Streamlined Procedures for Encapsulation Area

Author: Abner E. Rivera Recto
Manufacturing Competitive
Quality Management Program
Design Project Advisor: Dr. Rolando Nigaglioni, DBA..

ABSTRACT

A streaming analysis in the Encapsulation Manufacturing Area was performed with the purpose to identify opportunities of improvements for current changeover process. Current changeover process has the following steps; waste product collection, cleaning process, assembly, disassembly, batch entry and setup. The current assessment shows a total of twenty-nine (29) procedures which includes over six hundred (600) pages and around eight hundred (800) entries. The goal of the project is to simplify and standardize the Work Instructions, Qualifications, PPM's, eliminate and consolidate SOP's and update the Learning Plan and curriculum for operators. The benefits obtained were the following: a reduction from 29 procedures to 20 which means 31%, 616 pages were used with documents related to changeover now 309 pages are used for a 50% reduction. In the documentation entries, before there were made 893 entries after the implementation, 193 tickets are made for a 78% reduction.

DEFINE

PROBLEM STATEMENT

The capsules' filling area is currently performing the cleaning, assembly, and disassembly activities using a set of complex documentation and procedures. The current assessment shows a total of 29 procedures including over 600 pages and 800 entries.

It was found that some of the procedures could be consolidated to meet the company's needs. The current qualification procedures are impacting availability of qualified personnel in the testing activities. The customer's input indicated they take around one hour for filling the cleaning documentation.

The area also demonstrate inconsistencies in the equipment's assembly and disassembly procedures that required standardization. Part of this initiative includes the simplification of cleaning procedures and the update of the curricula and learning plan.

The objective of this project is to simplify and standardize the work instructions, qualifications, procedures and jobs aids as a part of the Capsule Changeover Operational Excellence Project. These activities include updating standardized, documentation procedures should be eliminated, and consolidate in new procedures for assembly and disassembly, the elimination and consolidate procedures and update the learning plan and curricula

RESEARCH DESCRIPTION

The cleaning process for the encapsulation area consists of six (6) different system procedures. When the operator receives the documentation then the cleaning process begins. An operator disassembles the machine while another operator in the production room removes the parts and transfers it to the wash pit area. The two operators start the cleaning process following the validated procedure.

RESEARCH OBJECTIVES

- To operate the cleaning process with one operator meeting the production standards assuming a 50% increase in efficiency.
- Increment the productivity

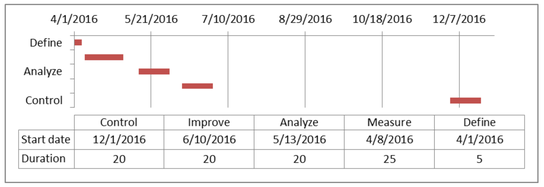
RESEARCH CONTRIBUTIONS

Meet the encapsulation process standards assumed in the Business Plan, and meet the 100% of the Production Plan requirements with the approved headcount. With this information create the best solution. Cost reduction due to new procedures will allow for no overtime expense and headcount.

METHODOLOGY

The problem-solving methodology that will be followed in order to eliminate the second person verifier will be the DMAIC improvement strategy from Six Sigma. It is primarily based on the application of statistical process control, quality tools, and process capability analysis. This methodology uses a process-step structure that generally is sequential.

Project Plan



	Control	Improve	Analyze	Measure	Define
Start date	12/1/2016	6/10/2016	5/13/2016	4/8/2016	4/1/2016
Duration	20	20	20	25	5

Figure 1 "Project plan Gantt chart for Streamlined Procedures for Encapsulation Area".

MEASURE

The purpose of the process map is understand the process steps. During this process analysis we can identify areas of opportunities and improvement. Another important information obtained from the process steps, the process map allows to understand the critical areas and how is the performance.

- ✓ Solutions:
- ✓ Several procedures were eliminates
- ✓ Consolidate Instructions
- ✓ Consolidates Procedures
- ✓ Align practice with procedures
- ✓ Eliminates unnecessary entries
- ✓ Standardize the documentation
- ✓ Standardize and align the cleaning sequence activities
- ✓ On the Job Training
- ✓ Process Schools

MEASURE

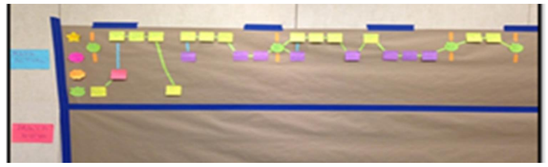


Figure 2 "Actual cleaning process".

Baseline:
The cleaning, assembly, and disassembly activities was established per product change over for the encapsulation machine.

ANALYZE

The Value Stream Map was created in order to gather ideas for documentation and cleaning reduction. The Process was divided in different process. This allowed for an easier pinpoint the procedures that could be reduced or consolidated. In this phase, a multidisciplinary team was used, operation and quality personnel are involving for better process understanding..

Figure 3 "Actual cleaning process vs future cleaning process

IMPROVEMENT

The procedures was decrease 31% before the project the area has 29 procedures after the consolidation now consist of 20 procedures (SOP's). The pages used for the documentation steps before the implementation consist in 616, after the implementation 309 pages area used. This represent a 50% of reduction of pages used. The documentation entries for signatures and dates was reduce in 78% before the implementation the operator make 893 entries now after the implementation the operator make 193 entries..

CONTROL

- The complete implementation in the major cleaning process was December 2016
- Process School was completed December 2016
- Monitoring Data Entry Human Error for Q1 2017
- Use the VOC collection Q12017
- The following Pie Chart graphs show the 50% time reduction

Capsules H&K Productivity Pie Chart from Jan/2016 to Sep/2016

- 16% Equipment
- 15% No equipment
- 3% Other
- 66% Change Over

CONTROL

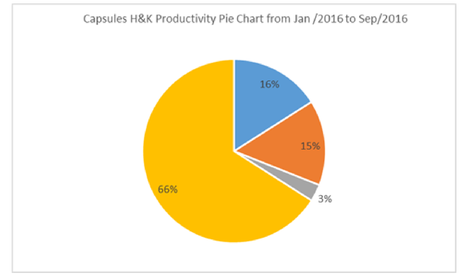


Figure 4 "Capsules H&K Productivity Pie Chart from Jan/2016 to Sep/2016".

Capsules H&K Productivity Pie Chart from Oct/2016
13% Equipment
30% No Equipment
4% Other
51% Change Over

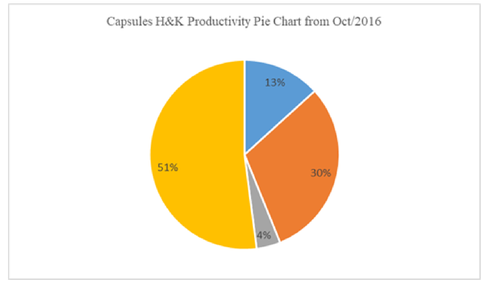


Figure 5 "Capsules H&K Productivity Pie Chart from Oct/2016".

CONCLUSIONS

The Six Sigma methodology provide the necessary structure to perform an evaluation the quantitatively process perform and how the operational activities are performed. The information obtained during the evaluation is used to reduce the waste and improving the process with the purpose of reach the project goal.

Using the Six Sigma methodology, the capsules filling area was evaluated. The cleaning, assembly, and disassembly activities contain complex procedures and documentation.

As part of the Define phase, in the VSM map, the capsules filling area were improved in order to reduce the cleaning process, assembly, and disassembly activities using the a new procedures and documentation that eliminate the 50% of the activities related to the cleaning process.

REFERENCES

[1] Jardzioch, A. and Skobiej, B., "ANALYSIS OF VARIABLE CHANGEOVER TIMES IMPACT ON THE REVENUE IN MANUFACTURING PROCESS", 2013.

[2] Patel, K. T. and Chotai, N. P., "Documentation and Records: Harmonized GMP Requirements", 2011.

[3] Jardzioch, A. and Skobiej, B., "ANALYSIS OF VARIABLE CHANGEOVER TIMES IMPACT ON THE REVENUE IN MANUFACTURING PROCESS", 2013