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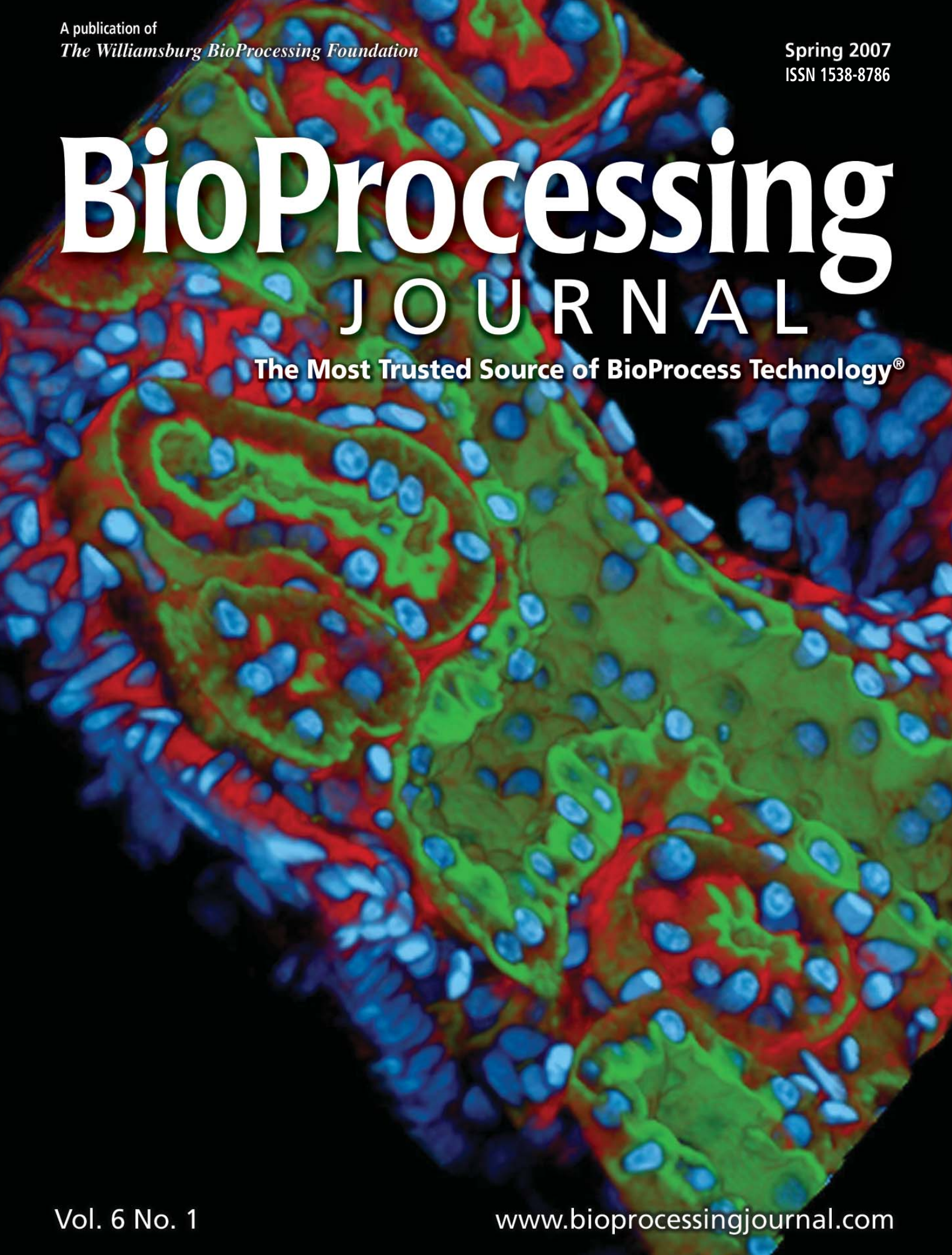

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The Development Lab is the New Frontier of Lean Management

By LASSE MØNSTED

The "Lean" manufacturing process management methodology is derived largely from Toyota Motor Corporation's automotive production system, implemented as a response to the problems they observed within their production facilities over 50 years ago. The principle of reducing costs by eliminating waste—also known as "Lean Thinking"—has been gaining momentum as a continuous improvement philosophy for all sorts of industries outside of its automotive industry origins.

In recent years, we have seen several examples of successful Lean implementations in the pharmaceutical and biotech companies. Multinational corporations such as Merck, Pfizer, and GlaxoSmithKline have reported significant gains by applying Lean not only to manufacturing, but also in critical areas like quality control, regulatory adherence, and administration management. Development labs are now the next area to go Lean. The potential here is enormous—if development times can be shortened, then new products will be delivered to the market faster.

The greatest challenge of incorporating Lean into the labs is not in applying the tools and principles, but instead, in engaging a culture not used to comparing itself to shop floor manufacturing. Secondly, administrative managers and academic facilities often lack the basic operational management understanding, tools, and skills in: a) how to efficiently schedule tasks, people and equipment in order to avoid bottlenecks and poor resource utilization; and b) having an adequate knowledge of production leveling, theories of constraints, capacity planning, and waste elimination—often not considered applicable in development. On the contrary, these important skills are very applicable to the development realm.

Based on more than 80 Lean projects within the life sciences industry, we have adapted the traditional Lean manufacturing approach to a pharma/biotech methodology while taking into account the specific cultural and process-related characteristics of these areas. One of the primary lessons to come from Lean is learning to recognize that administrative and laboratory work do have similarities to manufacturing, and can benefit significantly by applying its best practices in order to achieve more speed, quality and cost-efficiency. Recognizing this also means understanding: Lean is more than a set of tools; it is a management system which above all, requires leadership while challenging the management style.

Lean as a Management Philosophy

The objective to Lean is to create more value with fewer resources; in short, to increase productivity. The potential is enormous because Lean provides management and supervisors with an understanding, competence and tools that have been perfected in manufacturing where productivity improvements have set the agenda for survival in the industry for decades. We often hear objections like, "*We do intellectual work*

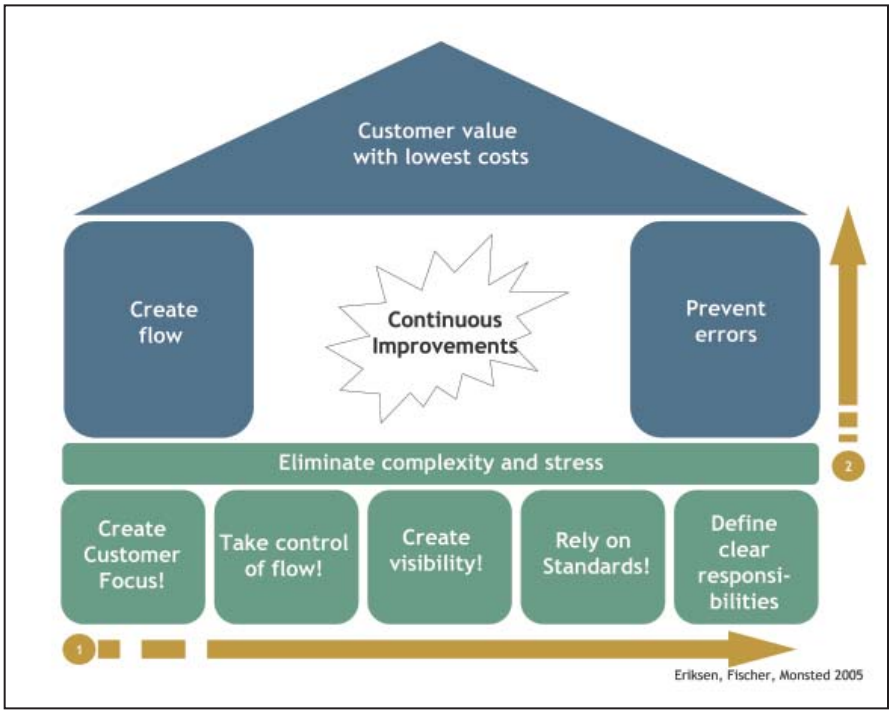

Figure 1. The building blocks of the Lean laboratory.

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and that cannot be industrialized!" or "*Operational management? Not here—my people are self-managed!*"

Unfortunately, this often leads to these typical lab situations:

- Unclear goals and objectives
- Lack of visual management and systematic follow-up
- Little transparency provided in planning, workflow and performance
- Exceptions define process standards and methods
- Individual behavior: "*My way is the right way*" creates variability in time and output
- Low process quality in specifications and output

But lab work has many similarities to manufacturing, and we have seen many cases where the process of performing analyses can be organized, monitored and managed as a manufacturing process. Even within development processes working in stages, the application of performance measures, visible management, waste elimination and even flow management can significantly improve performance and reduce lead-times and return loops.

Data Driven, Not Data Drowned

Choosing the Lean approach to process improvements means to define and monitor process performance. There is a good amount of data collection and analysis related to Lean, but when compared to other techniques like Six Sigma (Motorola, Inc.), there is much less data needed to start the process, and it is much easier to compile with Lean. Certainly Six Sigma is efficient and is easily combined with Lean; but if you are just starting out on a process improvement initiative, you can progress quickly by applying some of Lean's generic concepts without having to make tons of process data available—crunched to the last decimal—before making the first improvements.

Where to Start?

The process of implementing Lean in an organization can be compared to building a house. The order in which things are to be done is not without significance—it is important to create the right foundation before you start to build upon it. In fact, there are nine basic features (Figure 1) that every department needs to consider in order to make their materials flow naturally.

The "roof" of the house symbolizes what we hope to achieve by Lean: to create more customer value, done faster and with fewer resources deployed. The final objective can, of course, only be achieved when the rest of the house is completed. The first five building blocks are considered the foundation of the house and are for creating flow, preventing errors, and ultimately creating high customer value. The foundation is comprised of: a) getting a customer focus and organizing, prioritizing and managing tasks and resources accordingly; b) creating operational performance measures; c) visualizing the workloads, bottlenecks and status throughout the organizations; and d) defining simple standards, and clear roles and responsibilities for the process. Whenever these basic elements are overlooked, Lean initiatives will fail.

A solid foundation is the basis for a robust process. The next two steps—the two main pillars of the house—involve creating flow and preventing errors as a means to achieving customer satisfaction at high speed with low costs. The center point in the finished house involves the continuous improvements, which involves everybody from top management to shop floor, constantly challenging the existing process while striving for perfection.

Create Customer Focus and Understand the Nature of the Tasks

To understand the customers and organize the tasks accordingly is the first building block of the Lean foundation. Many administrative areas do not have a tradition for systematically building and maintaining an understanding of customer needs. In fact, we often see that the higher the academic level, the less focus (or interest) in customer needs we see. So, how well do we know our customers, internally as well as externally? Are we producing tests, reports and papers to meet their needs or to satisfy our own desire for perfection, or are we overproducing documentation in an attempt to make sure that all regulatory requirements are met, even though it might not be necessary? We have seen many instances where countless hours are spent producing obsolete reports and documentation. From the Lean perspective, such work is considered waste because the resources used could have been better deployed in doing value-added work.

We often hear the argument that "*no two tasks are alike and therefore we need to handle each case separately.*" As logical as this may sound, the unfortunate result is that by not recognizing the similarities in the tasks, the potential for optimizing task management, resource allocation and time is not achieved.

The Lean approach is to map out the overall task types that the organization is working with, looking for similarities rather than differences. Often it appears that although the issues or content of the task might be different, the actual process of solving the task goes through very similar steps every time. Once this is established, we can start to define how many tasks come in, how long they typically take to complete, and what competencies are needed to solve these tasks. Then by looking at the competencies available in the organization, a basis is made for allocating and managing resources.

Of course, many development projects are very long in nature (several years, in many cases) but one can always break overall projects into lesser tasks that are manageable on a day-to-day or week-to-week basis.

Take Control of the Process

Once the nature of the tasks has been uncovered, tools like capacity planning, forecasting, performance targets and productivity measures can be applied in order to monitor and manage the processes. We frequently find that laboratories and other administrative areas do not have a tradition for proactively planning and managing the flow of tasks on a day-to-day basis. Very often, the management of tasks is done within specific departments and not across the entire delivery process. This in turn is related to how the work is organized by functional department

managers. In Lean, we often introduce a process leader role to take responsibility for delivering results across functions directly targeted at the end customer.

Create Visibility

Creating visibility means making the status of work processes, performance and results visible for all on a daily basis. A department manager or employee should at all times be able to get a clear overview of current workload and any current bottlenecks or quality issues. By consciously working with visual management, staff can be empowered to make a proactive effort in leveling the team's workload and to prioritize tasks according to organizational goals without consulting a manager. This way, work can flow more easily and there will be fewer unpleasant surprises.

Creating visibility requires: a) establishing visual, logical processes; b) visualizing goals and achievements; and c) continuously following up, and adjusting accordingly. In many situations, a simple visual representation of the process is especially helpful. In several labs, we have posted the status of analysis reports on the wall in a manner that visualizes at what process step their analyses are currently at. This needs to be combined with a performance board, highlighting the daily performances and daily or weekly meetings with staff on performance, deviations, and corrective actions.

Rely on Standards

Here is an area where biotech companies are typically quite capable of developing and maintaining SOPs. However, there is a need for developing standards related to how the productions process and the flow are handled, such as:

- What volumes are our processes designed to handle?
- How do we deal with variations and backlogs?
- How do we prioritize when urgent orders happen?

Lean also applies simple manual (often visual) standards for how work is organized and performed.

Define Clear Responsibilities

The standards of controlling the flow of work require a set of clear responsibilities. In Lean, we often introduce process leaders instead of functional leaders, and we assign responsibilities for operational decisions to staff rather than managers. This is done to make the work flow more easily, and not stop, while waiting for a management decision on basic flow-related issues like how to prioritize tasks. Predefined standards account for this, and the measurement systems will capture deviations.

Create Flow

With the basics in place, we are now ready to make materials flow in the most efficient manner. In order to make this happen, we need to understand our process, and hence, to map it out for all to see, pinpointing bottlenecks and critical areas that needs special attention. In

laboratories, we very often introduce a concept called "cycle planning" which captures the importance of timing in the process and combines it with the relevant resources, competencies and equipment, in order to make the process predictable.

By introducing cycle planning, visibility of the process is created and thereby reduces lead-times. Thus, many procedures that have evolved due to the lack of flow will be eliminated—procedures for following up on where things are in the process, replanning, and reprioritizing. The result is a sharp reduction in rush orders and backlogs.

Prevent Errors

Many companies will start by targeting the symptoms rather than the root cause of why errors occur. Our argument is that the basic features of "the house of Lean" will eliminate many of the inherent causes for errors. By preventing backlogs and establishing a clearly defined visual process, the effect that process errors have upon lead times, quality, and cost becomes much more obvious. By having this clarity, we can start working systematically to eliminate errors and begin monitoring the effects of our efforts.

Continuous Improvements

Finally, with all the basic features in place, we are capable of constantly monitoring our process performance and will quickly detect deviations and problems. An important principle of Lean is, however, that the improvement work never ends. We can always do better, so we formalize the continuous improvement work by having weekly sessions for all employees where performance issues are discussed, improvement ideas are put forward, and responsibilities for designing new solutions are assigned. Typically, supervisors and/or management will also be present at these 15 minute meetings, affording the ability to sanction any idea or initiative that is immediately applicable or to decide whether or not to create a formal improvement project, if larger issues are detected.

The Road Map

When engaging on a Lean voyage in the laboratory, we propose a road map like this:

- Build a case for change
  - Identify a crisis
  - Benchmark against best practices
  - Lean simulations and games
- Map out the value streams
- Create a future-state vision and a master plan for implementation
- Decide how to monitor progress and how to cash-in
- Build competence

In the following paragraphs, these points of the road map will be elaborated upon.

Build a Case for Change

Creating a mindset for change requires that people feel a need to change. One proven method is to identify a crisis, a story to identify with, and targets to commit to. In other words, "*Why are we doing this?*"

Identify a Crisis

The laboratory is an area of great potential: a) it is a heavy cost-driver; b) it has long/varying lead times; c) it often has quality problems—reprocessing/reanalysis; d) it has a complex analysis flow; e) it operates at a low efficiency (analysis per head count); and f) has a complex planning scheme.

Benchmark Against Best Practices

One way of creating attention is to be inspired by the results of others. We have seen achievements in areas like:

Improved Analysis Flow
- 40% productivity increase (output per full-time equivalent)
- 50% lead time reduction

Increased Quality (Right-First-Time)
- 50% reduction of reprocessing/re-analyses

Improved Service Level to Customers
- 98% on-time-delivery of analysis reports

Lean Simulations and Games

A way of creating involvement and to change the mindset of people resistant to embracing a Lean initiative is to simulate the improvement. Lean simu-

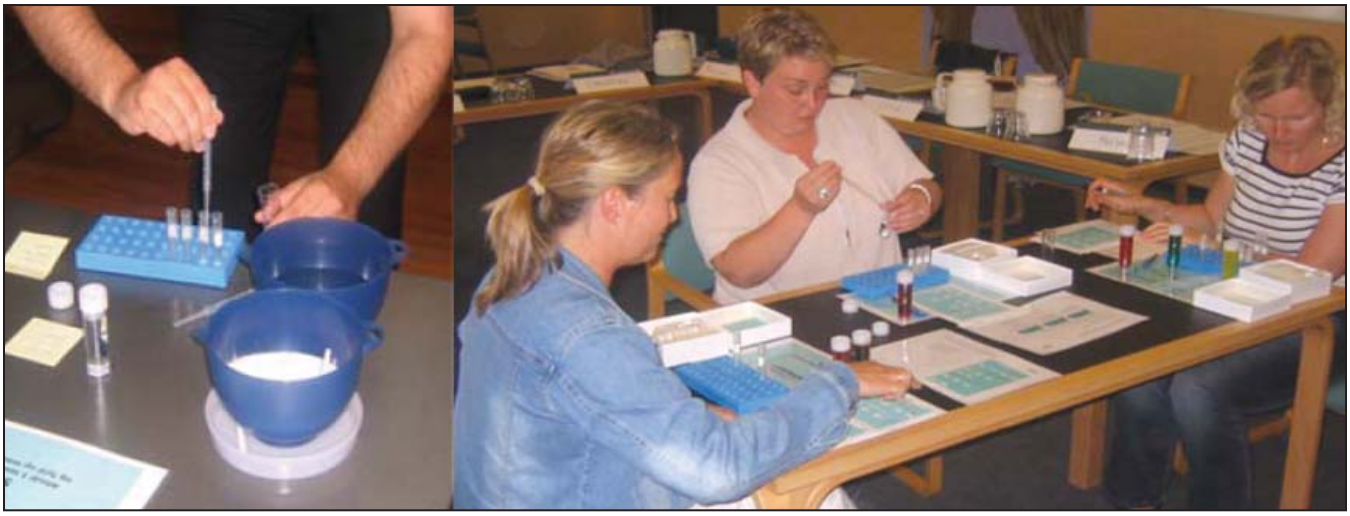

Figure 2. The Lean lab simulation illustrates process-related issues and areas of improvement.

lations help illustrate a typical process with some or all of the usual process challenges like bottlenecks, planning issues, and how concepts of waste, flow and layout influence performance.

We use a simulation specifically targeted for the laboratory—an actual recreation of analytical process flow (Figure 2). It is has been our experience that these hands-on exercises, more than anything else, break down resistance, create understanding for the approach and the potential, and carve the way for embarking on a Lean journey.

Map Out the Value Streams

The next step in the process is drawing process maps of the current state of primary processes in the lab. This could include mapping the overall projects and how to generate subtasks in the lab itself.

In Lean terminology, processes mapping is called value stream mapping (VSM), and this is a powerful tool used to identify potential improvement areas like bottlenecks, steps creating rework, volumes, etc. The current state map will be the basis for drawing an ideal future state process, and to start identifying improvement initiatives.

Vision and Master Plan for Implementation

Once the overall concepts and potentials are understood, management needs to formulate a vision for what they hope to achieve with the Lean initiative. There must be the ambition to set high goals; goals that are not easily achievable, and that requires more than just a little stretching. Then an overall master plan with clear milestones must be developed. Here the issue of "scope-creep" applies. Do not try to solve all problems at once. Start with initiatives that help in building the Lean foundation and move on from there.

Decide How to Monitor Progress and How to Cash-In

In order for the program to be successful, it is absolutely crucial to identify and quantify the goals. This way, results can be monitored and celebrated afterwards. If the ambition exists to improve productivity—meaning to increase the amount of output per person—it is also very important from the outset to determine how the benefits should be realized. Lean requires a high degree of staff involvement, and it is not a good idea to use Lean to reduce staff. It would be much more beneficial to absorb growth by not increasing hiring; thereby improving output per head.

Build Competence

We strongly recommend that laboratories embarking on a Lean initiative start building competencies in-house from the outset. The basic understanding of tools and principles are essential to success with Lean. The bulk of the training should be concentrated on a few process-excellence champions, but the ambition should be that everyone has a basic understanding of tools and techniques in order to get an idea of the potential. They must participate actively in the improvement work.

Conclusion

Whereas Lean principles have been an integrated part of many pharmaceutical and biotech company manufacturing plants for many years, the potential is equally high in the critical areas of development laboratories. The challenge, however, lies in cultural barriers and the ability to build a compelling case for change. Evidence shows that the tools apply and can significantly improve performance.

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