



“The Tool Trap”

Implementing Lean in life sciences

By **Fred Greulich**
Maxiom Group

LEAN MANUFACTURING HAS BECOME equated with operational performance at a world-class level. It has emerged as the single most important approach to improving the competitiveness of production operations. Enterprises are attempting to implement Lean, often because they feel they don't have a choice. Many are realizing that if they do not “become Lean,” they will likely fall behind other industry leaders and be left in the dust. From its inception within manufacturing at Toyota, Lean applications have expanded to virtually all operating functions and industries. Recently, with margin pressure brought on by a combination of generic products, managed care pricing, and thin pipelines, Lean has garnered much more attention in pharmaceutical and other life sciences companies.

The potential benefits of a well managed Lean implementation are at a level of magnitude that represents a step function change. A sampling of representative results gleaned from *Industry Week* magazine's “Plant of the Year” competition from a few years back include: manufacturing cycle time reduced by 88%, product changeover times reduced by 50% to 90%, total manufacturing costs reduced by 30%, ROA increased to 55%, and order lead time reduced by 65%.

The bad news in this story, however, is that while many companies have tackled Lean and realized some measura-

ble operational benefit, a large number have not been able to sustain these benefits. In these same companies it is often the case that the Lean effort itself has faded and sometimes died. These organizations have found Lean success difficult to come by, with benefits less than planned and implementation painfully hard.

One key reason for Lean failure lies in the fact that many organizations confuse the attempted implementation of one or a handful of Lean tools as “implementing Lean.”

Successful Lean implementation requires much more than the knowledge and application of a set of Lean tools. It requires a fundamental re-thinking of the way business is done, often revisiting (and giving up) many of the beliefs and practices held sacred in the past. Engagement of the entire workforce to identify and eliminate waste, developing process versus functional excellence, and embracing a bias for change are all examples.

In the life sciences industries, a few of these behaviors are

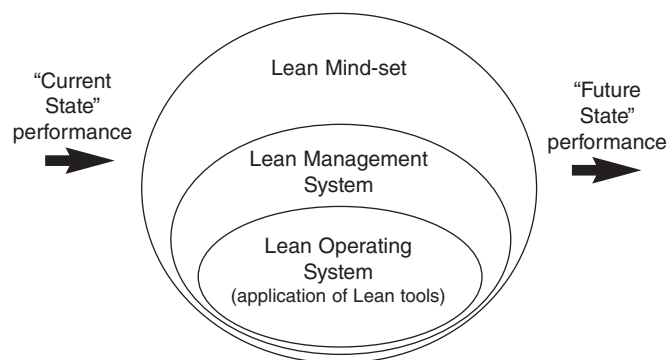
Fred Greulich is Director of Operational Excellence in the Strategy and Operations practice at Maxiom Group, a strategic business and IT consulting firm exclusively serving the life sciences industry. He can be reached at fgreulich@maxiomgroup.com or (781) 250-4955.

more difficult to assume than in other industries. For example, the regulatory environment can sometimes run counter to a key tenet of Lean, to “go do.” The requirement to validate that business process changes will maintain or improve quality frequently means that companies design improvements and then need to wait, sometimes months, before they implement. Clearly, to realize a successful Lean implementation, pharmaceutical and biotech manufacturers have to stay with it longer than companies in other industries.

Additionally, employees of life sciences companies are generally siloed in their outlook and approach to their work: “I’m in QA, he’s in Facilities, she’s in Regulatory Affairs,” and so on. This behavior fails to consider the needs of the customer, who doesn’t care about functional silos. An organization might have a world-class QA department, but if it still has a 100-day product lead time, do its customers feel satisfied?

Application of specific tools is a necessary, but not sufficient, approach to Lean implementation. In addition to the fundamental business re-think, it includes adoption of a systemic approach to Lean implementation organized along three separate, but integrated, dimensions — a Lean Operating System, which is implemented, sustained, and improved through a Lean Management System, both of which are driven by a Lean Mindset that underlies both systems. Much has been written and discussed about these elements on an individual basis, but not as much about the power and interconnectedness of these elements in forming

Figure 1: Lean Implementation and Management



a system. It is certainly true that most organizations haven’t adopted, at least with much rigor, this systemic view of Lean implementation. This is evidenced by the many examples of frustrated employees complaining about the lack of organizational discipline required to sustain improvement results, of leadership behaviors that run counter to Lean thinking, of organizations not providing the resources required for Lean success, and on and on.

Let’s spend a minute and outline the elements, not in intricate detail, but in a way that shows how they relate to produce a successful Lean system (see Figure 1).

Lean Operating System — the combination of people, processes, and technology used to produce the products and services which the customer values. For pharmaceuticals and biologics manufacturers, this includes facilities and equipment (bioreactors, chromatography columns, analytical testing equipment), processes (suite planning and scheduling, cell culture, stability testing), technology (LIMS, ERP, Document Management), layout, staffing, and the like. These Operating System elements taken together comprise the micro-process level (operating level) of the organization, which is the place where Lean manufacturing tools are brought to bear. These tools aim at identifying and eliminating the impediments to operational excellence such as variability and waste. Therefore, it is through the Lean Operating System that business process improvement occurs at the micro-process level in organizations.

In the course of developing the Lean Operating System, a key opportunity area for many improvement leaders lies in identifying which tool or toolset to introduce to the organization. An array of toolsets are available (see Figure 2) and many organizations tend to embrace one or two over the others, “We’re a Six Sigma organization,” or “We’re a Lean organization,” or “We’re a Lean/Sigma organization.” Huge amounts of time and energy are spent in philosophical discussions and evaluations about which toolset to use, rather than making things happen.

This typical situation has led us in our consulting work to become “toolset agnostic” — choosing the proper tool for the job at hand, regardless of the toolset in which it traditionally resides. Avoid the trap of only acknowledging and applying those tools that relate to a particular one or two toolsets . . . there’s great benefit in understanding a range of tools across the various toolsets and using them appropriately. Remember the old adage, “When all you have is a hammer, all your problems start to look like nails.”

Lean Management System — the Lean Operating System depends on the Lean Management System to make certain that the systems, organizational structure, governance model, roles, responsibilities and metrics that support implementation and ongoing management of Lean within the organization are in place. The Lean Management System includes elements that drive and support the continuous focus on micro-process level improvement on a daily basis. These elements include such things as:

- Identification and nurturing Lean leaders within the organization

- Usage of “Visual Factory Concepts”
- Metrics relating to the health of the Lean system
- Lean leadership structure and governance model
- Process(es) to elicit, capture, and act on employee improvement ideas
- Lean business process audits

A critical benefit realized when these elements and others are executed well is that a high level of organizational discipline is attained, an attribute which we find is absolutely necessary to implement and sustain the new Lean processes and behaviors. These processes and behaviors over time form what is frequently referred to as the Lean culture.

The sentiment, “It’s easier to act yourself into new ways of thinking than it is to think yourself into new ways of acting” has been adopted by most organizations that have attained real Lean success. The idea is that a Lean culture is not developed through discussions and thinking about it. It is, however, developed through practicing and experiencing the new processes and behaviors, since this is the way most people will see value and begin to advocate for Lean.

Many companies encounter difficulties moving to the “practicing and experiencing” stage. One common obstacle

vast array of improvement tools available, it is easy to swamp an organization with training. By applying just-in-time concepts to training, the organization helps ensure that training is only occurring for those tools that have near term applicability. Additionally, point-of-use training is more effective overall since it allows the training to be much more targeted and tailored to the particular requirement. Also, it is usually better received by the trainees, since it is delivered in the context of an actual business situation, eliminating questions like, “Why are they wasting time teaching me this?” Finally, the immediate application of the training in the workplace both reinforces the tool and eliminates the training-application lag, a period where much can be forgotten.

Lean Mindset — All organizations focus on achievement of results. It is in how the results are realized that separates traditional organizations from Lean ones. Traditional organizations attempt to manage directly to results, fire-fighting and doing whatever it takes to “muscle” to the results on a daily basis. On the other hand, a Lean organization puts in place sound business processes that are consistently managed and continuously improved as the way to results achievement. In the Lean world, *the business process is king!* In addition, there are a series of other Lean principles and tenets that successful Lean organizations adopt, such as:

Figure 2: Examples of Improvement Toolsets

Lean	Six Sigma	TQM	Design for Six Sigma	Others
<ul style="list-style-type: none"> • Waste Elimination • Workflow Improvement • Cycle Time Reduction 	<ul style="list-style-type: none"> • Quality Improvement • Variability Reduction • Defect Reduction 	<ul style="list-style-type: none"> • Quality Improvement • Employee Involvement 	<ul style="list-style-type: none"> • Used to Design New Products, Services or Processes • Builds Quality into the Process 	<ul style="list-style-type: none"> • High Reliability Tools • Statistical Process Control • Business Process Re-Engineering • Operational Risk Management

is that in some cases, organizations train large groups of employees in one or more of the improvement toolsets referenced previously, but do not leverage the new skills into action. The result is usually a scenario where only a handful of the tools are actually put into use in the near term, some are put into use at a later point (necessitating refresher training), some are never or infrequently used, and still others, which are part of other toolsets, are required for use but weren’t included in the training.

It is beneficial to facilitate “practicing and experiencing” by applying training in a way that fosters action using Action Learning, or training at the point-of-use. With the

- Lean is a business system, not just a manufacturing system
- Lean is a set of principles to be followed, not simply a toolset
- Business process discipline is crucial
- The organization must, down deep, believe that focus on business processes will lead to excellent results
- Lean system effectiveness must override the drive for functional efficiency/excellence

- Value is added at the micro-process level in organizations where people perform the “real work” every day. This is where focus needs to be kept.

These and other mindsets can be shared and discussed with the workforce and can even be included in Lean training. At some point, however, individuals must begin internalizing these principles and tenets as integral to the way business is done. Some people will find these items difficult to grasp and very foreign . . . a lot of coaching and follow-up will be required. Others will easily and willingly embrace the items, while still others will demonstrate an unwillingness and/or inability to adopt them at all.

For Lean to truly succeed there can be no room for people to demonstrate principles and tenets other than those associated with Lean; the risk to the change effort is simply too great. This clearly leads organizations to determine how to manage members of the workforce in the latter category. Dealing quickly and decisively, yet fairly, with resisters is a characteristic of most organizations that have achieved Lean success.

As has been discussed, Lean is, after all, a business management system and the appropriate usage of Lean tools is certainly critical to success. However, the lack of examples of companies that have realized “game changing” results with Lean is likely due to the all-to-common idea that “we have implemented a few tools, therefore we’re doing Lean.”

Part of the issue may lie in the concept many have about “implementing” or “installing” Lean — the words them-

selves tend to lead people to a tool oriented mindset. The fact is that Lean is not “installed” or “implemented.” Real Lean success is established or created by applying a continuous and relentless focus on identifying and eliminating the endless number of small instances of waste that, by definition, do not add value to a product or service.

In one recent case, a biopharmaceutical company, having been on the Lean journey for the last few years, eliminated tactical Lean goals from its enterprise dashboard. The organization found that Lean has taken root in the organization as the means to continuous improvement and competitiveness. Therefore, the need for the types of goal statements that were required early on to drive implementation such as, “Implement four Lean projects,” are no longer appropriate. Lean is no longer an incremental initiative for this organization to take on; rather it is the means by which the company achieves its true business objectives!

Since the advent of Lean in the U.S. in the 1980s, it has become clear that companies cannot expect real Lean success by applying only a piece of the business system (the tools) across a limited footprint within the organization. Lean implementation is a complex change management process, not a tool installation exercise, and requires a thorough and complementary blend of the three dimensions — Lean Operating System, Lean Management System, and Lean Mindset. ■

Maxiom Group is a leading strategic business and IT consulting firm exclusively serving the life sciences industry. We help transform emerging, established and mature biotechnology, pharmaceutical and medical device companies at each stage of their life cycle by solving mission critical business issues. From drug discovery and development, to clinical trials, to commercial launch and sustained market leadership, Maxiom Group clients rely on our unique focus, insight and approach.



Transforming Life Sciences

Maxiom Group’s Operational Excellence (OE) Practice helps clients plan, design and execute waste elimination and continuous improvement processes to help streamline and improve productivity. Rather than relying on any one approach, we help assess the leading philosophies and tools for continuous improvement and determine the best approach for business needs, culture and objectives. Our experienced practitioners work with client teams in areas including:

- Lean manufacturing
- Business process design
- Best practices assessment
- Six Sigma
- Cycle time reduction
- Performance management
- Risk management
- Workplace organization
- OE Program implementation/remediation

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