Implementation of lean production systems in small and medium-sized pharmaceutical enterprises

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Abstract

In order to ensure a sustainable supply of the population with affordable medicines, it is necessary to organize pharmaceutical production processes efficiently in terms of costs, process quality, time and flexibility. Lean Production Systems (LPS) have proved as an effective way to respond appropriately to these requirements. To date, the transfer of established models to the pharmaceutical industry and especially small and medium-sized enterprises (SMEs) is difficult, because of special characteristics regarding production processes and regulatory requirements. At the same time, SMEs often lack the necessary knowledge to develop suitable LPS themselves. The paper describes Lean success factors and barriers and proposes an LPS implementation process taking into account the unique features of SMEs in the pharmaceutical industry. Special attention is given to the consideration of human-oriented factors and the appropriate selection of Lean methods, which are aligned with business goals.

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1. Introduction

The inherent goal of pharmaceutical enterprises is to produce and deliver affordable and safe medicines to extend or enhance life. The sustainable supply of those medicines requires the balancing of economic, social and ecologic issues [1]. For the pharmaceutical industry these issues include the improvement of resource efficiency of production...
processes, reducing emissions of harmful substances into the environment and facilitating access to medicines for underserved populations [2]. A study published by the World Health Organization in 2011 concluded that even for an adult respiratory infection treated with generic drugs, the costs amount to over two days’ wages in over half the countries studied, while costs of one-day’s salary are generally considered affordable [2]. Since production costs account for up to 50% of these costs, improvements in the pharmaceutical production are an important lever [3]. Subsequently, pharmaceutical companies have to improve their service level, flexibility, costs and quality and at the same time satisfy demanding regulatory conditions and economic factors, such as research and development costs and post approval risks and returns. This is especially relevant for pharmaceutical SMEs that make up the majority of pharmaceutical enterprises. Out of 669 pharmaceutical companies registered in Germany in 2016, 17.3% had between 100 and 499 employees and 76.1% even less than 100 [4]. SMEs in general lack opportunities and resources to harness the economics of scale exploited by large companies and are therefore inherently vulnerable where they have to compete with them [6].

Within the scope of this paper, the focus is on companies that produce pharmaceutical drugs themselves. The first step of the pharmaceutical production process is the preparation of the active pharmaceutical ingredient (API), e.g. from chemical synthesis, bioprocessing or herbal/plant origin. Afterwards, during the formulation, the API and additional excipients are combined into a pharmaceutical product, most commonly in the form of tablets, capsules, pills, salves or liquids. Packaging represents the last step of the production process.

To address these issues in a production environment, the application of the Lean philosophy can be an appropriate approach. Lean focuses on the elimination of waste while relying on the employees of a company for continuous process improvement. Lean Production Systems (LPS), as enterprise-specific methodical systems of rules for comprehensive and continuous designing of enterprise processes, have proven their ability to enhance operational efficiency and effectiveness in a production environment [7]. In contrast to other industries that adopted LPS relatively quickly and successfully, the pharmaceutical industry has been slow in deploying them. Regardless of business size, implementing a LPS whilst taking into account the enterprises strategies and while meeting all rules and requirements of the current Good Manufacturing Practices (cGMP) proves to be a challenge [8].

Because of those difficulties, several studies have been released to facilitate pharmaceutical enterprises to deploy LPS. Some of them focus on the compatibility of Lean concepts with cGMP environments [9] while other pinpoint general factors influencing on the success in medium-sized companies [10]. Approaches for the pharmaceutical production focusing on specific production processes like bio-manufacturing [11] as well as more holistic viewpoints regarding operational excellence [8] have been proposed but are lacking a practical step-by-step process. Therefore, the goal is to develop such an implementation process and adapting it to the conditions of pharmaceutical SMEs.

2. Literature review

2.1. Lean success factors and barriers

The successful implementation of LPS can lead to shorter lead times, less rework, higher financial savings and less inventory, which in turn makes lean enterprises more responsive and flexible in dynamic markets [12]. However, not all LPS implementations have produced such results [13]. A high number of factors has to be considered, ranging from technological to cultural aspects. To give an overview of these factors a literature analysis of 27 research papers was conducted. Out of the selected papers fifteen describe a general background [14 – 28], seven focus on SMEs [6, 29 – 34] and five specifically address healthcare or process industries [9, 35 – 38].

Figure 1 shows a list of common Lean success factors and barriers respectively. In general, human-oriented “softer” factors predominate. The most important success factors revolve around leadership and aspects related to the qualification of employees. If these are not taken into account sufficiently, they act as barriers. Derived from the companies’ strategy, the implementation follows generally a top-down approach. Since the use of Lean methods and tools often necessitates a major change in the work environment, initial resistance of the employees is to be expected. To address this, it is necessary for management personnel to represent the implementation credibly and lead with good examples [17]. In order for the employees to apply Lean methods and tools, they must be appropriately qualified. Favorable approaches are practice-oriented qualification measures like learning factories and workshops directly at the workplace.
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