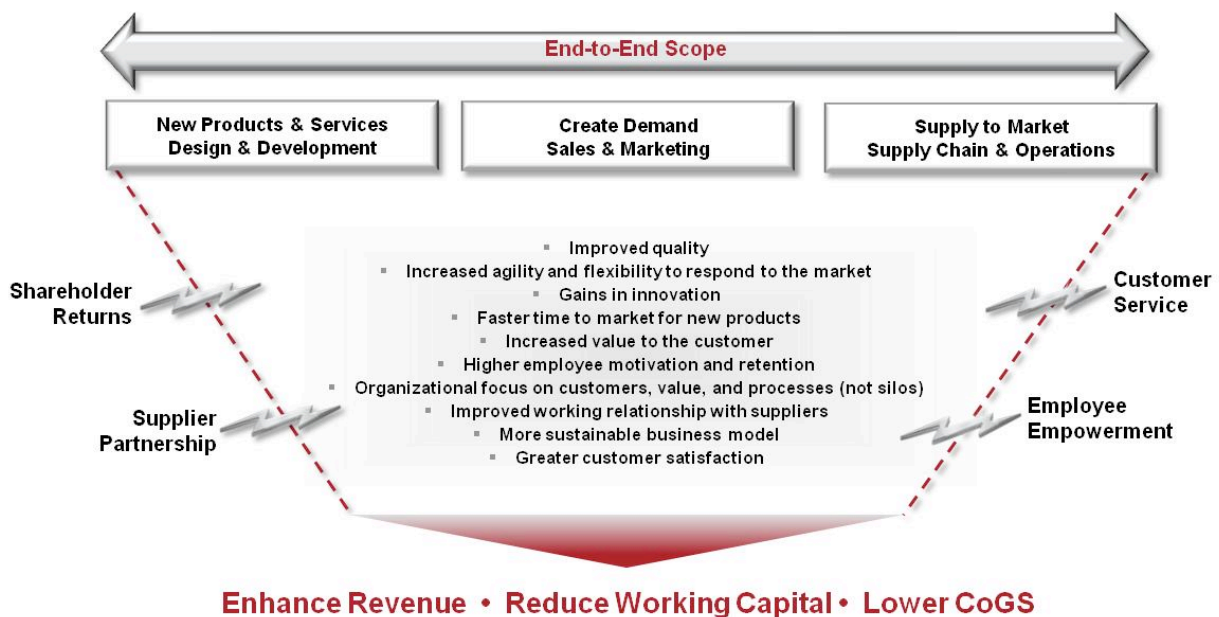


Figure 2: Combination of methodologies working along the value chain, not just in the factory

The chosen approach must be holistic so as to enforce process improvements throughout the entire value chain. For laboratories this implies that not only the ‘shop floor process’ steps need to be assessed but the full, integrated end-to-end business processes. The implementation of a comprehensive, pragmatic yet flexible approach – founded on TOC, Six Sigma and Lean principles – is usually the best solution.



## Typical Barriers to Operational Excellence in Laboratories

Before analyzing the key success factors of successful operational excellence, it is important to understand the barriers typically experienced during implementation. Because even with a perfectly tailored improvement strategy, many programs still do not meet expectations. The expected results are either not fully achieved, or are not sustained in the long term. There are various reasons for failure. Often the business is not ready for change; the improvement targets are not realistic, or not even measurable.

Typical barriers exist in almost every organization and are linked to processes, people, systems and data. Barriers such as lack of trust and commitment, resistance to change, and political and cultural hurdles cannot be mitigated by the tools and techniques offered by the improvement strategies. In order to successfully overcome these barriers, additional change management measures must be taken.

### Process-related barriers

Laboratory processes may be poorly defined and lack any active ownership. As a result, low levels of standardization persist in many labs. Process champions are not defined and process ownership is more often than not delegated to a piece of paper. Continuous improvement cultures are rarely established, key process control parameters remain unknown, and industry benchmarks or best practices are rarely considered.

Too often laboratories take an isolated view, and the organization lacks a drive for innovation. The process view is restricted to the laboratory shop floor operations and no integration is established with key supply chain functions such as logistics and finance. Laboratory management functions often lack supply chain knowledge and process changes are mainly driven by new legal requirements or changes in compliance needs rather than operational effectiveness needs.

### People-related barriers

Key laboratory people are often long-term employees who have been very successful in their environment. However, during their careers they may have had limited exposure to financial, supply chain or change management, and may not have had sufficient opportunity to develop these management skills. People tend to be snowed under with daily work and often do not have the time and energy needed to invest in change. This situation is then aggravated by the lack of urgency that limits the ability to identify practical improvements.

Where creative and innovative ideas exist, they are not always well received by managers. Working relationships in labs can be fragmented and ineffectual. This often leads to a “not invented here” mentality (“nothing will ever change...”, “we have tried this several times and failed...”, “this is the way it has been done since the beginning and this is the way it will always be...”). People know the individual elements they are working with (process steps, systems, data, people) very well but the bigger picture and the integrated end-to-end process are rarely seen and not communicated effectively.

### Systems and data related barriers

Labs do use state-of-the-art systems (e.g., LIMS, ELN) to support their operations but these systems are rarely integrated into the wider supply chain. Simple point-to-point interfaces to key ERP functions exist but even within the lab environment, technical integration of equipment remains an issue for many companies. As a result, time and resource-consuming ways are devised to work around the problem, and a large amount of manual data transfer is required to achieve integration with key finance and logistics functions. To make matters worse, KPI systems are not measuring current practices, but are designed for reporting blame and justifications.

Over the years, laboratories have established highly complex yet isolated solutions. Many of these single-purpose systems are not easily adaptable to the reality of changing business models. Though many labs aspire to the ‘paperless’ world, low levels of automation, a reluctance to invest in new technologies and a lack of in-house knowledge of expansion options and best practices result in an ineffective use of technology. As a result, multiple sources for simple reports and data remain distributed across multiple systems and technologies.

## Key Success Factors

In order to overcome these barriers and to achieve operational excellence in a laboratory environment, there are four key factors for successful implementation:

- Selecting the right improvement methodology
- Involvement of people
- Approach to IT
- Ensure transparency and sustainability

Though the importance of these four key success factors are well understood, they need to be tailored and adapted to your organization and implementation goals.

## Selecting the right improvement methodology

The best results are achieved through a holistic and flexible approach, founded on ToC, Six Sigma and Lean principles, to enforcing process improvements throughout the entire value chains. Long-term sustainability is most likely when both the value chain and the individual process steps are optimized. An isolated local optimization may not benefit your organization as a whole. Look at your integrated, end-to-end business processes. An isolated perspective on laboratory and manufacturing shop floor operations restricts your ability to achieve and sustain real process improvements. Aligning all business processes allows the organization to focus its efforts and achieve benefits where they are most needed. The chosen approach should not be restricted to day-to-day operations, but should also incorporate strategic planning in order to achieve a true transformational change.

Use benchmarking to obtain knowledge on best (or better) practices within and outside of your industry. Do this not only to set goals and targets, but also to work out how to implement your initiative. Companies across a wide range of industries have successfully embarked on Operational Excellence journeys. Their experience is either directly relevant to laboratories or requires a little 'translation' to make it fit – e.g., are you creating a flow of product or a flow of decisions, which is considered "waste" in your lab.

## Involvement of people

Once you have chosen an improvement strategy, you need to identify and understand those barriers that require mitigation. Generate involvement with and enthusiasm for the implementation of operational excellence. Make sure you have a strong communication plan in place and enforce collaborative work. Use honest and human conversation to foster a community where each person has a chance to speak, feels heard and listens well. Ensure measurable targets are defined and make achievements visible to everybody in the organization. Finally, reduce fear in your community – some people believe operational excellence automatically means reducing the number of people rather than utilizing resources more efficiently to achieve business objectives. Ensure that you relieve the fear and resistance to change in your organization by keeping people involved every step of the way. Focus on results; harvest the low hanging fruit early on in the program so as to build confidence and get people on board. Ensure that your people experience the benefits of the change first hand.

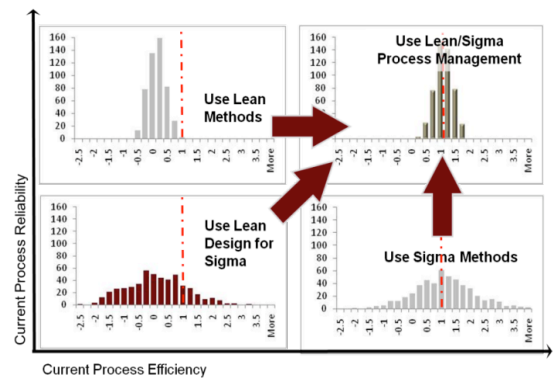


Figure3: Selecting the appropriate improvement method to the issue at hand – applicable from lab bench to business processes.



Figure 4: Three of the five dimensions of a lean sigma transformation are people related

## Approach to IT

IT is an intrinsic part of your business. Therefore, your IT projects should be run as operational excellence projects. One way to do this is to enrich your IT project teams with improvement strategy experts. This ensures the application not only of project methodologies that satisfy the needs of the software vendors, the consulting companies, or any legal requirements, but also of process improvement strategies – wherever feasible and as early as possible.

**Ensure IT systems are aligned with your drive for excellence and adaptable to changing business needs.**

Too often, although state-of-the-art systems are implemented according to ‘best practices’, at the end of the day the solutions are inflexible, not scalable to changing needs and do not bring the expected process improvements. Standard software packages and implementation approaches are not designed to support improvement strategies by default. Ensure that you understand your business objectives and focus all your activities and investments on adding the highest possible value. Implement an IT-architecture designed for flexibility and in line with your business goals.

## Ensure transparency and sustainability

Measuring your business performance not only tells you how well you are doing and where you need to focus your improvement efforts today, it also allows you to monitor performance post implementation to ensure that standards don’t slip and your efforts are sustained. To do this, you need to design and implement a system of Key Performance Indicators (KPIs) that allows you to measure performance where it matters (rework, decision lead time, cycle time, deviations, responsiveness, ...). Link the measures to your vision and to your business case for improvement. Ensure that the relevant processes and systems deliver the right data. This is especially important when implementing new Laboratory IT solutions – revised KPI definitions should be in place prior to selecting new software or new systems, not the other way around. Put in place clear data definitions and data owners. Implement continuous improvement measures such as simple cyclic reviews of your KPI definitions.



Figure 5: Measure what you want to improve and sustain – a vision of the future translated into a measurable business case, tracked by a scorecard to ensure focus and progress.

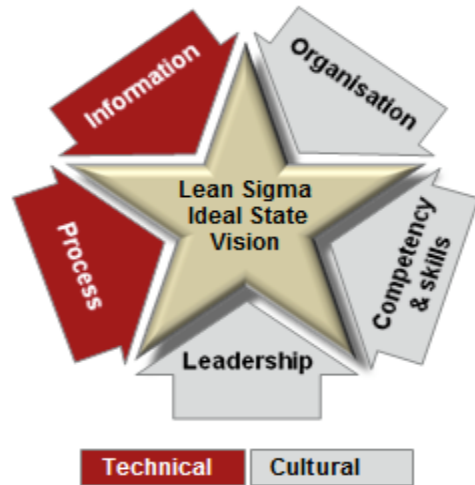
Finally, avoid KPI reporting just for its own sake or for purely retrospective justification purposes. All KPIs should be directly relevant to your business. Measuring everything that can be measured quickly results in “analysis paralysis” that stifles the momentum for improvement, whereas purely retrospective reporting may not help you to meet tomorrow’s challenges and often creates a blame-report culture.

# Conclusions

Laboratories can draw on other industries' experience and develop their own flexible improvement strategy by combining the best of the proven approaches: Theory of Constraints (TOC), Six Sigma and Lean. The best results are achieved by choosing a holistic approach to process improvement, not restricted to laboratory 'shop floor' operations but stretching along the entire extended value chain.

To ensure that the improvements are sustainable in the long term, measurable targets must be defined and KPI frameworks should be implemented. In addition, the business excellence approach should be expanded to other areas, such as laboratory IT projects, for which improvement strategies need to be an intrinsic part of the project implementation.

Finally, tools and strategies will only get you so far, it takes people to make it happen. To achieve a cultural change and to embed operational excellence as a way of thinking in your organization, it is crucial that people are involved at every step of the way. Getting the people in your organization on board, from the board room to the lab bench, is the only way to set off on a successful improvement journey and reap the benefits of your transformational change.





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