LOT HISTORY RECORD STREAMLINE: A CASE STUDY

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Abstract

This case study details a process improvement performed at XYZ Pharmaceutical facility in Puerto Rico guided by the use of Lean and Six Sigma tools like DMAIC (Define, Measure, Analyze, Improve, and Control). The case study presents each DMAIC phase application in order to reduce the amount of manual entries and paperwork at a particular manufacturing line. For confidentiality purposes, the company real name, production lines and products will not be identified in depth of detail.

Introduction

For Companies that participate in a regulated environment by the Food and Drug Administration (FDA) it is critical not only to stay financially healthy but to be in compliance. If the company does not adhere to the required regulations in could incur in millionaire fees or even go out business. Being in compliance is a key factor to Medical device companies. More and more companies have been moving towards being a Lean enterprise by implementing Process Excellence tools not only as cost saving activities but to implement more robust processes as well. Lean enterprise, according to Stephen and James Rooney on a glossary featured in the June 2005 Quality Progress edition, is a manufacturing company organized to eliminate all unproductive effort and all unnecessary investment, both on the shop floor and in office functions.

Process Excellence and Lean initiatives have been pioneer by companies such as General Electric and Toyota. Toyota is well known for it Toyota Production System (TPS). TPS ensures that inventory is reduced to a minimum, employees are empowered to solve problems immediately, working cells are aligned together to assist communication among employees and ensure flow. This has been a determinant factor for Toyota to be competitive. In a comparison made between a Toyota Assembly plant and a General Motors (GM) plant in the book **The Machine that Changed the World** (Womack, Jones, Roos, 1990) showed in Table 1, it is clear how Toyota can lower costs by being more productive.

Table 1
General Motors Assembly Plant versus Toyota Assembly Plant (1986)

	GM Facility	Toyota Facility
Gross Assembly Hours per Car	40.7	18.0
Adjusted Assembly Hours per Car	31	16
Assembly Defects per 100 Cars	130	45
Assembly Space per Car	8.1	4.8
Inventories of Parts (average)	2 weeks	2 hours

Source: Womack, Jones, Roos (1990) **The Machine that Changed the World** p.81

In a similar fashion Genentech, a biotechnology regulated company, chartered an error proofing project using Six Sigma tools that led to significant improvement. According to the authors, Bottome and Chua, Genentech was able to reduce their discrepancy rate from an average of 9.87 to 3.74 by applying DMAIC and statistical tools.

All these applications have been no difference at XYZ Pharmaceutical in Puerto Rico. Cultural transformation has been taking place at that facility since 2003 when the vision and challenge given to the leadership team and the employees was to be a World Class Manufacturer by 2006. To support this strategy, XYZ enforced the use of Process Excellence tools like Lean, 5 S, and DMAIC strategy. It provided the tools and knowledge to the employees to be able to attack systemic issues, process issues, or areas of opportunity with the appropriate tools. This has been part of their continuous improvement philosophy. This case study illustrates one project related to the reduction of manual entries using Process Excellence tools.

Background Information

Company

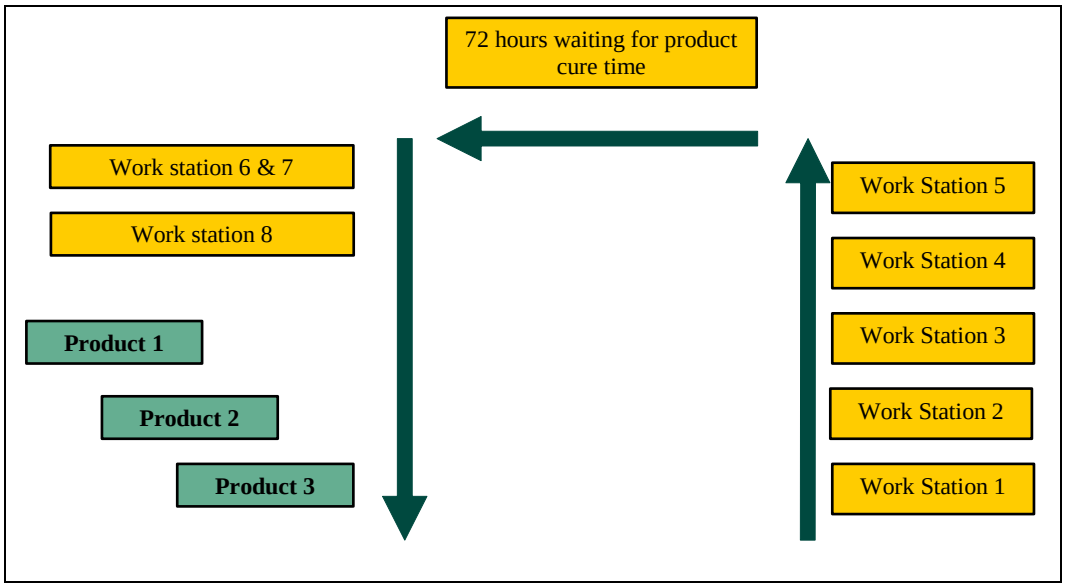
XYZ is a world class manufacturer of medical devices focus on innovative solutions and products for health care, including products for cardiovascular problems. The Puerto Rico facility has approximately 1,200 employees with both sides of the business: the cardiac surgery and the cardiac rhythm management. The Cardiac Surgery business has several lines dedicated to each product. Again, for confidentiality purposes, the lines and products will not be identified in depth of detail.

Problem Statement and Objective

One of the Cardiac Surgery lines processes three different products. Based on the Federal Drug and Administration (FDA) requirements, each lot needs to have a Lot History Record (LHR) which gathers all traceable information related to the

manufacturing of the lot. Therefore, for each product there is a unique LHR assigned to it. Figure 1 below details the High Level Product Process map of the mentioned line.

Figure 1
High Level Product Process Map



The requirements of the three different LHRs are the same for work station 1 up to 5. Because of the 72 hour cure time requirement, manufacturing personnel starts to process the product and records the information three times because they do not know which product will be required by the Master Production Plan (MPS) when it comes out of the 72 hours.

If by that time the product comes out of the cure operation it will not be processed, the attached LHR is void and product continue with the required LHR. It is a waste of paperwork, entries, and document handling as well as an increase in opportunity for error exposing the process to a traceability mistake and/or compliance risk.

The objective was to reduce the handling of paperwork related to LHRs at the manufacturing line and the amount of manual entries by at least 30%.

Business Case

When the amount of paperwork and entries are reduced, the compliance risk is reduced. A missing entry and/or misplaced LHR could cause a non conformity (NC) which will take approximately 13.75 hours of an Engineer's time just for investigation purposes. Lead operators are responsible for consolidating all paperwork in order to deliver to document control for retrieval. The more the paperwork the hardest it is to perform this task, and more mistakes can occur. When document control receives the paperwork they have to scan page by page the document and stored in a fireproof cabinet.

As paperwork increases more cabinet space is required and more time is lost for the document control specialist.

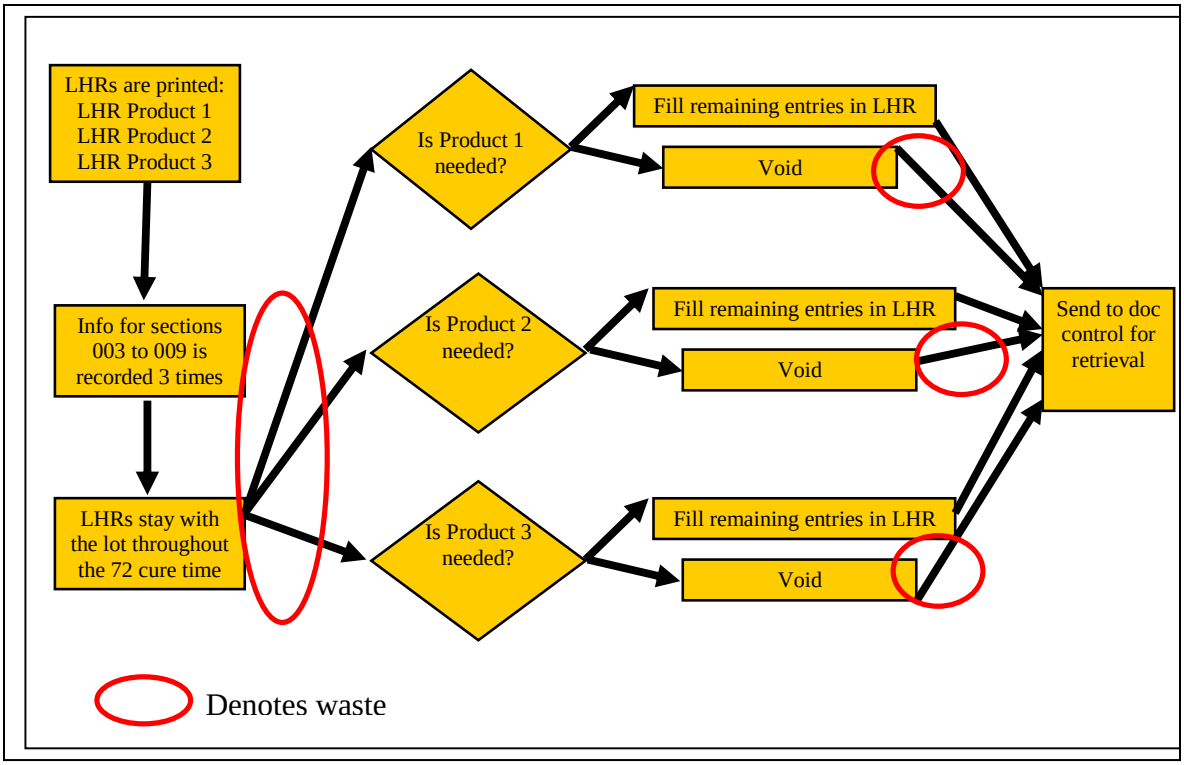
Project

The LHR Streamline project was implemented using Process Excellence tools like Lean and DMAIC. DMAIC phases are detailed above and serve as the case study analysis for the streamline of documentation.

Define Phase

A snapshot of the process was taken to understand the process flow (refer to Figure 1) as well as the High level process map. The High level process map allowed in identifying waste which denotes areas of opportunities that can be targeted as showed in Figure 2.

Figure 2
High Level LHR Process Map and Waste Identification



It serves to understand process inputs and outputs while observing the impact on suppliers, customers, and the SIPOC process (Suppliers, Inputs, Process, Outputs, Customers) and how the analysis was performed.

The SIPOC identifies the suppliers as those providing the required resources; in this case, the lead operator is identified as the supplier because he/she provides the LHR to

the manufacturing line. The inputs are resources required by the process. Because the process is the filling of the LHR, the inputs are the required entries. The process describes the top level activities, for the case study, they are the required LHR section and entries and need to be complete and accurate. The outputs are those deliverables from the process defined for the case study as the completed entries required in each LHR section (for example: equipment, components, and materials used). The customer is anyone who received the deliverable or output, in this case, the quality review personnel.

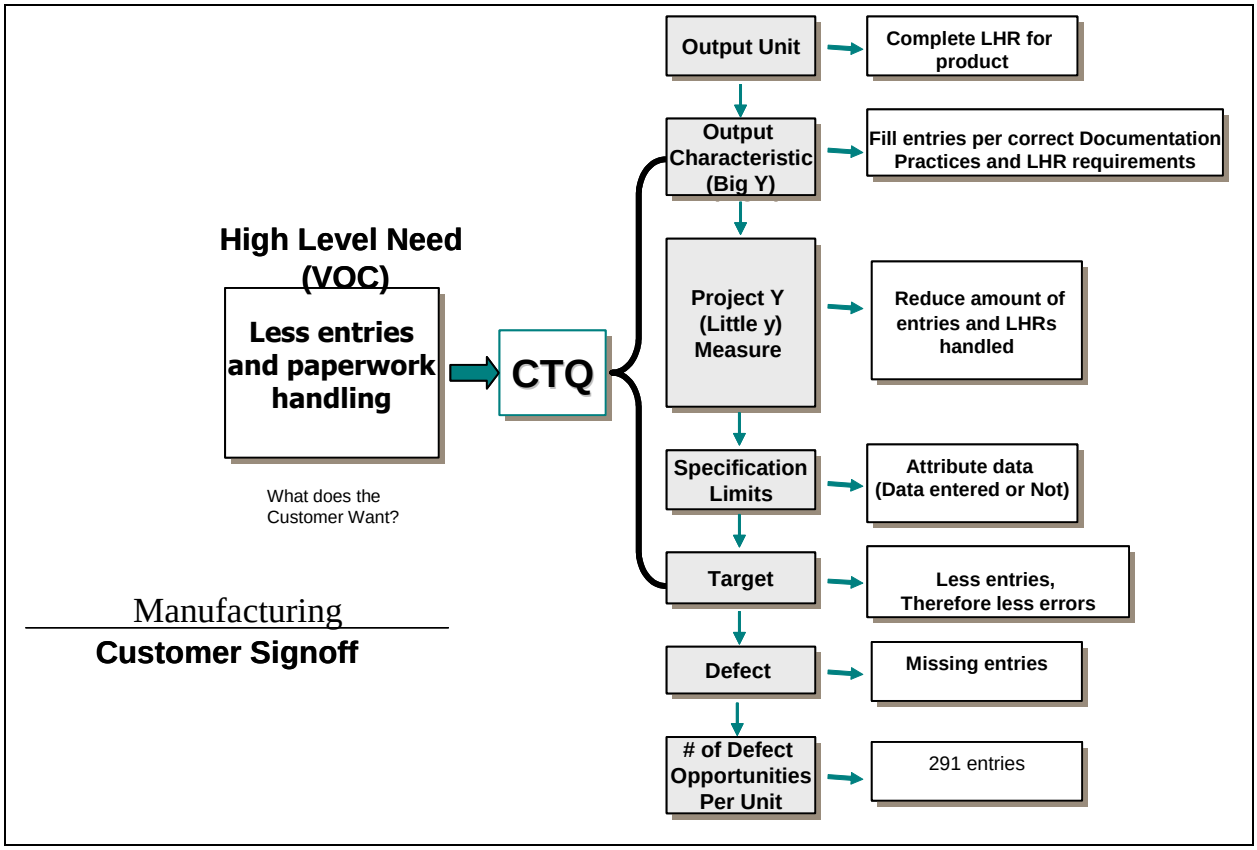
Figure 3
SIPOC

Suppliers (Providers of the required resources)	Inputs (Resources required by the process)	Process (Top level description of activity)		Outputs (Deliverables from the process)	Customers (Anyone who receives a deliverable from the process)	
		Requirements			Requirements	
Group Lead	Entries	To enter all required LHR section entries completely and accurate		Completed section of LHR with 8 equipment #s, 2 UV readings, 4 component lot #, and operator signature	Complete and accurate LHR section	Quality data review
	Entries			Completed section of LHR with 3 equipment #s, 2 component lot #, and operator signature		
	Entries			Completed section of LHR with 2 equipment #s, 2 component lot #, and operator signature		
	Entries			Completed section of LHR with 2 equipment #s and operator signature		
	Entries			Completed section of LHR with 1 equipment # and operator signature		
	Entries			Completed section of LHR with 2 equipment #s, 1 component lot #, 12 entries, and operator signature		
	Entries			Completed section of LHR with 4 equipment #s, 2 component lot #s, 12 entries, 2 UV readings, and operator signature		
Group Lead	Entries	To enter all required LHR section entries completely and accurate		Completed section of LHR with 2 component lot #s and operator signature	Complete and accurate LHR section	Quality data review
	Entries			Completed section of LHR with 7 component lot #s and operator signature		
	Entries			Completed section of LHR with 1 equipment #, 2 component lot #s, 2 scan formats, and operator signature		
	Entries			Completed section of LHR with 7 component lot #s and operator signature		
	Entries			Completed section of LHR with 2 equipment lot #s and operator signature		
	Entries			Completed section of LHR with 2 equipment lot #s and operator signature		
	Entries			Completed section of LHR with 1 equipment #, 2 component lot #s, 2 scan formats, and operator signature		

Note: Name of the specific operations from the Process section has been omitted due to confidentiality agreement with the evaluated company)

A voice of the customer (VOC) and CTQ analysis was performed to ensure that important customer required details are met which are also critical to CTQ. The analysis details measures, limits, characteristics, target, defects, and number of opportunities for error. Refer to figure 4 for CTQ and VOC analysis.

Figure 4
CTQ and VOC Analysis



Measure Phase

Because the amount of entries is the driver for the defect opportunity it needed to be measured in order to be reduced. Based on the current three types of LHR, the total amount of entries was 318; breakdown is detailed in Table 2.

Table 2
Types of LHRs and entries per each one

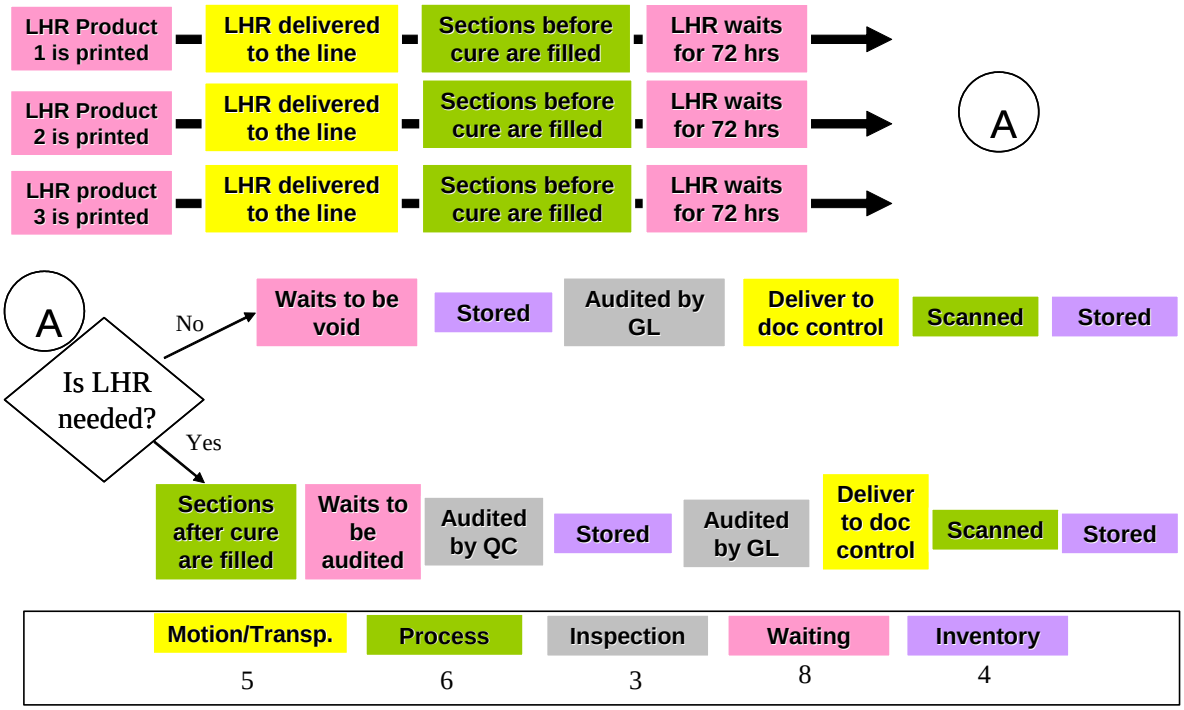
Types of LHRs	Entries per LHR
LHR Product 1	113
LHR Product 2	115
LHR Product 3	90

The FDA regulation also requires the entries to be accurate and complete. If there is a missing entry and/or incomplete or incorrect entry, a Non Conformance Material Report (NCMR) is generated. As a baseline, 5 months of information was taken were there were 18 NCMR generated due to traceability issues, meaning, incorrect or missing entries.

Analyze Phase

In addition to high level process map, activity process map assist in determining areas of opportunity to eliminate waste. In this case, waste means those non value activities. A color coding activity process map was created to classify activities in motion/transportation, process, inspection, waiting, and inventory. Being process the only value added activity.

Figure 5
LHR Activity Process Map before changes



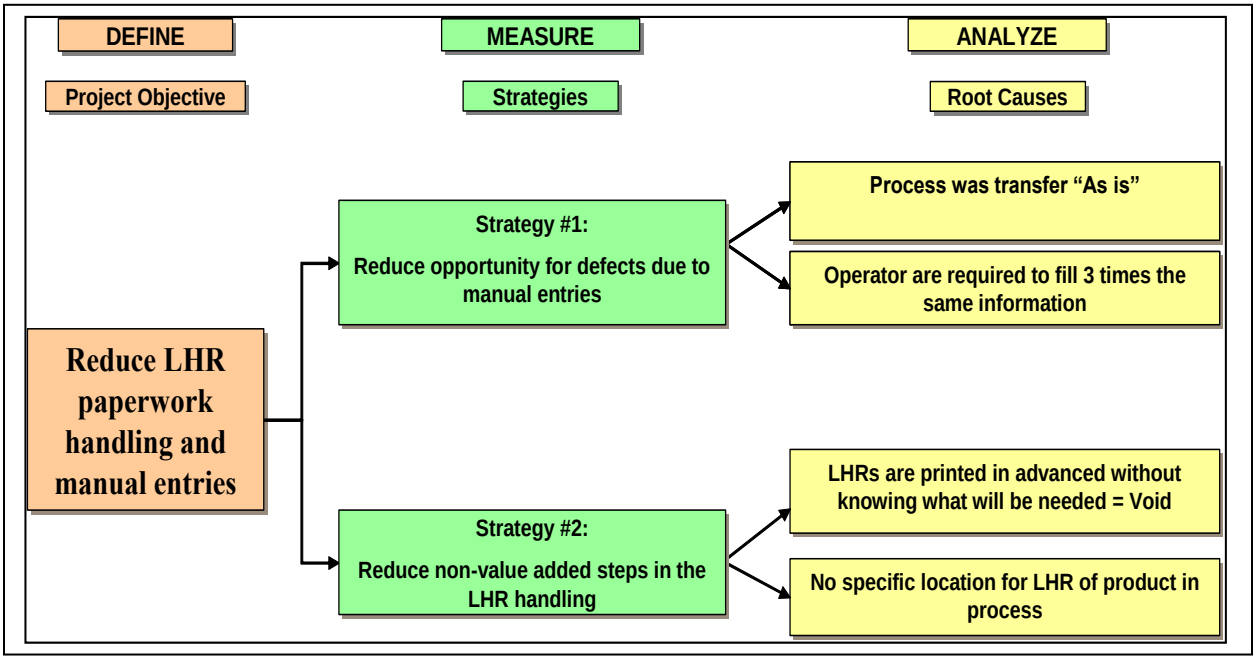
Three different areas were evaluated to identify where waste or non value added activities were taking place: Manufacturing, Document Control, and Quality Review. In addition, because the company participates in a regulated environment, this evaluation was also key to eliminate any compliance risk.

In Manufacturing operators recorded the same information 3 times which represents waste of entries and a compliance risk because of the opportunity for error (missing/incorrect entries) and information being transcript three times. Unused LHR were void which was a waste of time for operators to fill paperwork, lead operator to reconcile, and Engineers to explain with memos. In addition a compliance risk since there was no explanation recorded in the LHR on why raw data was voided. LHRs were stored in the fire proof cabinet until reconciled to be delivered to document control. This was a waste due to excess of paper handling and storage and a compliance risk because LHRs could be misplaced.

In Document Control all LHRs are scanned and stored which is a waste of time scanning and waste of space retrieving unused LHRs. For the Quality review it was excess paper handling, generation of NCMR increased, and a compliance risk because void LHR were most likely not audited.

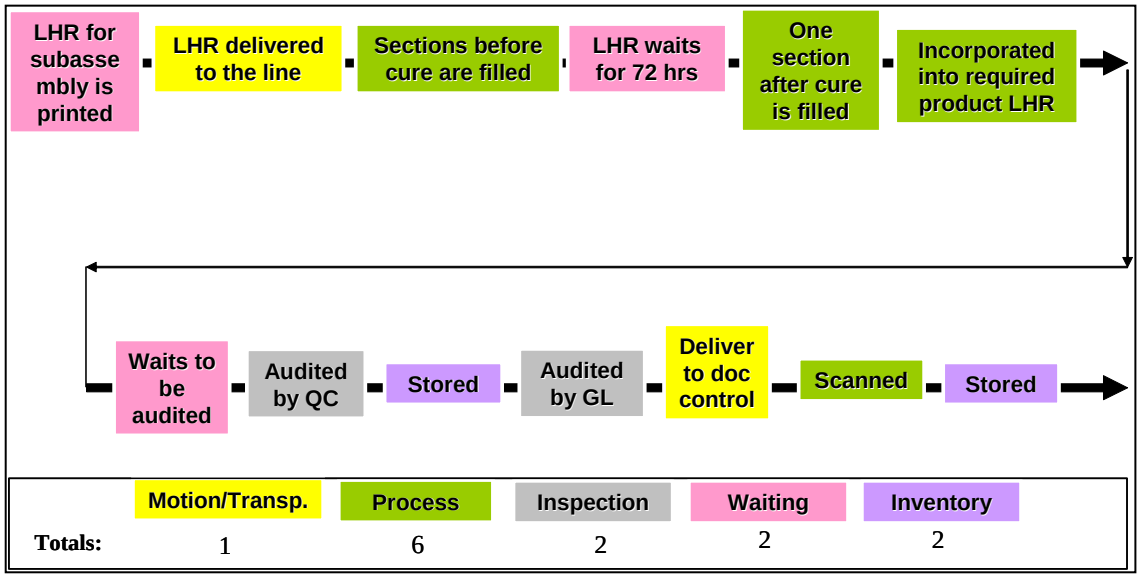
The opportunity was identified by following a strategy of combining shared LHR sections into an LHR sub assembly and printing the final portion for products 1, 2, or 3 as needed. To implement the strategy and understand the root cause of the problem, schematic showed in figure 6 was created. It details how to go from project objective to root cause analysis.

Figure 6
From strategy to root cause identification.



The opportunity identified proposed the reduction of those non value added activities as well as compliance risk situations. The non value activity reduction was proposed as detailed in figure 7.

Figure 7
Proposed Activity Process Map



Improve Phase

To be able to implement the opportunity identified, three strategies were used: communication to stakeholders, participation, and training. In terms of stakeholders, the project scope and intend was presented to the area team (supervisor, Manufacturing Engineer, and lead operators), the area operators, and the area Quality Specialists. An overview of the proposed new LHR format was provided to change approvers (Regulatory Affairs representative, Manufacturing Engineer, Document Control specialist, and Product Development Engineer). In relates to participation, feedback was gathered from the stakeholders and gained their commitment to embrace the change. A change request for current LHR was submitted for review/approval. Training was provided to operators and Quality Specialists.

The main purpose was the entry reduction, but there were several other changes that were submitted to take the advantage of the change order and their detail and purpose are highlighted in Table 3.

Table 3
High Level changes submitted and purpose

Change	Purpose
Include all LHRs into one Build Method system-wise	**Eliminate compliance risk** - avoids changing one LHR and not including the change in all of them
Create a Sub assembly LHR for operations prior to cure time (LHRSA)	**Eliminate waste** – replaced and avoids printing all LHRs ahead of time and filling the same information 3 times **Eliminate compliance risk** – already filled LHRs are not voided if they are not used
Create an entry for LHRSA lot number in each end product LHR	**Eliminate compliance risk** – provides a proper traceable area for lot incorporated into the finish good

The results were based on manual entry reduction, which was 31% overall meaning the total manual entries went from 318 to 219. Figure 8 summarizes the detail for each LHR. In addition, non value added activities (Motion/Transportation, Inspection, Waiting, and Inventory) were reduced in 65%. Figure 9 presents the detail of the non value added activity reduction.

Figure 8
Implementation results – manual entries

Before implementation

A. Manual Entries

Types of LHRs	Entries per LHR
LHR Product 1	113
LHR Product 2	115
LHR Product 3	90
Total entries	318

After implementation

Types of LHRs	Entries per LHR
LHR Product 1	62 (45% less)
LHR Product 2	64 (44% less)
LHR Product 3	35 (61% less)
LHR SA	58 (new)
Total entries	219 (31% reduction in total)

Waste & Compliance Risk Reduction

Figure 9
Implementation results – non value added activities

Before Implementation

A. Non Value Activities in Process Map

Type	How Many
Motion/Transp	5
Inspection	3
Waiting	8
Inventory	4
Process	6

After Implementation

Type	How Many
Motion/Transp	1 (80% less)
Inspection	2 (33% less)
Waiting	2 (75% less)
Inventory	2 (50% less)
Process	6 (same)

Reduction in Non Value Added Steps

Another opportunity identified was that LHR did not have an identified location to be placed while they were being processed in the manufacturing area. A quick, simple, and low cost solution was implemented following the lean concept. Packaging slips were attached to cure bins to hold LHRs while lot was still in process. Refer to Figure 10 for an example.

Figure 10
Packaging Slip attached to cure bin

Control Phase

Effectiveness was measure in terms of NCMR generated per traceability issues. As mentioned before, the baseline was 18 NCMR. The first two weeks after the implementation there were zero NCMR, and within the last 2 months of implementation, there have been only 3 NCMR. Figure 11 details the drop or trend down after the implementation.

Figure 11
Non conformities generated before and after the implementation

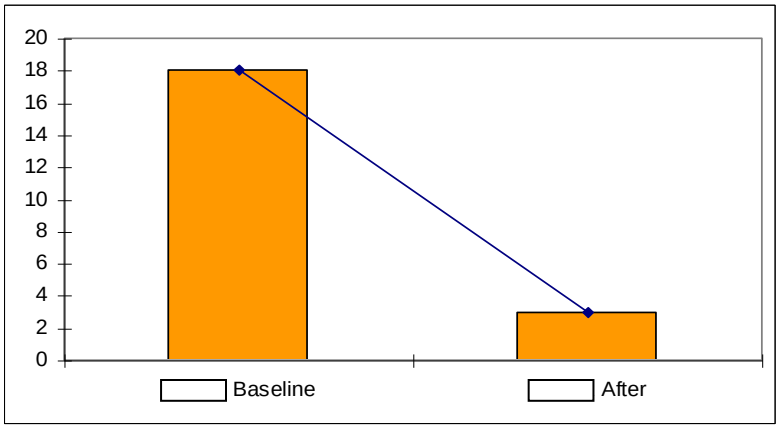
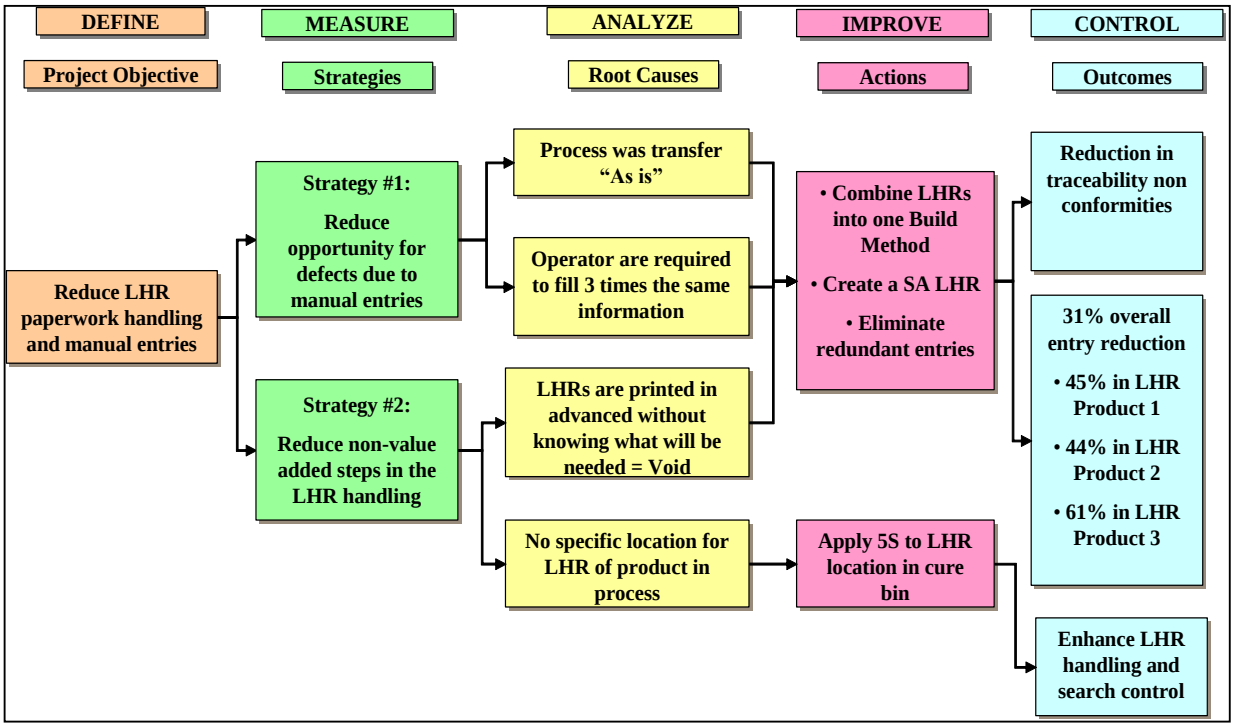


Figure 12 details the overall DMAIC roadmap followed to complete the case study and be able to measure the results.

Figure 12
Complete DMAIC Roadmap



Conclusion

XYZ Pharmaceutical promoted the use of Process Excellence tools. It started focusing only in Six Sigma but has evolved into Lean Six Sigma, being this case study a sample of the application.

It is imperative that companies keep their material cost and labor costs to the minimum, low inventory volumes, and wastes elimination to be able to maintain their competitiveness. Lean and Process Excellence tools assist support these goals and assist in eliminating non value added activities. It also aids in having a more robust process that adds value to the product and which should be aligned to want is consider valuable to the customer.

Reducing entries reduces error opportunity (non value added). This lessens the compliance risk allowing the regulated company to stay in business. Bottom line, this all translates into adding value and having a healthier financial status.

References

Bottome, R. & Chua, R. (2005, July). Genetech Error Proofs Its Batch Records. ***Quality Progress***, pp. 25 – 34.

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