

# **Operational Excellence (OPEX) through Optimization**

## Content

The Pharmaceutical Industry .....	2
Quality circle .....	3
A knowledge-based workforce .....	3
LEAN, Six Sigma, TPM.....	5
'Time and tide wait for no Man' .....	7
Conclusion .....	7

## The Pharmaceutical Industry

The global economic downturn and the expanding generic drug market are affecting our industry and instructing change. But what form and direction will this change take? Which framework will best help us meet the challenges before us?

Quality management initiatives and the streamlining of production environments have been on the agenda since the Hawthorne Experiments in the 1930's. Technology, production requirements and global business have changed considerably since then. But, through the many evolutions industry and business has gone through, the push for efficiency - underscored by a 'do more with less' philosophy - has been ever present. The Hawthorne experiments were focused around the motivation of people and their operations. In the 1980's and 1990's, quality and streamlining initiatives mainly focused on the engineering and the development of process automation. Significant gains were made. Now, in the current climate of 'Lean Six Sigma' we have gone full circle. Pushing further has revealed that the production environments didn't stop at the equipment, the operators, their managers and the engineers - and that the higher management influenced the outcome. In short, quality, streamlining and efficiency initiatives only become fully effective when people are motivated and the whole organization is evaluated and pulled in the same efficient direction.

LEAN Manufacturing and Six Sigma embraces the history of quality and streamlining businesses, from production environments to management strategies, across industries and other environments such as the medical field. They are influencing positively all levels of an enterprise, that is if they are administered correctly with continued supervision which never loses focus from the golden benchmark.

This whitepaper aims to underscore certain LEAN Manufacturing and Six Sigma requirements and, moreover, to open a discussion about facilitating change in line with these two philosophies by embracing process, equipment, and people.

## A knowledge-based workforce

The two philosophies of LEAN and Six Sigma are intricately incorporated into production environments, business philosophies, and process control. Control systems play a vital role in the capture and analysis of data. They serve not only to show production data, but also to motivate operators and users through a comparison with the 'golden batch' and its associated goals for speed, quality, and material usage. A good control system becomes a vital tool, interfacing effectively with people, the process and business.

As an automation supplier to many different industries, COPA-DATA sees how important mapping the process - and any connecting processes - in the visualization, and then presenting the information to the operator in the format most suited to them, can be in terms of efficiency gains. The operator influences the quality and efficiency of production. Because of their proximity to the process they are better placed to identify bottlenecks and shortcuts to quality and speed. Being given the power and tools to leverage this knowledge base is highly motivating for the operator, and can deliver effective new workflows for the business. To facilitate this, a flexible automation system is required: zenon gives intelligent and effective HMI & SCADA tools which open up opportunities for the user and their operations.

## Quality circle

COPA-DATA's Industry Manager for Pharmaceutical, Robert Harrison, has direct experience of quality circles in the 1990s, which throws light on some of the modern day issues associated with LEAN and Six Sigma:

*„The prime question for me as an engineer, and a pivotal challenge in the whole process, is what indicators to use. As a keen engineer in the production environment, I could identify many process indicators we could use – yet none were in the MES. How frustrating to be confronted by the potential for so much change, when it was so limited by the business's production information and communication. The MES relied on manually entered data and the indicators used were primarily engineering interventions. My observations of the maintenance technicians identified a conflict between what really happened, the origin of the event, the duration of the actual intervention and the need to justify an 8 hour shift period. For me, this was a steep learning curve which established that manually entered data is prone to errors. And, if these errors are then used to predict certain outcomes, these predictions are rarely accurate and consistently fail to hit the mark.”*

This historical situation outlined by Robert Harrison clearly shows the constraints of the traditional MES system and the impact this has had on business planning and performance - and the perception of MES systems in some quarters. Yet, improvement initiatives based on LEAN and Six Sigma philosophies require accuracy – firstly to identify the areas for improvement to tackle, and then to monitor results and the effects of interventions meaningfully. This is particularly true of Six Sigma, as it is a data-driven methodology that strives for perfection in the entire value chain by studying variation and the root causes of performance variations. This requires business-wide clarity, and statistical tools are a vital component for achieving breakthrough improvements.

Of course, today we have technology that can access all data across all systems. For example, zenon's hardware independence enables it to link into most, if not all, of the process control systems and equipment, then acquire data through historians, audit-trail and alarms. The information is then processed and presented through its SCADA platforms to the operator and business management hierarchy. Through a process gateway, many different protocols can be used to pass information bi-directionally to MES and ERP systems.

This bi-directional communication is essential when adopting the kind of business-wide approach that Six Sigma demands. For this reason, it is also useful if the same data and systems can be accessed site-wide. The 'zenon Analyzer' optimizes information transfer to the management structure and business systems. zenon Analyzer covers the entire site, offering reporting possibilities to truly analyze production operations: including batch reporting, report by exception, maintenance and performance. When zenon's communication capabilities are combined with this site-wide reporting tool, Lean and Six Sigma possibilities are realized, with real-time feedback on their performance.

Now we have the capability to obtain data, process and analyze it, then push it to the people that can be influenced by the information in the most optimal format. All actions and intervention are securely logged to be regulation-compliant in a closed system. The function of such data is to create a framework for quality and streamlining, create benchmarks or 'golden batches' and compare current processes in real time. Only when a user is more informed about the impact on the process that their actions have, can their workflow become more efficient.

The benefits don't stop at operator workflow efficiency: mapping the whole production environment, and having transparency across departments, plants and responsibilities, creates a collaborative platform where a holistic view of the processes is gained. From this, true quality management initiatives can intervene directly at the heart of the restriction or compromising operation.

## **LEAN, Six Sigma, TPM**

### **Lean Manufacturing:**

- Simplify
- automate
- streamline
- make error-proof

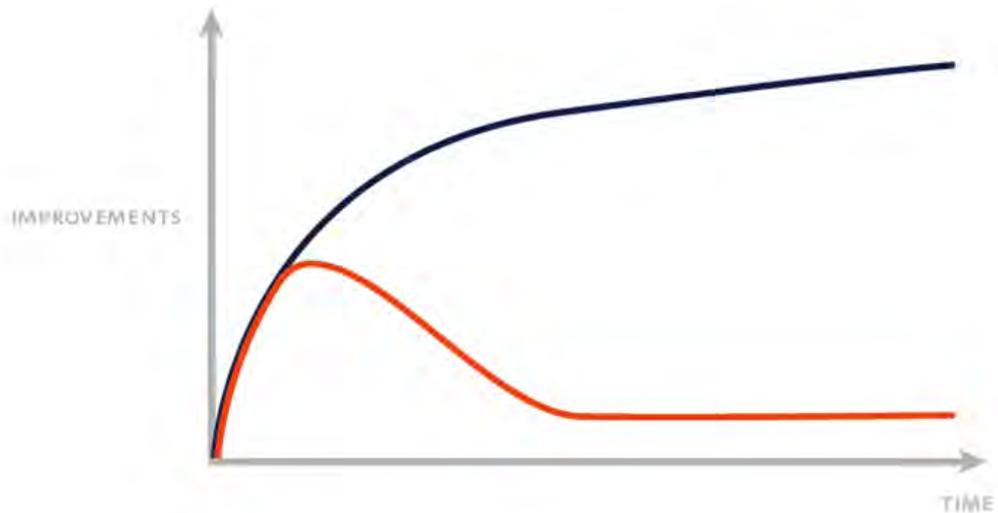
### **6σ:**

- Minimize variation
- Define-Measure-Analyze-Improve-Control
- Identify & control causes of defects
- improve process understanding
- stable and predictable process results.

### **TPM:**

An important part of Lean Manufacturing with OEE (Overall Equipment Effectiveness), Kaizen, MDI (Management for Daily Improvement).

Each of these approaches provides different ways of understanding the same processes and requires much of the same information. They require that the process be mapped and understood, that the resulting data is acquired with a high level of quality and can be pushed out in the format needed for each goal of the continuous improvement strategy.



In different industries where continuous improvement exercises have been carried out, experience shows us that the people involved predict the improvements will carry on (the blue curve). What really happens is the initiative gains significant ground in the beginning stages, where it has the focus of the entire team. This is also the time where there are the most possible improvements to make. Once the movement is underway, the focus of the team members begins to wane, the 'low-hanging' improvements have been made, and we have changed the world for the better. The improvements made (red curve) cannot be left unguarded; if they are, the process will be better than when we started but not as good as the predicted outcome and could well fall short of the opportunities available.

The modeling of a process and the acquisition of its data helps to define benchmarks which can then be visually presented. Continuous focus on the improvement process is realized effectively in an advanced industrial visualization system. In my experience, zenon has the flexibility to grow as the needs of the processes grow. Acquiring the data in a collaborative environment, that can integrate into your process with little or no change to existing validated equipment, reduces the business risk such a system can incur.

The Quality Management Structure can utilize one or more of the avenues of 'LEAN Six Sigma' in differing combinations; the results can be viewed in the most effective format depending on the specific model or specific process. Then, impacts on the process can be viewed immediately in response to actions, deviation from the benchmark can be signaled without delay, and a firm culture of optimization is inherently designed into the process.

## **'Time and tide wait for no Man'**

If today's leaders stand still they will be overtaken within the next three years.

Performance today is evolving through 'LEAN Six Sigma' activities and philosophies. The choice of how to embrace them and drive them forward in your enterprise is a delicate balance – but getting it right creates excellence. The energy and passion of 'LEAN Six Sigma' needs key technologies, such as zenon, which integrate people, process, equipment and business, and open your platforms to future cycles of improvement initiatives.

## **Conclusion**

As was the case with the Hawthorne Experiments in the 1930's, it is people, their motivation and their involvement in the process which are as important to a quality or streamlining initiative as the engineering and equipment improvements. Keeping a well informed workforce empowers staff and leverages their knowledge of the process, gains their commitment and secures their beneficial impact on the continuous improvement process, a process that is itself continuing to improve. Taking the right platform to develop 'LEAN Six Sigma' (or whichever framework you decide to use to achieve your unique goals and strategy) is the first step of confidence and achieves commitment to the desired outcome.

This is the platform we have created with zenon: it grows as you want it to grow - modular, scalable and flexible. You may well have a different view on the best system (or systems) to provide fitness for purpose - we have, after all, arrived here via different paths. However, it is evident that a system needs to model the processes accurately through open communication and good visualization and accommodate the different themes such an initiative will encounter during its lifecycle.

If it does, then it will help to establish a culture of motivation and leadership, as well as giving you the structure, discipline and a logical progression for achieving operational excellence.

*The design of this paper was to open discussion points and share experiences. Your interpretation of the issues may be different, since your experiences are different. In this light, I very much welcome your input and invite you to contact me.*

**Robert Harrison**

Industry Manager Pharmaceutical

[Pharmaceutical@copadata.com](mailto:Pharmaceutical@copadata.com)



© 2011 Ing. Punzenberger COPA-DATA GmbH

All rights reserved.

Distribution and/or reproduction of this document or parts thereof in any form is permitted solely with the written permission of the COPA-DATA company. The technical data contained herein has been provided solely for informational purposes and is not legally binding. Subject to change, technical or otherwise. zenon<sup>®</sup> and straton<sup>®</sup> are both trademarks registered by Ing. Punzenberger COPA-DATA GmbH. All other brands or product names are trademarks or registered trademarks of the respective owner and have not been specifically marked.