# Implementation Challenges Affecting the Environmental Improvement Performance in Pharmaceutical Production:

Martin Kurdve, Monica Bellgran, Jouni Korhonen, Seyoum Birkie



# Implementation challenges affecting the environmental improvement performance in pharmaceutical production: Results of a green kaizen pilot

Seyoum Eshetu Birkie[1], Martin Kurdve[2], Monica Bellgran[1], and Jouni Korhonen[1]

[1] KTH Royal Institute of Technology, SE-100 44 Stockholm, Sweden
[2] Chalmers University of Technology, SE-412 96 Gothenberg, Sweden
seyoume@kth.se

**Abstract.** This paper reports on working findings in an action research-based project, implementing a green kaizen pilot in a European pharmaceutical manufacturing company. The aim of the study is to investigate how continuous improvement initiatives with focus on environment originally developed for the automotive manufacturing industry could apply to the pharmaceutical industry. It also aspires to understand the enabling and hindering issues are for such implementation. There are considerable similarities of implementing lean in general in the two sectors, however, some key differences and challenges were apparent when implementing this specific green kaizen method called Green Performance Map. An implication for pharma practitioners implementing the green kaizen method concerns how to improve working procedures and production equipment to become more environmentally friendly amid high regulatory demands on process quality. Implementation challenges are discussed in terms of fidelity, locus and extensiveness of lean practices implementation.

**Keywords:** Sustainable production, continuous improvement, green performance map

## 1 Introduction

Proponents of lean production posit that the principles and underlying practices of lean should be applicable to any industry and any business process [1,2]. However, implementation in different industries could be at varying level of maturity. Some researchers debate that European pharmaceutical manufacturers might not have the readiness to implement lean practices [3]. It is argued that in these companies, lean implementation is often employed as an isolated project-based solution rather than as a holistic approach. However, this situation seems to be changing with tightening requirements on the production performance in different industries; the pharmaceutical business is no exception. This condition creates the necessary incentives at corporate level to emphasize the implementation of a more integrated lean management system, rather than ad hoc lean initiatives. Besides, some pharmaceutical manufacturers are embarking on initiatives that also respond to green or environmental issues.

Researchers recognise that green is a natural progression to lean and that continuous improvements holistically applied in the organization could enable the achievement of reduced waste in both operational and environmental fronts [4,5]. However the lean-green agenda is yet far from being promoted despite the potential opportuni-

ties for long term sustainable productivity. There is limited empirical base on how such integrative approach can be implemented and whether a common platform of such approach can be devised across different industries [4].

The green kaizen pilot presented in this paper was performed at a European pharmaceutical manufacturing company, supported in operations by a global lean management system developed during more than 15 years. The purpose of the pilot was to investigate how a green kaizen method developed for discrete manufacturing, (mainly in automotive sector), could be implemented in pharmaceutical industry as a means to facilitate environmental improvements at all levels. The pilot comprised of testing a green kaizen method called Green Performance Map (GPM) in practice within two separate production lines. The implementation aspects are the focus of this study and the two research questions set forth to answer in this paper are:

- RQ1: What are the implementation aspects of using a green kaizen method for environmental improvements in pharmaceutical production?
- RQ2: How could the implementation of methods for environmental improvements be facilitated in a pharmaceutical lean environment?

## 2 Frame of reference

### 2.1 Lean – implementation and innovation

Lean production is by some regarded as an integrated socio-technical system with main objective of eliminating waste [6] while others consider lean production as a concept [7]. On the corporate level, the term lean is often used to signal the involvement of the whole company and not only production. Regardless of the labelling, elimination of waste is considered a fundamental component of the whole lean concept. This waste elimination is achieved by reducing variabilities in internal processes as well as those connecting with supplier, customer and other stakeholders. Lean is based on guiding principles described as e.g. focus on people, a value driven process view, problem solving, and long term thinking [1,2]. These principles are translated into observable operational practices, which can be bundled into consistent and interrelated practices. Some bundles like total quality management, and total productive maintenance (TPM), focus on internal processes while others address external connections [6]. The journey towards a system aligned with the principles is driven by strategies like continuous improvement (or kaizen) and teamwork.

Lean implementation is often path dependent and unique for an organization [8]. Therefore, undergoing a lean transformation process can be considered as a way of diffusing innovative practices in the enterprise. In this view, lean practices implemented in an organization can be characterized in terms of fidelity and extensiveness [9]. *Fidelity* refers to the in-kind resemblance of the adopted practices to the features of previous version of practices; that is, if the practices are implemented according to the state-of-the-art, while *extensiveness* refers to the degree or extent of implementation of the practice, compared to that of a previous version. As an additional dimension, *locus* refers to the multitude of units or divisions in the organization that are part

of the implementation. This is important because silo-type lean implementation not only undermines performance benefits, but also restricts diffusion of innovative practices. For pharma, this is a relevant implementation aspect to consider due to regulatory process standardization and approval.

### 2.2 Green lean, and green performance map

The global environmental and climate reality is pushing manufacturing companies to take responsibility, driving towards sustainable and $CO_2$-neutral operations. With the recognized benefits of eliminating waste and pursuing continuous improvement, lean is sometimes adopted to incorporate the environmental (green) actions. The potential synergy between lean and sustainability has been a topic of recent research engagement [10] and lean and green could e.g. be viewed in integration as strategies or management systems [10,11]. In some of the studies, performance indicators were also introduced to capture environmental and social dimensions of sustainability [11,12].

Corporate environmental management involves several similar elements as in lean production [13]. Green production could be integrated with lean [13] but both suffer from the similar implementation challenges such as how to engage personnel and to manage team based improvement work. One approach mentioned is the adaptation of different lean analysis tools such as environmental value stream map to support green lean implementation. However, only a few tools are designed to support environmentally focused continuous improvement practice. With this as a background, the GPM [14] is a tool that was developed by a research team including two of the authors, with the purpose of facilitating environmental improvement work in industry.

Most of the lean practices appear to support and improve environmental performance of firms in different sectors. Starting with Toyota's achievement of considerable emissions reduction with green lean, similar improvement examples are reported for food and drinks as well as retail sectors [5]. However, there are some challenges for implementation. This argument seems to suggest that lean practices need not be strictly implemented to enhance environmental performance. However, one may argue that the benefits of a single practice should not undermine gains at an overall system level lean implementation [8].

## 3 Methodology

A qualitative and action oriented systems approach was applied when performing the pilot study with implementation of the GPM tool at the pharma case company. The empirical data was collected over a period of 6 months through different techniques; assessment survey conducted at the two lines (the respondents were the production team member, 12 in total), observations at the production lines (both as included in the GPM structured 5-step procedure and as follow-up), individual interviews with selected respondents and group interviews and discussions with the production operator teams and the supportive team (lean manager, lean change agent, production engineers, environmental expert and coordinators, energy experts and production leaders).

Data was also collected during a number of working and project meetings. The pilots selected were two semi-automated production lines for pharma-products operating in two-shifts. The production processes were both quite similar to the character of discrete manufacturing. The meetings, observations and interviews were documented and stored in a common project directory. In addition, eleven student thesis projects performed at the case study company during the past ten years were reviewed to get a historical perspective of the company's lean transformation progress. The review served as a comparison to the pilot in identifying and comparing challenges when working with continuous improvements and where green kaizen is emphasized.

## 4 Empirical findings

With the need for accelerating operational excellence the case study company initiated their lean transformation process during the early 2000. Preconditions like design of production equipment and production engineering competence were emphasized and operational tools like visual management, 5S and lean leadership were introduced. During the first phase, management worked extensively with lean related questions before it was transferred to the operator level. One production unit took the lead and showed quite soon annual productivity improvements results. This progress of the "lean front-runner" inspired other units at the site. Some, however, chose a reverse implementation procedure emphasizing the operators and first line managers. With a bottom-up approach, the implementation challenge was to maintain top managers' interest. Despite the challenges faced, the lean journey continued and six years later, the lean engagement on operator level was noticed also outside the company. Education and lean training was key element for creating the operator engagement.

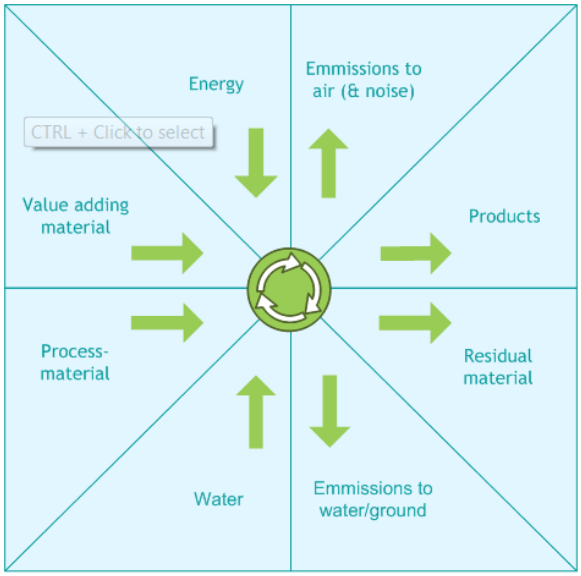


**Fig. 1.** The Green Performance Map implemented [14]

The case company visualized their production system as a house with a base of "standardized work flow oriented leadership and teamwork", the two pillars "right-from-me" and "just-in-time" combined with goal principles related to "customer focus" and "elimination of losses". The classical PDCA cycle was used to follow continuous improvements, and a set of performance priorities was determined as overall goal. At the selected business unit, lean improvements are currently driven at team level by working with daily visual management and weekly PDCA improvement meetings. Besides, improvements are driven by implementing lean tools such as 5S combined with good manufacturing practice (GMP) and TPM. The implementation of tools and practices are often run as pilots before rolled-out on a broader scale. Environmental aspects have been integrated in the kaizen initiative; however, no extensive attempts have been made to highlight the environmental improvements specifically.

A green kaizen pilot was initiated in the case company to emphasize environmental improvements, with the GPM tool implemented at operator team level (see Fig. 1). The predefined 5+1 step procedure was followed and the input-output model was used for identification of a large number of environmental aspects. Measurement possibility, "low hanging fruit" potential, and improvement performance vs effort on operator level were the main motives for selecting five environmental aspects considered as waste and prioritized for further improvement activities, see A – E:

**A) Use of standardized rubber gloves**: Gloves of a cleanliness level above the requirements were used, implying individual extensive packaging. No material recycling was collected, i.e. both packaging and gloves were thrown in mixed trash. Two proposals came out of the green kaizen pilot: 1) to use a plastic recycling bin and 2) to order gloves in multiple packaging. Implementation challenge: The teams were reluctant to change packaging due to uncertainties regarding pharma standard.

**B) Amount of cotton gloves used/day per person**: The standard, based on GMP, demanded higher cleanliness gloves at the specific station compared to other stations. The consumption of gloves was, however, almost three times as high as expected by the standard. Implementation challenge: from a behavior perspective, consumption of gloves was directly reduced to almost theoretical level as a result of the attention of the pilot. The issues concerned how to identify the best way to measure the glove consumption, and how to reduce the consumption while at the same time fulfilling the pharma requirements of the specific station.

**C) Reuse of "scrap"**: A component often fell on the conveyer belt in one station becoming scrap, although it was not contaminated. The severe waste this caused could easily be eliminated by a small technical redesign. Implementation challenge: The pharma standard was an obstacle for making the redesign since the proposal had to go through an extensive change procedure due to the tough pharma regulations.

Two additional environmental aspects were prioritized; **D) measuring the energy consumption** at one production station (by energy experts), and **E) reduction of packaging material waste** from one cell (on operator level at the production line). Here, the implementation challenges had to do with resources and behavior rather than pharma standards and regulations.

Environmental aspect A (solution 1) and B could be improved locally by the operator team, while the rest required participation from support functions, and A2 addi-

tional involvement of suppliers reducing the tempo of the implementation. Solutions to B, C and E had large duplication improvement potential since they were generic and possible to implement within a number of production lines at the company. The potential for making a broader successful implementation depended on lean maturity, resources, and organizational support including management commitment.

**Table 1.** Implementation challenges and enablers found in empirical studies

| Implementation aspects | pi-lot | Papers (published 2007-2017) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| **i) Implementation challenges** | | | | | | | | | | | | |
| Batch production | A | X | | | | | | | | | | |
| Lean leadership not fully implemented | N | X | X | | | X | | X | | | | |
| Standardised work not team driven | S | X | X | X | | | | | X | | | C |
| Regulation control of operation practice & changes | A | X | | | | | | | X | | C | |
| Lack of engagement, reluctance to participate | C | | | X | | | | | X | X | | X |
| Lack of resources to implement improvements | A | | | X | | | X | | C | | X | S |
| Lack of time/resources to follow up improvements | A | | | | X | | X | | | | | |
| Standardised work not followed/fully implemented | N | | | | X | | | X | X | | | |
| Deviation reporting and improvement proposal not handled properly | S | | | | X | X | | | X | | C | |
| Lack of support (OP-Maint/ Tech) competence | C | | | | | X | | | X | | S | |
| Documentation requirements complicated | S | | | | | X | | X | | | S | |
| Insufficient co-operation between teams / functions | S | | | | | X | | | X | | | S |
| **ii) Implementation enablers** | | | | | | | | | X | | S | |
| Focus on value creation/operations | A | X | | | | | X | | X | | X | |
| Quality focus | A | X | X | X | | | | | X | | | |
| Flow focus | S | X | X | X | X | | | | | | X | X |
| OEE, reporting system for deviations | S | X | X | | | X | | X | X | X | X | |
| Visual management | A | | X | X | X | | X | X | X | X | X | |
| Weekly Safety-Health-Environment meetings | A | | | | X | | X | | X | X | | |
| Engagement /teamwork | A | X | P | P | | | X | | X | | X | X |
| Use of lean analysis tools (VSM, SPC, 5Y etc.) | A | P | P | | | | | | X | X | X | X |
| Use of Lean implementation tools (5S, OP-M, PDCA, SMED, etc.) | A | P | | | X | | | | X | X | X | X |
| (Team driven) standardized work SOP | C | | | P | | P | | | | X | X | X |
| Team driven improvement meetings & projects | S | | | X | X | | X | | X | X | | X |
| Available time for improvement implementation | S | | | | | | X | | | | X | X |

***Note:*** 1) A=Apparent/evident, X = mentioned, C = contradicted, P = pilot implementation, S = some occurrences/evidence, N=not observed; 2) green kaizen pilot performed in 2018

In order to relate the environmental improvement maturity to the traditional kaizen, an analysis of 11 lean kaizen projects conducted at the production site for a period of 10 years was made. Implementation challenges and enablers were identified, most lean improvements not specifically considering green improvements.

The analysis indicated that the case company had a rather mature operational improvement system. Team driven visual management and improvement work was apparent and support functions worked in standardised ways with improvements. The analysis indicated that the maturity has grown, showing fewer implementation issues after ten years. This can be seen, e.g., by the contradicting observations (marked as C in Table 1) in the pilot of issues which previously considered challenges of implementation. The major remaining challenges included perception of lack of time/resources

for improvement work, rigid documentation demands making it difficult to change standard operating procedures (SOP), and insufficient inter-team cooperation.

## 5 Discussion and conclusion

The empirical findings indicated that the participants in the pilot had primary focus to strictly follow business and corporate standards specific to the pharmaceutical industry. Lack of willingness to question the standards was an obstacle for green kaizen actions. Following standards and regulations is fundamental to pharmaceutical and value of changes must be ensured. Investing time and resources to drive the change process to assess and change the standard, was a general obstacle. This indirect calculation of the reasonable "business case" is probably made intuitively by employees.

The regulatory requirements in pharmaceutical industry are extensive including how the production processes should be operated at all steps dealing with the product (value adding activities) and must be accurately communicated to the authorities; similar regulatory patterns exist in other safety critical industries such as the airlines. The requirements are detailed including also what type of equipment that will be used. The regulatory process restrictions could become barrier for some lean and green kaizen within pharma, as in food industry, for example. One conclusion is that it becomes important to make really good business cases for each proposed change, i.e. the costs should be worth the economic benefits of a change. Measuring and follow-up of improvements might also push towards further challenging standards.

The empirical findings also indicate that lean implementation in the pharmaceutical industry context is not that different from the manufacturing industry in terms of daily lean practice routines. However, pharma is more focused on process and quality. "Hunting waste" and optimizing the production flow is not as important as the delivery of (extremely) high quality in pharmaceutical processes and products. The study confirmed that the production part is often very small compared to product and process development costs in the pharma business. These differences, along with path dependent idiosyncrasies affect incentives for implementing lean in the two sectors.

When it comes to green initiatives, the lean practice bundles connecting with external actors in the value chain could provide superior environmental improvement. In terms of extensiveness, the lean implementation varies in the organization; some practices and tools are exercised in general while others are implemented to a lesser extent, possibly also due to individual differences of team leaders.

The innovativeness of lean implementation journey can be viewed in terms of fidelity, locus and extensiveness [7]. In terms of fidelity, the lean practices implemented in the case company appear to resemble those common in the automotive sector, which has been forerunner in lean implementation. This is also valid at higher aggregation levels as in practice bundles; this may not necessarily be a good thing considering that lean (and green) journey is path dependent and tailoring to specific context is often imperative. Even so, the case company has challenges to address and exploit some lean principles. A strong extensiveness in implementation could be signalled by questioning existing routines that neither add to fulfilment of regulatory requirements,

nor contribute to economic or other forms of value. The implementation of lean tools and practices seemed to vary among different operation units (locus) in the case company. Extant literature suggests that more benefits are likely to be gained from lean transformation (with or without green issues) when such efforts cover processes on shop floor and beyond. The challenges observed in the pilot and reported in earlier studies suggest that further environmental improvement potential might have been masked away-hinting the urgency to systematically address those challenges.

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