



BioPharma
Solutions

 white paper edition

Implementing LEAN Techniques in
Quality Control

Optimizing and Leveraging
Improved Efficiency

Baxter

Implementation of LEAN Techniques in Baxter's QC Laboratory

Applying LEAN techniques can result in improved productivity, workflow efficiency and cost savings. The Quality Control Laboratory at Baxter's contract manufacturing facility in Halle/Westfalen, Germany, has been applying LEAN techniques since 2007 with the goal of reducing release lead times. To achieve this goal, several key steps were undertaken and completed, as outlined throughout this whitepaper.

Beginning the Journey: LEAN Training

Operators and other personnel at the facility were trained on the major LEAN tools and how to apply each. Next, a LEAN team was built, consisting of colleagues from the chemical and microbiological areas, to set uniform standards in each lab area. The initial focus of this team was to navigate through the 6S procedure as a first milestone.

6S, Kanban

The 6 S's from the 6S cycle are abbreviations for the following process steps:

1. Sort Out
2. Set in Order
3. Shine
4. Standardize
5. Sustain
6. Safety

The first step was to **Sort Out**. All articles in the laboratory which were no longer used were removed at the beginning of the cycle. Each was marked with a red dot and then placed into a special dedicated area for a period of three months before disposal. As a

result, this provided space for new improvements or new orders.

For the second step, (**Set in Order**), the individual analytical processes were examined including consumables and instruments, and were set in an order that fulfills the required needs for the process, space and ergonomics.

Next, all necessary requisites were cleaned (**Shine**) after the reorganization. In this context, the word "cleaning" stands for purification on the one side and also for putting things into a well maintained status.

The fourth step was to fix this status once reached, (**Standardize**), so "shadows" were used. This indicated clearly where things belonged and ensured that a place was identified for the item to be returned after work was completed. Time-consuming search activities were reduced as a result of this measure.



Use of shadows in the QC lab

The sixth step, (**Safety**), is actually ongoing throughout, with awareness of this goal built into all activities. This is extremely important for a lab which handles CMR (carcinogenic,

mutagenic and reprotoxic) substances and affects, for example, the disposal of older instruments.

This undertaking was driven both by the European Baxter Lab Council (a group focused on sharing best practices across facilities), as well as by the manufacturing facility. In regular 6S audits (**Sustain**) that are performed by the lab supervisors, the lab manager and black belts check the status and make suggestions for future improvements, helping to create an “always ready for an audit situation” laboratory.

The implementation of Kanban systems for consumables, as well as for reference standards, was another milestone in achieving the goal of reduced lead times. These systems are visual indicators for the material stock and ensured that these materials were ordered early enough to circumvent any “out of stock” situations. This enhances the customer service level since delays can be prevented.



2-Bin system for reference standards

After these necessary prerequisites were put into place, a narrower look into the product-specific processes could begin.

A3 Technique, Control Charts

A Pareto analysis of all contract manufacturing batches planned for the corresponding year allowed the identification of potential opportunities in the product portfolio. The following criteria were taken into account:

- The number of batches produced per material
- The analysis times per batch
- The number of operators involved in the lab
- The potential for standardization

Improvement projects for the identified products were started thereafter. The objective/goal and actual situation were fixed on paper in an A3 format which identified future measures. Corresponding A3 teams were built. These teams included members from all lab areas involved in the analysis process, together with the responsible lab supervisor and product-manager who possessed the product-specific knowledge.



Weekly A3 team session

These A3 teams met on a weekly basis. Besides the release performance, the product schedule, trends in analytics regarding the product, events and special information related to the production schedule were discussed and solutions for the future were agreed upon. Then, next steps were fixed on Control Charts to be followed up on in the next meeting.

This team approach revealed much deeper process knowledge for all members and emphasized the importance of broader involvement and engagement. The flow of information became more homogeneous and trends occurring on the shop floor level could be traced on a daily basis.

Based on the understanding of those specific single processes, a more general approach focusing on the total lead time was a result.

Successful Reduction of Lead Time

A swim lane diagram including all functional areas involved was created and discussed to get an overview on the complex flow of materials and documents that lead to release approval. This was helpful to understand how the different parts of the lab, including chemical and microbial parts, worked together, providing the insight to allocate potential for eliminating late corrections and establish information flow and prioritization in such cases.

For the employees, it was important that “critical analysis first” was a rule since it affected service level to customers. Lead times could be better guaranteed, even in

cases where deviations or OOS (out of stock) results appeared, due to a newly trained and dedicated taskforce.

“This team approach revealed much deeper process knowledge for all members and emphasized the importance of broader involvement and engagement”



Based on this approach, the analysis time for some products was reduced up to 25% thus far. In addition, the former independent releases in the chemical and microbiological labs were synchronized, helping to ensure all tests were completed on the date the sterile testing was reviewed.

Overall, applying LEAN techniques throughout the laboratory has led to a deeper process understanding by all involved employees, a demonstrated commitment to continuous improvement, and a direct, positive impact on our service level to our clients due to decreased lead time. This same approach is being leveraged for application throughout the facility and globally across Baxter QC laboratories. Clients are taking note, too, with one recently stating, “I haven’t seen such a well-organized QC lab before”.

Term Glossary

LEAN – A manufacturing/production system best characterized as relentlessly eliminating waste from all of its activities and operations.

Kanban – A Japanese term meaning “visual record” or “card”. In LEAN Manufacturing terms, KanBan has come to mean “Signal”.

A3 – The A3 problem-solving method and document, in combination with the value stream map (VSM), both borrowed from practices of the Toyota Motor Company, have shown their value in reducing waste and error. Why is the method called A3? In Europe, the nearest metric equivalent to 11” x 17” paper is designated “A3”. The method confines a team to what will fit on that size sheet of paper, forcing simplicity and quick communication. This assures the work can be realistically completed within this constraint. It demonstrates successful change and motivates workers to do even more problem solving. (excerpted from LEAN DIRECTIONS, the e-newsletter of LEAN Manufacturing – [click here to read article in its entirety](#)).

Pareto Analysis – Pareto analysis is a statistical technique in decision making that is used for selection of a limited number of tasks that produce significant overall effect. It uses the Pareto principle – the idea that by doing 20% of work, 80% of the advantage of doing the entire job can be generated. Or in terms of quality improvement, a large majority of problems (80%) are produced by a few key causes (20%).

Control Chart – Monitors variance in a process over time and alerts the business to unexpected variance which may cause defects.



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