Streamlined Procedures for Encapsulation Area

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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.*

Key Terms *— DMAIC, Encapsulation Area, Procedures, Standardization.*

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 demonstrates 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. When the operators complete the cleaning process in the wash pit area they move to the process room and cleaning the machine and the room. The lengthy process is taking four (4) shifts to complete.

RESEARCH OBJECTIVES

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

- Obtain an effective shift structure.
- Man hour's reductions.
- Reduce training hours.

- To increase productivity.
  - Maintain continuous operation.
  - Reduce the delay orders.
  - Reduce the overtime.

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.

LITERATURE REVIEW

The pharmaceutical process is a regulated environment because it affects the health of the patients. The good manufacturing practices is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. The good manufacturing practices (GMP's) are aimed primarily at diminishing the risk inherent in any pharmaceutical production [1]. The good manufacturing practices (GMP) are that part of quality assurance which ensure that products and activities related to the pharmaceutical manufacturing process are consistently produced and controlled to the quality standards appropriate to their intended use [1].The good manufacturing practices are a set of rules developed by the government in the U.S. Code of Federal regulations (21CFR). These are the rules that were written to require food and drug manufacturing to proactively maintain proper product-safety measurement [2]. The pharmaceutical process use the standard operating procedures (SOP's) documents to provide specific step by step instructions for performing the operational task or activities. It is critical that good procedures are in place to ensure a controlled and consistent performance. Clearly written procedures prevent errors resulting from spoken communication, and clear documentation permits tracing of activities performed [1]. Based on these risks, a pharmaceutical facility develops procedures and processes with engineering and cleaning controls like Good Manufacturing Practices (GMP's) to ensure that all of its products are manufactured following the standards and requirements observed by different audit agencies throughout the world [2]. The method to obtain the desired results include batch records, standard operating procedures, equipment, facilities, and others systems.

The CFR 21 contain the Subpart D – Equipment establish that the equipment and utensils shall be cleaned, maintained as appropriate [1]. The cleaning process is one of the most important processes to guarantee that the equipment's and accessories and facilities are decontaminated to maintain continuous process. [2] During the different types of cleaning processes working instructions and verification instructions are established in order to be followed during the execution process by manufacturing operators. The pharmaceutical standard requires one manufacturing operator related to the task and second operator for verification the execution of the task according to the procedure. The records of major equipment use, cleaning, sanitization and/ or sterilization, and maintenance should show the date, time, product, and batch number of each batch processed in the equipment and the name and signature of the persons who performed the cleaning and maintenance [1]. Documentation is the key to good manufacturing practices compliance and ensures traceability of all development, manufacturing and testing activities [1].

The time needed for a changeover depends on the scope of necessary activities. The time is variable; in fact not only do they depend on the type of a job to be processed, but also on what a given machine was processing before [3]. A streaming analysis in the Encapsulation Manufacturing Process was performed with the purpose to identify opportunities of improvement

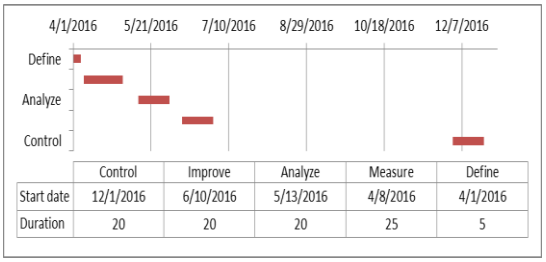
for the current changeover process. During the continuous improvement project the current changeover processes were assessed this includes the different types of cleaning. A risk assessment was conducted and documented the technical and scientific approach use to analyze, prevent and control the risk associated to avoid the cross contamination, commingle, mix-up and carryover of product between batches [2].

The evaluation of this risk was considered in the assembly, disassembly, and waste product collection, cleaning batch and entry setup. The purpose was to simplify and standardized the Work Instructions, Qualifications, and Procedures as a part these work .This reduces the cost, changeover time and increase the manufacturing capacity incrementing the efficiency of the manufacturing process [3].

METHODOLOGY

The problem-solving methodology that will be followed in order to simplify the documentation and the entries at 50% will be use 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. The steps of the DMAIC are:

- **Define Phase:** This step consists in defining the scope, goals and the work effort of the project. It will determine possible opportunities of improvement and the people that will be benefit from the overall results. A project plan was developed to have a standard approach.
- **Measure Phase:** The objective of this step is the collection of the key aspects of current process performance. It this step the data available at its source will be identified. A data collection and detailed process flow diagram is often used. The tools to be used to show visual representations of the current state are graphs, charts, flowcharts and a SIPOC diagram.
- **Analyze Phase:** This step consists on identifying the root causes with the objective of isolating the problem. The key components of this phase include cause-effect, root cause and value- non value added analysis. Value stream map will be used to analyze the data.
- **Improvement Phase:** The objective of this step is optimizing the current process based on data analysis. It is based on the identified root cause(s) in the prior step and directly addresses the cause with an improvement.
- Project Plan
  In this process it helps to establish the scope of when it will be implementing the project. It is one of the most important processes of project management.



	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

Figure1
Project plan Gantt chart for Streamlined Procedures for Encapsulation Area

RESULTS AND DISCUSSION

Communication of final results and conclusion is formally documented by the approval report. The results of the official report will be communicated to the Team members prior the beginning of the implementation of the change. All the activities performed in the current changeover process were evaluated as waste product collection, cleaning process, assembly and disassembly steps. The proposal change during the changeover activities do not represent a risk of cross contamination during the changeover processes. The current cleaning process has identified the critical areas that need to be inspected to avoid the risk of cross contamination .These areas will continue inspected using the current clearance procedures and visually inspection by qualified personnel. Production

Department will be train all personnel in the new changeover strategy through a process school.

- **Define Phase** - The capsules filling area is currently performing the cleaning, assembly, and disassembly activities using a very complex documentation and procedures. Current assessment shows a total of 29 procedures with include over 600 pages and 800 entries. We found that some working instruction could be consolidate another need to be aligned to new business needs. The actual qualification documentation is impacting availability of qualified personnel in the testing activities. In addition, voices of the customers from the user are said they take around one hour for filling the cleaning documentation. We also have inconsistency in the assembly and de-assembly instruction of the equipment and need to standardize. As part of this initiative, it was required to simplify the cleaning documentation.
- **Goal -** The goal of the project is to simplify the documentation and reduce the entries at least 50%.
- **Business Impacts** - Reduction of the man hours during the cleaning process and reduction of the training hours during the manufacturing operator's certification.
- **Project Scope**
  - **In Scope** - Capsule filling change over associated documentation: Work Instructions, Qualifications, PPM's, Procedures (SOP's) and Training Curriculum.
  - **Out Scope** - **M**anufacturing Tickets, Mixing & Incorporation steps Change over associated documentation.
- **Team Members:**
  - Engineering
  - QA Assurance Rep.
  - Production
  - Training
  - Operators
  - Sponsor

- **Project Plan**

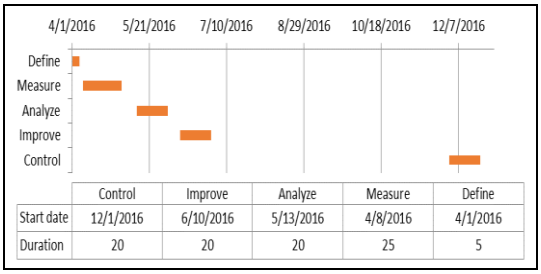


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Figure 2
Project Plan for Streamlined Procedures for Encapsulation Area

- **SIPOC -** Root Causes:
  - Too many procedures pages
  - Too many entries (sing/Date)
  - Duplicate information
  - Chronological order
  - Excessive documentation time
  - Data entries errors
- **Measure Phase**
  - The purpose of the process map is to understand the process steps. During this process analysis we can identify areas of opportunities and improvement. Another important information obtained from the process steps is the process map which allows for the understanding the critical areas and how these areas perform.
  - **Solutions**:
    - ✓ Procedures were eliminates.
    - ✓ Consolidate instructions.
    - ✓ Consolidate procedures.
    - ✓ Align practice with procedures.
    - ✓ Eliminate unnecessary entries.
    - ✓ Standardize the documentation.
    - ✓ Standardize and align the cleaning sequence activities.
    - ✓ On the job training.
    - ✓ Process Schools.

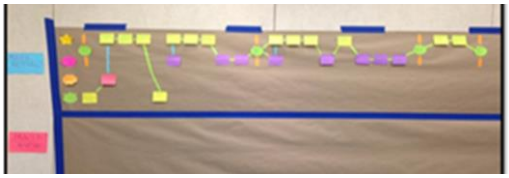

Figure 3
Actual Cleaning Process vs. Future Cleaning Process

- **Baseline** - The cleaning, assembly, and disassembly activities was established per product change over for the encapsulation machine.
- **Analyze Phase** - The Value Stream Map was created in order to gather ideas for documentation and cleaning reduction. The Process was divided in different steps. 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 4
Actual Cleaning Process vs Future Cleaning Process

- **Improve Phase** - The procedures were decreased by 31%. Before the project, the area had 29 procedures after the consolidation now it's of 20 procedures (SOP's). The pages used for the documentation steps before the implementation consisted of 616, after the implementation, it was reduced to 309 pages. This represents a 50% of reduction of pages used. The documentation entries for signatures and dates was reduced by 78% before the implementation. The operator made 893 entries, now after the implementation the operator makes 193 entries.
- **Control Phase**
  - The implementation in the major cleaning process 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.

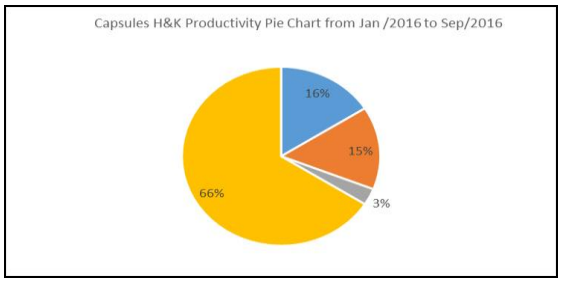

Figure 3
Capsules H&K Productivity Pie Chart from Jan/2016 to Sep/2016

16% Equipment
15% Equipment
3% Other
66% Change Over

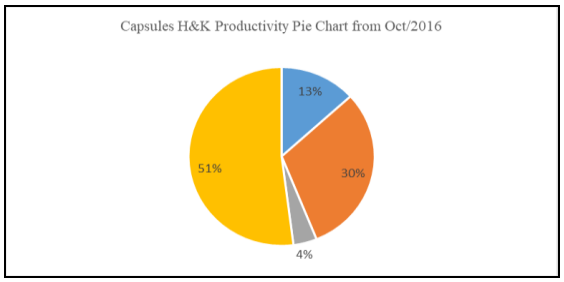

Figure 4
Capsules H&K Productivity Pie Chart from Oct/2016

13% Equipment
30% Equipment
4% Other
51% Change Over

CONCLUSIONS

The Six Sigma methodology provided the necessary structure to perform an evaluation, the quantitatively process performance, and how the operational activities were performed. The information obtained during the evaluation was used to reduce the waste and improve the process with the purpose of reaching 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.

The QA department must revise the procedures and all personnel involved in the execution of waste product collection, cleaning, equipment assembly

and disassembly must be properly trained in the new strategy of change over.

No adverse impact in product or process is expected with the implementation of these changes. A cleaning validation will be performed in order to ensure the success of the change. After implementation of these change when changeover is performed a swabs sampling strategy will be used to ensure that the change do not impact the cleaning effectiveness of the Encapsulation filling Area.

As part of the define phase, in the Value Stream Map, the capsules filling area were improved in order to reduce the cleaning process, assembly, and disassembly activities using the new procedures and documentation that eliminated the 50% of the activities related to the cleaning process.

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