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Short communication

Improvement of the dosing and packaging process through lean six sigma methodology

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Introduction

This topic is currently ongoing and focuses on measuring and minimizing downtime of a dosing and packaging machine for medicinal liquids, with the ultimate goal of improving the overall process efficiency. The project originates from a collaboration between the department of Production of Liquids and the Continuous Improvement Department.

The study is being carried out using the Lean Six Sigma methodology, a powerful data-driven approach that combines the waste-reduction principles of Lean with the defect-reduction and process-improvement tools of Six Sigma. Together, these two frameworks enable organizations to streamline processes, reduce variability, and deliver consistent, high-quality results (Pyzdek and Keller, 2014).

The project follows the DMAIC structured improvement cycle, which consists of five phases:

Define, Measure, Analyze, Improve and Control (Pyzdek and Keller, 2014). At present, the study is in the Improve phase; however, positive results and solution are already becoming evident, with measurable improvements in the dosing and packaging process observed even at this stage.

Materials and methods

Value stream mapping

The first method employed in this study was Value Stream Mapping (VSM), a Lean management technique used to visualize and analyze the flow of materials and information required to bring a product to the customer (Rother and Shook, 1999).

In this initiative, VSM was applied to map the entire production process of Ibuprofen suspension, spanning from the preparation of the semi-finished product all the way through to the final packaging of the finished goods. This end-to-end mapping allowed the team to gain a comprehensive understanding of the process flow and identify key areas where downtime and inefficiencies were most prominent.

Measurement of downtime

As part of the second phase of this study, a baseline was established for the dosing and packaging process of Ibuprofen suspension. This was achieved by systematically measuring every type of downtime occurrence across three main categories: technical, organizational and material. Downtime data was collected over the course of 6 different production batches, providing a representative and reliable dataset. Through this structured measurement approach, a clear picture was formed of the most frequent and most time-consuming downtime occurrences, laying the groundwork for a targeted and data-driven analysis in the subsequent phase.

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Root cause analysis

During the Analysis phase, root cause analyses were conducted using the Ishikawa diagram. To ensure accurate and comprehensive findings, workshops were conducted with the employees directly operating the dosing and packaging machine, as well as with the machine's service technicians. For the purpose of this analysis, 4 downtime types were selected for in-depth root cause investigation, based on two key criteria: frequency and duration. This targeted approach allowed the team to focus improvement efforts on the most impactful sources of inefficiency within the dosing and packaging process.

Action plans

The project has currently reached the fourth phase - the Improve phase - in which action plans with concrete improvement steps were developed for each of the four identified downtime types. Every activity within the action plans was clearly defined and paired with a corresponding monitoring measure, allowing the effectiveness of each action to be properly validated and confirmed through measurable outcomes.

In addition, standardization measures were developed for the implemented activities, ensuring that the improvements are not isolated corrections but rather become an integral part of the regular operating procedures of the medical liquid dosing and packaging machine.

Results and discussion

The selected downtime is associated with the mixing of the suspension in the intermediate tank prior to the initiation of the dosing and packaging process. This downtime occurs due to the absence of a third shift in the department, which requires the process to be interrupted overnight. During the baseline measurement phase, this downtime was recorded 8 times across the 6 measured production batches, accumulating a total of 6 hours of lost production time. This clearly identified it as one of the most impactful and recurring sources of inefficiency in the process. Following the root cause analysis conducted through the Ishikawa diagram, an improvement measure was defined in the action plan: the intermediate tank mixing would be activated during the third shift by an electrical technician, ensuring that the suspension is ready by the time the dosing and packaging process resumes.

Since the implementation of this measure, it has been successfully applied 17 times, resulting in a total time saving of 765 minutes. These preliminary results are highly promising and clearly demonstrate the effectiveness of the Lean Six Sigma approach in addressing process inefficiencies in a structured and sustainable manner.

Conclusion

This study demonstrates that the structured application of the Lean Six Sigma methodology and its DMAIC framework represents a highly effective approach for identifying, analyzing, and eliminating process inefficiencies in pharmaceutical manufacturing. Through systematic downtime measurement, root cause analysis, and targeted improvement actions, significant and measurable results have already been achieved, even while the project remains ongoing.

As the initiative progresses into the Control phase, the standardization of implemented actions will ensure the sustainability of these gains and lay the foundation for a culture of continuous improvement within the Department of Production of Liquids. These results affirm that Lean Six Sigma is not only a powerful problem-solving tool, but a strategic driver of long-term process excellence in regulated manufacturing environments.

References

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