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The contribution of lean manufacturing tools to changeover time decrease in the pharmaceutical industry. A SMED project.

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Abstract

Every industry has a growing need to improve quality, output and voice of the customer satisfaction. The purpose of this paper is to exhibit the achieved results after implementing SMED tools at a certain production line in the Romanian pharmaceutical industry. Completing Changeovers between products on a certain packaging machine using Single Minute Exchange of Dies (SMED) technique offers the possibility to shorten the machine downtime, increasing the final output. Implementing Lean Manufacturing philosophy, major Changeover time at the bottleneck process decreased by 30% in 12 months. Along with the economic benefits from the SMED implementation, process quality, standardization and teamwork have been improved.

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Keywords: SMED; pharmaceutical industry; changeover time; lean manufacturing; Gemba walks.

1. Introduction

Being able to evolve in industry at different operating levels means not only the fact that every employee has to over-perform each day; it also means that a stable and reliable workflow has to be established in order to support and sustain performance. Lean Manufacturing offers the proper tools in order to reduce the waste inside and between different processes, being able to increase the value of the product. Lean principles sort the activities for

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achieving a product into Value added (VA) and Non Value Added (NVA). The waste elimination principle is to minimize the NVA and focus on the VA activities [1][2][3]. Obtaining fast results in the shortest period of time is every company’s target, but which are the optimal methods in achieving this? Among other lean tools, the Single Minute Exchange of Dies (SMED) may be a very efficient method for reducing inventory [4] and mainly CO times in the production area between different batches, products or machine setups especially by converting internal steps (while machine is stopped) into external ones (while machine is still running) and shortening the steps that remained [5]. SMED assures a quick and efficient change from the currently running product to the next one.

The Changeover time is the amount of time spent between the last good piece of one product until the first good piece of the next product. The paper aims to present the implementation sequence and level of importance regarding Lean-SMED techniques at a pharmaceutical solids production site.

### Nomenclature

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>SMED</td>
<td>Single Minute Exchange of Dies</td>
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<tr>
<td>CO</td>
<td>Changeover</td>
</tr>
<tr>
<td>VA</td>
<td>Value added</td>
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<tr>
<td>NVA</td>
<td>Non-Value added</td>
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<tr>
<td>OEE</td>
<td>Overall Equipment Efficiency</td>
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<td>KPI</td>
<td>Key Process Indicator</td>
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<td>FTE</td>
<td>Full Time Equivalent</td>
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<tr>
<td>DMAIC</td>
<td>Define Measure Analyse Improve Control</td>
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<tr>
<td>EMS</td>
<td>Electronic Manufacturing Software</td>
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<tr>
<td>LM</td>
<td>Lean Manufacturing</td>
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</tbody>
</table>

### 2. SMED background and benefits

Single Minute Exchange of Dies assures a quick and efficient change from the currently running product to the next one. The Changeover time is the amount of time spent between the last good piece of one product until the first good piece of the next product. This amount of time is spent on cleaning and changing the machine parts and setup for next product. Appropriately implementing SMED improvement system may represent the key factor into a rewarding batch size reduction objective, which would assure more flexibility and improved product flow in the manufacturing area [5]. Single Minute Exchange of Dies described by Shingo [6] assumes that a Changeover should take place in a single digit expressed time (under 10 minutes). Nowadays the techniques for achieving a single digit Changeover time were acquired and implemented in the manufacturing areas in order to shorten and standardize the downtime between two batches by implementing different tools and techniques [7]. By observing the current methodology, separating the internal and external activities, streamlining the process of Changeover and continuous training the major SMED steps will be achieved and implemented [5]. The expected results will return an economic benefit reflected in an increased product output. Beyond the economic VA benefits, by decreasing the Changeover time further NVA achievements such as better ergonomic conditions, standardization, teamwork and workload are expected [8]. An integrated Overall Equipment Efficiency (OEE), a Key Process Indicator is expected to be raised by decreasing the equipment downtime lost with Changeover [9], [10], [11].

### 3. Current needs analysis

The targeted company for applying the SMED project had a current need for shortening CO times at a certain production line. At the bottle filling machine are working 2 FTEs and a number of 37 CO processes had to be conducted each year with a mean CO time of 25,3 hours. The set target was reducing this time to 16 hours (37% decrease) by implementing Lean Manufacturing – SMED tools in order to shorten CO time, stabilize and reduce the standard deviation of the process [2][12][13][14].

The up mentioned steps being achieved the reliability of the process will increase, an important financial gain will be obtained and production planning will increase in stability.
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