

Operational Excellence

Lean Concepts and Six Sigma in Action

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Operational effectiveness tools can increase efficiency and improve productivity.

As pricing pressure increases from customers and payors, and traditional margins become unsustainable, biotechnology and pharmaceutical companies are becoming increasingly concerned about cost effectiveness and efficiency in their operational performance.

More important, improving operational consistency and reliability can have a great impact on maintaining compliance. Operational variability not only compromises quality, but can also disrupt upstream and downstream operations. By paying attention to efficient and reliable operational performance, both xGMP and non-GMP processes can provide an important foundation for successfully meeting schedules, ensuring quality and compliance, and improving overall business performance.

Operational excellence techniques have been applied effectively across many industries for decades, and are now finding their way more and more into biotechnology and pharmaceutical companies. However, experience suggests that their application in this industry must be made in a manner consistent with rather unique product, process, and regulatory requirements. When adopted with due consideration, they can play an extremely important role in supporting a company's development and growth at any stage of its lifecycle.

Lean Concepts and Six Sigma are the two broad Operational Excellence "tool-sets" commonly applied within the biotechnology and pharmaceutical industry. Each has a different heritage and focus, which make them useful for addressing particular issues.

Far from being mutually exclusive, these tools are complementary, and can be applied together to address specific improvement opportunities. In addition, both techniques are most effective when applied as part of an overall strategy of empowering employees to creatively apply the tools to improve their jobs and their performance. The resulting front-line efforts can have a dramatic impact on productivity and performance.

As an example, one leading biopharmaceutical manufacturer was recently looking for ways to improve the process of managing samples. Samples are collected from raw materials, finished product, and many intermediate stages of production for the purposes of QC testing, stability testing, and retains. Diligent management of samples is critical to ensuring compliance and patient safety during and after manufacture. During the course of a year, thousands of such samples are collected. They are maintained in temperature-controlled areas for years until they are retrieved for anal-

LEAN CONCEPTS	Oriented toward production and supply processes. Focuses on eliminating waste and non-value-added activities.
SIX SIGMA TOOLS	Oriented toward quality and process control. Focuses on eliminating defects and reducing variability.

ysis, or for disposal at the end of their required retention period. In addition, the chain of custody for each sample must be documented and verified (tens of thousands of transactions during the course of a year!). Improper handling or management of the samples has the potential to affect the disposition of hundreds of thousands of dollars previously invested in production.

The Sample Management department had operated successfully for years based on their experienced and trained staff. However, as the company grew rapidly, the group began to show signs of strain. As the business grew, so did the need for freezer space; they were simply running out of freezer capacity. In addition, the sheer volume of sample transactions grew. It became increasingly difficult for the manual documentation to keep pace with the volume of transactions.

Additionally, as is common with biologics, samples at the company were stored in -80C freezers and monitored closely. Over time, excursions and freezer failures had resulted in the (compliant) dispersion of samples for similar products and time periods into many different freezers. This contributed to the complexity of managing samples, as the number of freezers grew into four rooms in two different buildings. It was becoming more difficult to find requested samples, and response times to requests were slowing.

Managers of the department knew they needed to get more organized and reevaluate their retention policies. In conjunction with the implementation of a LIMS system across the QC labs, they proposed implementing a “5S” program in their area as a means of redesigning and improving the sample management policies and processes.

WHAT IS 5S?

One of the “Lean” techniques, 5S is a structured approach to empower employees to make their work areas cleaner, better organized, and more productive. 5S uses very simple, low-cost tools and methods and is generally focused on eliminating nonproductive time and effort. In many cases it can also reduce mistakes and defects.

5S originated in Japan, and the five S’s stand for five Japanese words that

can be roughly translated into English: Sort, Set in Order, Shine, Standardize, and Sustain. A description of each is shown below.

The company formed a team consisting of frontline personnel in the

SEIRI	Sort: Identify and remove what is not needed
SEITON	Set in Order: Put things in the right places
SEISO	Shine: Clean the work area
SEIKETSU	Standardize: Formalize the changes
SHITSUKE	Sustain: Plan for adherence going forward

Sample Management area who were respected by their colleagues and who were knowledgeable in various areas across the function. They were empowered to make changes in their work areas, given that they maintained compliance and followed established processes for budgetary approval or change control. In an initial “Scan” of the current situation, the team identified three metrics that would effectively measure performance improvements from the effort:

- a) Time to find a sample
- b) Number of products per freezer
- c) Number of freezers in which a product is located.

Several “as-is” measurements were taken. Additionally, they took dozens of “before” photos of the work areas and travel routes. Then, during the course of several weeks, the team executed each of the 5S steps:

Sort. In the Sort activity, the team “Red Tagged” items in their work areas that did not belong there. The items were carefully documented and returned to a proper work area, disposed of, or moved to a temporary holding area. Team members red-tagged dozens of items, including a ladder, a broken ice-maker, a desk, a filing cabinet, and other items found languishing in the storage rooms. A great deal of space was freed up in these constrained areas, and the team enjoyed an early and very visible “win.”

Another Sort-related activity, which took much longer to complete, involved the identification and disposal of samples, which according to

regulations, were no longer required to be held. Thousands of samples were appropriately disposed of, leaving empty and half-filled freezers that could be reorganized systematically to make more efficient use of the space.

Set in Order. With the work area cleared of unneeded samples and extraneous items, it was time to organize what remained. The team created zones where samples are grouped by their key attributes—product

family, year of manufacture, frequency of request, and sample type.

Shine. In general, work areas in the pharmaceutical industry, and particularly GMP areas, are exceptionally clean and frequently audited. The team focused on specific cleaning tasks and created a more frequent cleaning schedule for particularly sensitive areas.

Standardize. In this stage, the team developed mechanisms to make the new arrangement understandable to employees both within and outside their group. They used graphical floor plans, freezer maps, and color-coded visual cues to ensure that anyone could locate a sample quickly and easily. Changes were also made to the process for managing freezer failures, one of the root causes of the prior trouble. Instead of dispersing samples randomly after a freezer failure, dedicated empty freezer space was made available in every room so that the samples and color-coded tags could be transferred to the new freezer. The new procedure also provided for returning samples to their original freezer as soon as possible after the event.

Sustain. To prevent employees from reverting back to old habits, the team developed a monthly workplace audit sheet, trained their colleagues on the new practices, and integrated key changes into existing Standard Operation Procedures. In addition, the team further committed to sustaining their 5S efforts by selecting a 5S “Champion” to lead future initiatives.

The effort quickly realized tangible benefits, as captured in an “after 5S” check of performance metrics. First and foremost, by reorganizing freez-

ers and their contents and revising policies, the average number of products per freezer was reduced from 3.6 to one, and the average number of freezers in which a product was dispersed dropped from 11 to three. Furthermore, by using simple visual cues, the time required to find a sample dropped from an average of 12 minutes down to just three minutes. Variability dropped as well, indicating that both experienced and new employees could reliably store and retrieve samples. In addition to these documented benefits, the entire work group grew noticeably more energized and motivated with the opportunity to take ownership of their work area and make it more productive.

Although representing just a limited example, this case illustrates the impact that tactical Operational Excellence efforts can have on performance. Companies instituting a systematic approach to Operational Excellence would typically have dozens of such improvement projects taking place. Imagine the effect of 5S projects in key areas—such as production suites and QC labs—along with other Lean or Six Sigma efforts focused on cycle time reduction, streamlining, mistake-proofing, or defect reduction. With a systematic effort, Operational Excellence can have a significant impact on your company's effectiveness, efficiency, and the effort and resources required to maintain compliance. ❖

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Client Life Cycle Stage	Key Challenges	Our Solutions
 <p>Emerging Companies Proceeding through clinical trials and beginning to think about and plan for commercialization</p>	<ul style="list-style-type: none"> Lack of resources and business infrastructure Significant financial constraints Balancing investments with business uncertainty Need to plan, design and build business infrastructure 	<ul style="list-style-type: none"> Strategic Decision Support Supply Chain Management Commercial Launch IT Strategic Roadmap Software Package Selection Quality & Compliance
 <p>Established Companies With one or more initial commercial products and a growing clinical process</p>	<ul style="list-style-type: none"> Growing complexity of business Changing product requirements Incomplete or inefficient business processes Not leveraging information systems to maximum extent Protect product supply chain 	<ul style="list-style-type: none"> Strategic Decision Support Supply Chain Management Business Process Design IT Utilization/Value Assessment Software Package Selection Software Package Implementation Project Management Office Quality & Compliance Brand Security
 <p>Mature Companies With multiple commercial products and a deep clinical pipeline</p>	<ul style="list-style-type: none"> Optimize performance of overall (often global) supply chain Implement specific systems Increase integration with key supply chain partners Implement advanced distribution strategies Seek continuous process improvement Protect product supply chain 	<ul style="list-style-type: none"> Strategic Decision Support Supply Chain Management Operational Excellence Software Package Selection Software Package Implementation System Integration Project Management Office Quality & Compliance Brand Security

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