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Quality Quandaries: Improving the Overall Equipment Effectiveness at a Pharmaceutical Company

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INTRODUCTION

An important concept in total productive maintenance is the overall equipment effectiveness (OEE). The OEE was developed by Seiichi Nakajime in the 1960s. It was first published in *Introduction to TPM: Total Productive Maintenance* (Nakajime 1988). Since then it has been one of the most popular measures to indicate how effective a machine or process is functioning compared with its ideal capacity. Most of the times it is given as a percentage.

Many improvement projects that aim at increasing the effectiveness of equipment focus on one of the following three aspects (Slack et al. 2010):

- Availability: the time that equipment is available to operate. The availability of the equipment is reduced by net worked time, setup and changeovers (when the equipment or process is prepared for another product), or production stops due to breakdown failures.
- Performance: the speed, processing time, or throughput rate of the equipment. The performance is reduced when equipment is idle; that is, the equipment is not being used, whereas it could have been. On the other hand, if equipment is running slower than necessary it also negatively affects performance.
- Quality: the number of defects produced with respect to the total number of produced goods. Defects mean that products do not meet the required specifications and hence you also lose capacity.

The DMAIC (define–measure–analyze–improve–control) road map of Lean Six Sigma can be employed to improve the OEE (cf. De Mast et al. 2012). In the define phase of DMAIC, one selects a problem that has a large potential impact for the company; for example, in terms of operational costs, revenue, or customer satisfaction. In the measure phase, one selects the critical-to-quality characteristics (CTQs): performance indicators that reflect the problem. In the analyze phase, the collected data expose the real problems. For instance, one finds that the quality of the products is within specification, but plenty of operations time is lost to idle time or production stops. The analyze phase ends with an open-minded generation of potential influence factors. In the improve

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phase, the most vital influence factors are selected; that is, the factors that have the largest effect on the CTQs and can be changed easily. Selection is based on (statistical) evidence. With this information, the main causes are discovered and appropriate improvement actions are designed. Lastly, in the control phase the process control system is adapted so that one can monitor the new process and take effective countermeasures if necessary.

In improvement projects that are about increasing the capacity of a process, such as increasing the effectiveness of a machine, the DMAIC method provides clear guidelines. As an example, we present an improvement project that took a place at a site of a large international pharmaceutical company in 2013. There was a great sense of urgency to enhance effectiveness, due to a planned closedown of a major production site. The project manager was a Lean Six Sigma black belt.

DEFINE

In the define phase, the black belt described the process to be improved and formulated the project objectives and their potential benefits. The process to be improved is the encapsulation process. The input of the process is a medicine bulk solution and gelatin, which are prepared in-company out of raw ingredients. The first step in the encapsulation process is that a machine surrounds the medicine with a thin layer of gelatin. After this step the capsules go through a drying tunnel where the gelatin shell hardens. The capsules are then visually inspected for nonconformities, such as leaks. Finally, the capsules are polished and bulk-packed, ready to be shipped to customers; that is, packaging companies. These companies typically pack these pharmaceuticals into blister packs or bottles. The encapsulation process delivers about 50,000 capsules per hour per line. A diagram of the process is given in Figure 1. The goal of this project is a 10% increase of the effectiveness of the encapsulation machine, because this step was earlier identified as the bottleneck of the process.

MEASURE

In the measure phase, the black belt operationalized the project objectives as requirements on quantifiable and measureable performance characteristics and established procedures to measure these characteristics. In Lean Six Sigma, these characteristics are often called CTQs. We can schematically illustrate how the CTQs relate to the project goal and strategic focal point of the organization by means of a CTQ flowdown (cf. De Koning and De Mast 2007). The CTQ flowdown for this project is shown in Figure 2. A CTQ flowdown is particularly useful to make a problem quantifiable and to focus on the most important quality characteristics.

In this project, the black belt split up the CTQ OEE into four measurable constituents:

1. Changeover and startup time. This is the time it takes to reinstall the machine for the encapsulation of a new batch. Reducing changeover or startup time will result in a higher availability rate.
2. Time lost by stops. This also affects the availability rate. The black belt distinguished two types: major stops (which are complete machine stops) and minor stops (small interventions by operators to ensure continuation of the encapsulation process).
3. Speed loss. This includes losses due to the fact that the machine is running at a lower speed than theoretically possible. Speed loss is considered a loss of performance.
4. Encapsulation time. Finally, when the changeover time, time lost by startups and stops, and speed loss are substracted from the planned production time, we get the encapsulation time, which determines the actual production time. Increasing encapsulation time, or equivalently decreasing one of the constituents above, leads to a higher OEE.

The OEE was measured on a weekly basis, and the constituents actual production times and changeover times were measured per batch. The consituent (production) stops was measured per day. To measure stops, the black belt used a newly designed form that

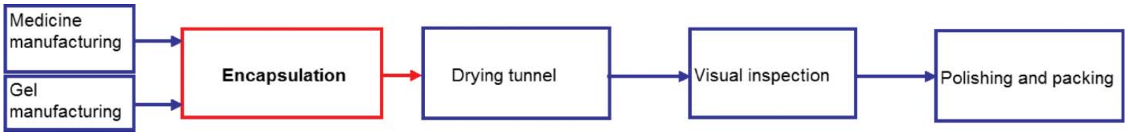

FIGURE 1 Main process steps.

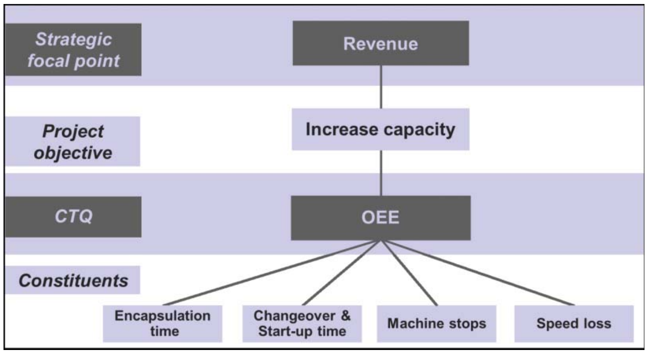

FIGURE 2 CTQ flowdown of the project.

enlisted all minor stops (machine stops that took less than 5 min) and left blank space to specify major stops (stops that took more than 5 min) in terms of time and cause. Before measurements started, the black belt assured commitment from the shopfloor and proper understanding of the measurement plan.

To obtain enough measurements, the black belt measured the constituents for a period of 3 weeks. The OEE was already being tracked about 15 weeks for the total encapsulation process by dividing actual production (effective production time) by design capacity. However, the validity of these measurements was questioned. To address this issue the black belt placed a digital counter measuring the actual encapsulation time of the machine. Because the *end time* − *start time* of a batch equals *changeover time* + *stops* + *speed loss* +*encapsulation time*, the black belt could validate his measurements. Moreover, the black belt had a better idea which constituent was dragging the OEE down.

ANALYZE

In the analyze phase, the current performance of the CTQs is determined, based on the collected data. A thorough analysis leads to a diagnosis of the problem and a list of potential influence factors. From the initial 15 measurements the black belt found that the mean of the OEE was about 69.0% with a standard error of 1.2%. The new measurements with a digital counter at the line gave nine more valid measurements with an average OEE of 67.3% and a standard deviation of 3.5%. A two-sample *t* test showed no significant difference. Moreover, the black belt let the operators keep track of all hours spent on changeovers, stops, speed loss, startup, and encapsulation. The decomposition of the planned production time into these constituents is depicted in Figure 3.

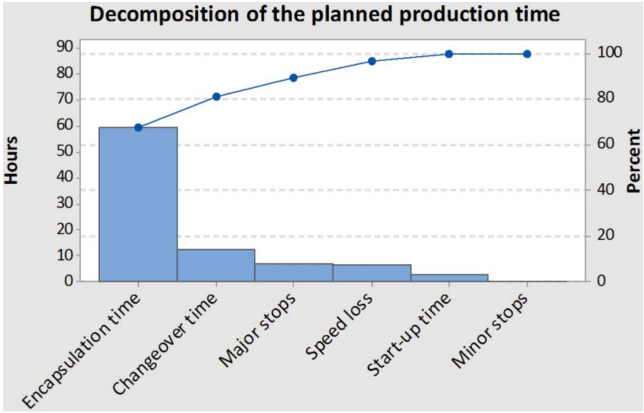

FIGURE 3 Pareto chart showing the decomposition of the planned production time of week 38.

Considering the constituents of the CTQ, we start with the changeover time, which is graphically illustrated in Figure 4. The black belt found that changeovers were taking approximately 4:51 h per batch, while the norm was set to just 4:00 h. Remarkable is the variation in Figure 4; if one knows the influence factors between fast and slow changeovers one can enhance the availability.

To find relevant influence factors for the changeover time the black belt performed a BOB vs. WOW study. That is, comparing the best-of-the-best (BOB) cases with worst-of-the-worst (WOW) cases. The BOBs were changeovers involving three operators. The few occasions involving high changeover times, the WOWs, were related to changeovers without a next scheduled batch or there was only one operator performing the changeover.

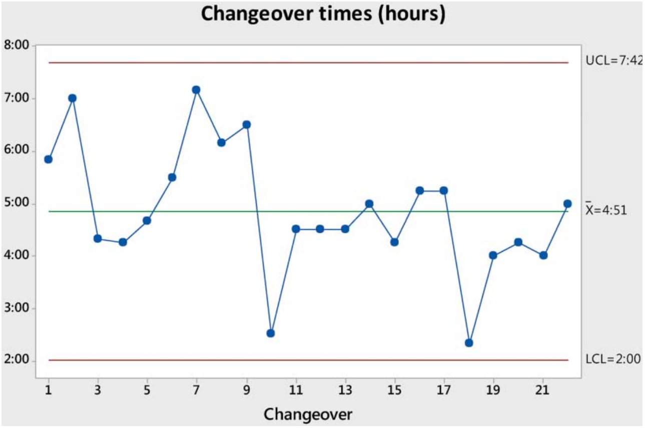

FIGURE 4 Control chart of the changeover times.

To find more influence factors the black belt went to the shop floor to study several changeovers in detail, which is called a Gemba study (Womack 2011). The black belt found that the necessary materials for a rapid changeover were often not available, so that personnel spent a lot of time acquiring the required materials. The black belt also found that the sequence of carrying out a changeover was not logical.

The constituent machine stops was divided into major and minor stops, both affecting the availability of the machine. While measuring, the black belt found out that minor stops occurred less frequently than expected. Combined with the fact that these stops are resolved within 5 min the black belt did not further focus on this constituent.

For the major stops, the operators were asked to precisely clock the amount of time it took to resolve the stop and to formulate the cause of the stop. An overview of the time lost by cause is given in Figure 5.

The empty Sbox is the machine stop in which the spreader box fails to spread up the gelatin properly and the oil application system (OAS) stop concerns the malfunctioning of the system. Most major failures come from specific shortcomings of the machine. The black belt found by these measurements that there are two main problems: waiting for soft gelatin and cutting-out problems. Focusing on these major failures, he found that cutting-out problems come from specific shortcomings of the machine. The waiting time for soft gelatin originated from poor production preplanning. Furthermore, the black belt performed a failure modes and effect analysis to find and prioritize each failure mode in the process.

The startup times and speed losses were also recorded but were not the focus during this project, because these constituents were performing better than expected. The improvement actions are focused on reducing changeover times and time lost due to major machine stops.

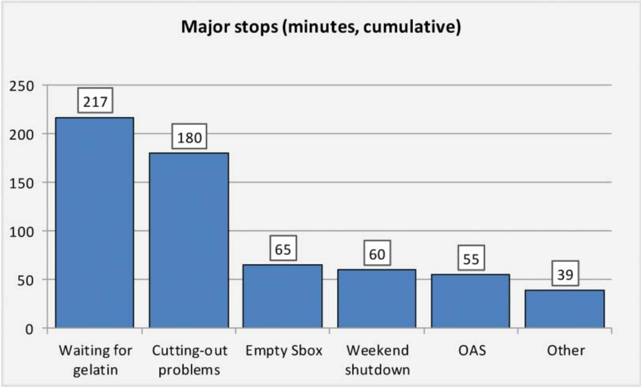

FIGURE 5 Bar chart of major machine stops.

IMPROVE

In the improve phase, the black belt selected the most important influence factors and provided evidence of their effects on the CTQ. Based on these influence factors he designed improvement actions that would result in a large improvement,

Firstly, the changeover times were reduced by about 40%, which is on average more than 2 h. A key principle is organizing rapid changeovers, originating from single-minute exchange of die (Ohno 1988). The following steps led to this improvement:

1. The belt defined critical aspects of a smooth changeover with help of the operators, and developed a changeover car accordingly; see Figure 6. By using this car the required materials for a changeover can be prepared beforehand and the used materials from the machine can be put on the car and can be washed all together. This eliminates excessive motion and waiting times. A standard operating procedure is designed based on best practices by senior operators.

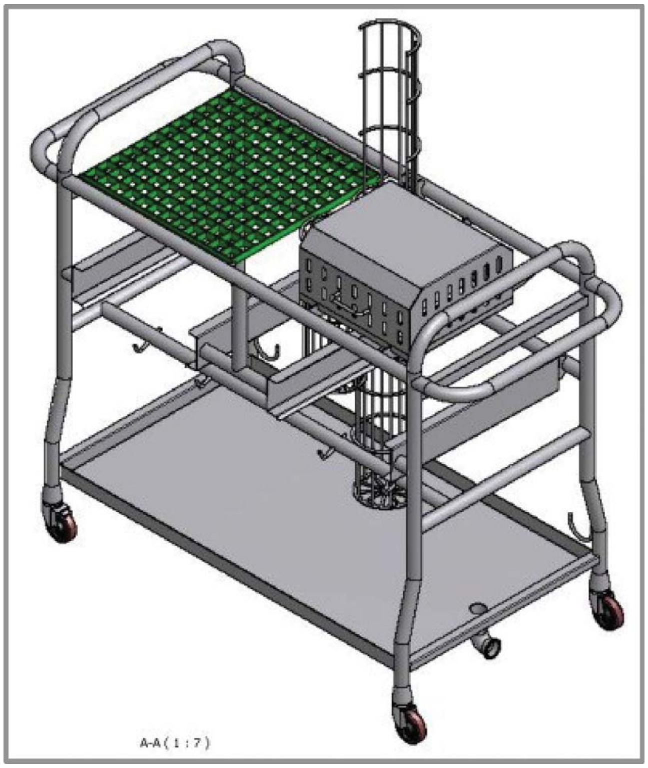

FIGURE 6 Newly designed changeover car.

2. A senior operator always helps for half an hour with a changeover or, when available, a second operator is also assigned to assist with the changeover.
3. The performance of the changeovers is being tracked daily by a production manager as part of the OEE tracking.

Secondly, the black belt improved the production cycle, so that every process step is subordinated to encapsulation machine. Subordinating other process steps to the process step that is the bottleneck is a fundamental principle in the theory of constraints (Goldratt 1984). Specifically, the black belt improved the following:

1. The process flow: A day ahead everything is set ready for a new batch. At this point there is still time left to take effective countermeasures when there are disturbances. This is signed off by the setup employee and senior operator as a formal handover 24 h prior to the actual production.
2. The inventories of machine parts to proceed batches, such as dies, pumps and spreader boxes, are redesigned and labeled according to 5S, which is typical for controlling a new process (De Mast et al. 2012). Every relevant material is inspected on its quality and labeled accordingly, so that operators know exactly which material they pick. Materials that do not match the quality norms are disposed.
3. Improved planning so that the major stop (i.e., waiting for soft gelatin) is resolved.
4. Implemented modifications on the machine in cooperation with expert operators, which resolved cutting-out problems, spreader box failures, and malfunctioning of the OAS.

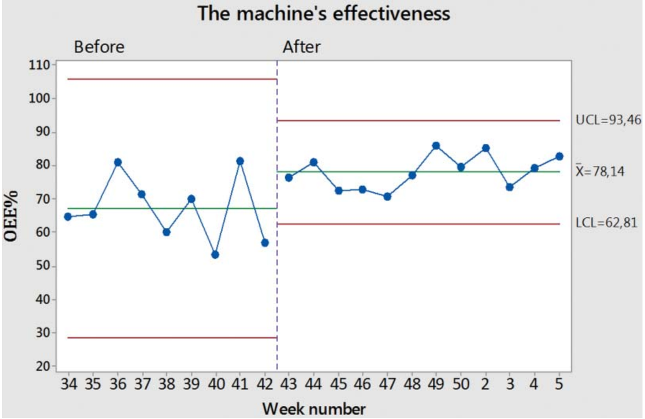

FIGURE 7 Control chart of the OEE on a line.

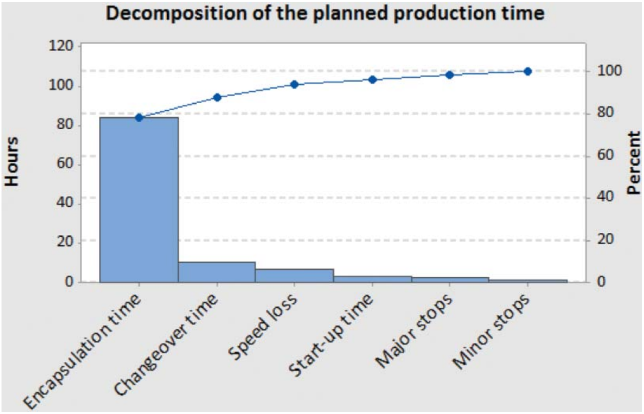

FIGURE 8 Pareto chart showing the decomposition of the planned production time of week 48.

After all of these improvements the black belt continued his measurements of the OEE and its constituents. He found that the OEE increased, which can be seen in Figure 7.

Evidently, a Kruskal-Wallis test supported these findings. The OEE for this line increased by 16.1–78.1%. At the same time, the variation in the OEE declined as well. The new decomposition of the planned production time is depicted in Figure 8 (week 48).

Note that the percentage corresponding to the encapsulation time is indeed the OEE% given in Figure 7. Comparing Figure 8 to the old situation (see Figure 3, week 38), the changeover time and major stops were reduced significantly. The other quality measures did not change significantly. The yearly monetary benefits are about €400,000 for this line. Because the site has five lines, which were improved accordingly, the estimated benefits aproch approximately €2 million.

CONTROL

In the control phase, the black belt improved the process control system. He documented the improved process, created a control plan to deal with irregularities in the process, organized continuous improvement, and defined roles and responsibilities.

To control the process after the improvement, the CTQs and some of its constituents are still monitored on a per line basis. These metrics are reported daily on dashboards, which are overseen by the senior production manager and management. The monitoring of the OEE is linked to an out-of-control action plan, which comes into force when the OEE is below its control

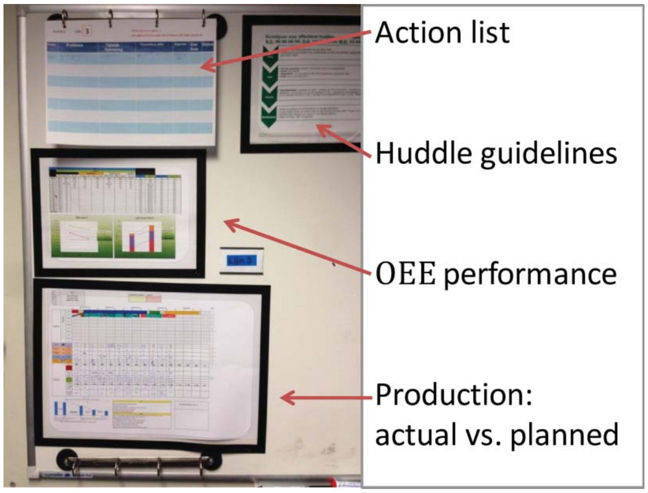

FIGURE 9 Monitoring line performance.

limits (cf. Does et al. 1999). See Figure 9 for the dashboard that is used for monitoring the line performance.

Next to the line performance monitoring, the black belt extended the visual management system for tracking various batches through the process. This extension was needed so that all operators know exactly when and what to prepare for changeovers and which raw materials have to be manufactured in advance. This is done according to a Heijunka production board and gives high-level management information. The Heijunka production board is a vital tool in lean management to sustain production efficiency (Ohno 1988).

CONCLUSION

This study provides an application of a Lean Six Sigma project on equipment effectiveness in a pharmaceutical company. Core principles of Lean Six Sigma, such as problem structuring with the help of the CTQ flowdown and a thorough analysis of the problem, helped a great deal to find effective improvements. Key principles such as the OEE, bottleneck analysis, single-minute exchange of die, and 5S are implemented to achieve an increase in production. The black belt improved the effectiveness of the machines by approximately 16%, leading to monetary benefits reaching up to €2 million each year.

Finally, the process is made manageable by implementing dashboards. These dashboards provide updates on a daily basis on the effectiveness and the current status of each batch at the production site. Furthermore, this visual management system helped to secure the new production levels at the pharmaceutical company.

ABOUT THE AUTHORS

Alex Kuiper obtained his master's degree in mathematics and econometrics from the University of Amsterdam in 2013. Currently, he works for the Institute for Business and Industrial Statistics as a Lean Six Sigma Consultant and is a Ph.D. student at the University of Amsterdam. His current research interests include applied statistics and stochastic optimization.

Michiel van Raalte is a Lean Six Sigma Black Belt and the owner of Durapharm BV. He obtained a master's degree in pharmacy in 1998. Since then he has worked as a qualified person and manager at many sterile manufacturing sites. He fulfilled roles as startup, production, and operational excellence manager. He has a broad experience in realizing quality and production improvements.

Ronald J. M. M. Does is Professor of Industrial Statistics at the University of Amsterdam; Managing Director of the Institute for Business and Industrial Statistics, which operates as an independent consultancy firm within the University of Amsterdam; Head of the Department of Operations Management; and Director of the Institute of Executive Programmes at the Amsterdam Business School. He is a Fellow of the ASQ and ASA and Academician of the International Academy for Quality. His current research activities include the design of control charts for nonstandard situations, health care engineering, and operations management methods.

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