Value Stream Mapping as a Basis for Process Improvement in the Pharmaceutical Industry

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2017-05-22

The pharmaceutical industry must learn that GMP not necessarily constitutes an obstacle when transforming towards an optimized future state. Through mapping the processes using VSM, managers can understand where improvement can be reached and move thus towards a lean state.

Imagine if your shady neighbor with no whatsoever knowledge of chemistry suddenly decided to start a small-scale pharmaceutical company in his basement. Would you trust his abilities? Probably not, and this is exactly why the pharmaceutical industry is highly governed by laws and regulations, such as Good Manufacturing practice (GMP). GMP presents guidelines on how companies can assure high quality through controlling manufacturing processes. Although GMP most certainly improves the quality of the end products, it also tends to complicate the production processes and hinder an efficient flow.

A single case study was performed at a Swedish pharmaceutical company. The aim was to investigate how GMP affects the business and to determine if any specific deficiencies were prominent in a GMP governed environment. Further, as GMP focus on effectiveness and quality rather than efficiency and flow, the objective was also to see if the current state could be improved through adopting the lean philosophy. The idea behind lean is basically to minimize non-value adding activities, i.e. improving the efficiency and flow in connection to the production. This can for example mean removing wasteful activities or amplifying the perceived customer value. The processes were mapped using the lean tool Value Stream Mapping (VSM). Lastly, the applicability of VSM as a tool for process improvement within the pharmaceutical industry was examined.

Some of the deficiencies that were found during the study, like issues regarding the information sharing, seem to be characteristic for the pharmaceutical industry. The communication issue has for example been commented on in previous literature.

Ultimately, ten improvement proposals with potential to mitigate the found deficiencies were presented to the company. For example, the company was recommended to add another room intended for packaging operations. This would increase the flow and capacity. Besides giving the company recommendations on how to mitigate the found deficiencies, the findings can contribute to the commercial and industrial life as well as the academia. The recommendations can for example be used as guidelines on how to eliminate or reduce the effects of certain types of waste or deficiencies. It can help companies understand how to align GMP and lean.

Although lean and GMP have different objectives and focuses, the study showed that VSM can be used successfully in a GMP environment to improve processes through lean thinking. It was also concluded that certain waste types were overrepresented and matched the objectives of the lean philosophy. These waste types were typically flow-impeding activities that occurred between process steps.

The pharmaceutical industry should not be intimidated by the straitjacket that GMP seemingly constitutes upon their operations - they can still be lean. Through applying lean thinking and moving towards an optimized future state, pharmaceutical companies can combine quality and efficiency.