Implementation and Replacement of an Engineering Drawing Solution in a Pharmaceutical Manufacturing from an Information Technology Standpoint

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Abstract *— The pharmaceutical industry is a highly and strictly regulated environment. The quality, support and management of its processes and data generated are important aspects this type of industry needs to sustain. The department of Information Technology (IT) is accountable for most of these processes driven by regulatory agencies and Good Manufacturing Practices. One of the many businesses Information Technology leverages is the Engineering Information Management (EIM). The influence of technology in manufacturing has evolved to a point where it is possible to have interconnected and integrated systems across global companies. A Commercial off-the-shelf software product was selected in an initiative, from the global Manufacturing Pharmaceutical Company X, to replace their multiple solutions to a single one; standardizing global procedures, increasing efficiency and improving end user experience in the process. Lean Six Sigma methodology was used to define requirements and to develop a global strategy for implementation of the solution.*

Key Terms *— DMAIC, Engineering Information Management, IT, Pharmaceutical Industry.*

INTRODUCTION

In Manufacturing, nowadays, Engineering and Information Technology (IT) are working more closely and integrated than ever. IT supports engineering processes and maintains applications that are key in having automated processes. Manufacturing pharmaceutical companies are examples where IT and engineering work together for common goals from different perspectives.

An important aspect in most manufacturing businesses is the Engineering Information Management (EIM). Today's technology provides the ability of having Engineering Drawing Management Systems or computer storage and control of engineering drawings instead of paper based storage, as it was years ago before the computer era, leveraging that way EIM.

A particular global pharmaceutical company, whose products are sold in over a hundred countries (it will be called here; *Manufacturing Pharmaceutical Company X*) has three Engineering Drawing Management Systems implemented, from different vendors, across its different sites in the world. With the objective of standardizing processes, there is an initiative of having a single solution from a vendor instead of the actual three, and implement them across all the sites. This is a major initiative that will incur in developing a strategy, choosing a vendor, negotiate contracts, migration and archival process of previous solution and implementation of the new one on each site.

This design project will focus in the optimization and standardization of each deployment, the development of a strategy as well as the creation of the requirements of this initiative from the IT perspective.

Research Description

In a global company with offices and sites over fifteen countries it makes sense if project implementations and applications are completed by phases and differently according to business needs. In the case of the Drawing Management Solution, for different reasons and over the past years, business decisions ended in having three solutions implemented across the different sites in the world, properly divided by zones. The divisions or zones

are not relevant, what will be important is the initiative of having a single solution and application from a single vendor.

As mentioned before this initiative will require engagement mostly from IT and Engineering teams. Engineering teams define processes and business needs where IT translate business language into technical.

To establish a clear status of the timeline of where this design project begins; The new global solution was already selected, negotiations with the vendor are finished and current status of Manufacturing Pharmaceutical Company X's initiative is comprised of planning of next steps. The following aspects will be taken into consideration for these: Traveling arrangements for the new Engineering Drawing Management Solution core team to a same location so activities can be driven as a team. Workshops will be conducted where new business requirements will be defined with the main purpose of handover them to the vendor therefore they can customize the application according to business needs. Training from the vendor and creation of training for end users will also be required.

It is important to develop this design project because it will contribute significantly in the implementation and deployment of this Global solution. Having standard and optimized processes across the different implementation in all the sites of this global solution will be essential, it will increase productivity and efficiency in the creation of engineering drawings and models. Lean Six Sigma tools as well as other manufacturing engineering concepts will be applied.

Research Objectives

Manufacturing Pharmaceutical Company X's initiative of implementing a global solution from the current three is the first step here of improving the whole system and EIM. The methodology of how it will be made and the approach opens the opportunity of leveraging this project by using available Lean Six Sigma tools. These design project's main objectives include:

- Develop a strategy using Lean Six Sigma methodology and thinking criteria for the deployment of the global Engineering Drawing Management Solution.
- Define standard business and system requirements in order to provide them to the vendor and subsequently being able to configure the application.
- Optimize current deployment methods and standardize processes.

Research Contributions

Contributions of this research project can be summarized as reduction in time, higher quality and standardized processes. By optimizing the strategy and the deployments of the global Engineering Drawing Management Solution the time or hours worked per deployment should be reduced. In manufacturing or in any other workspace less time in one task is equal to less money invested or additional time for other tasks.

During the global Engineering Drawing Management Solution's core team workshops it is expected for both engineering and IT teams to work together in order to deliver the correct procedures and strategy. Combining that effort with this design project's input will contribute in delivering high quality standards, procedures and a strategy which can be translated in less or none errors implementing as well as a better application for end users overall.

Having standardized processes will contribute in having same implementations across all the sites, as long as procedures are written with no ambiguity, they should guarantee same implementation no matter the person who is conducting the operation. This can also be translated in reduction of error.

BACKGROUND INFORMATION

Different aspects of the industry will need to be covered in this background information. The Pharmaceutical Industry, Manufacturing sites in general, how Information Technology (IT) supports

manufacturing and leverages EIM are some of the pieces that will need to be covered in order to better understand the development of this design project. Other topics that will be discussed are engineering and why it is crucial the cross functional work with IT. Some background information of document management will be given as well so it can be compared with how things were done in the past and how technology gives the opportunity of managing engineering drawings and content in general (i.e. Specifications, vendor documents, manuals, etc.)

After revising those important general details and providing the necessary theoretical background the reader will have the essential knowledge and will be ready to understand clearly the objectives of this research but more importantly the context and the background behind.

Pharmaceutical Industry

The Pharmaceutical Industry is one of the most regulated workplace across different manufacturing industries. It makes sense; After all, producing an active ingredient or medicine for humans (or animals) requires high quality with the objective of delivering a product in which the patients or the consumers can entrust their life. In every aspect of the Pharmaceutical Industry regulations, best practices, Standard Operating Procedures (SOP), security policies and much more will take place and as close to the product development they are, more rigorously they will be.

As any other industry or manufacturing company, assets need to be manage as well as their information. The department of engineering plays an important role there but it is very closely to Information Technology (IT) department, they all needs to work in a cross functional team nowadays. "Data storage is an important component of IT. In the early days of computers, most information was stored in files. The difficulty of updating information derived from a file led to the first database systems, such as the information management system created by IBM in the 1960's. In the 1970's, relational databases became the dominant method of storing data, although a number of competing technologies are also in use. For example, many corporate data are stored in large spreadsheets, many personal data are kept in word-processing documents, and many Web data are stored directly in Web pages." [1]

Information Technology

Information Technology (IT) supports manufacturing; business is in charge of defining processes whereas IT will leverage the management of information. "In general, IT includes any expertise that helps create, modify, store, manage, or communicate information. It encompasses networking, systems management, program development, computer hardware, interface design, information assurance, systems integration, database management, and Web technologies." [1] Relevant aspects to this particular design project is the current support of the three existing solutions available across the globe. Each solution requires daily support in incident management as well as regular support in Change Requests or Change Control. Some other fragments from the IT side includes: database administration, capability of creating reports, installations of new versions or patches and much more.

IT works very closely with, what is called the business or in this case with the engineers as well as the application users in order to establish the communication and have a better understanding of the manufacturing processes and the role of a Document Management System.

Document Management Systems

A document management system gives the opportunity of having controlled environment where the user can store, manage and approve different documents. In a document management system this is what is called version control, the ability of having organized documents depending on their version. This opens the capacity of having a particular document's history of previous versions on the same system or database. Different security can be apply depending on status or version of the

document thus making effective documents available to a specific population and restricting archived documents to others.

An important functionality of a Document Management System is the ability of having workflows for approvals, same processes that were previously paper based can be now programmed as desired. This works in conjunction with electronic signatures (Username and password) or in other words a computer equivalent meaning of a handwritten signature.

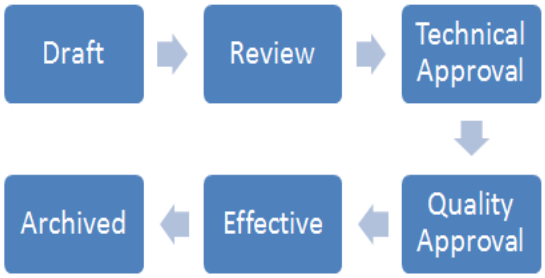

Figure 1
Workflow Example

As it can be seen in *Figure 1*

WORKFLOW EXAMPLE, an example of a workflow from a Document Management System where a native document initially enters the system in Draft status, then it will require some kind of business defined review, after the review state the document can proceed to its approval phase where it requires two steps: Technical and Quality approvals. After the approval phase the document can be promoted to its effective status and now available, if configured that way, to certain group of people. Then later on, if the document requires obsolescence it can be move to an archived status and be no longer available to the same group of people it was available (maybe a new version of the document will now be available).

Our Scenario

After having all the necessary background from the important areas and components of this design project next step is the discussion of the global Manufacturing Pharmaceutical Company X's solution as well as defining briefly some key terms on the approach of part of the methodology that will be used.

Lean thinking, as well as Six Sigma approach, will be used as part of the methodology. It is not a surprise that in 2017 many industries are implementing such methods as a result of evaluating and comparing results from peers. An example of excellence and one of the pioneers is Motorola. "Many companies, noting the success of Motorola, adopted this approach. It was estimated in 2003 that 100 billion USD of savings were obtained by the adoption of this method. The Six Sigma approach is still the most applauded global standard of quality in the United States, but it is not easy to implement and a slogan that characterizes it is: No pain, no gain." [2]

Six Sigma's methodology is composed of five steps: Define, Measure, Analyze, Improve and Control, also known as DMAIC, and each step can be theoretically defined as followed:

- **Define** – Starts by defining the process, state the problem, know who the customer is, identify the goals, and identify existing output conditions.
- **Measure –** Choose what parameters need to be quantified, categorize key characteristics, also measurement systems are verified and data is collected.
- **Analyze –** After the data is collected now is analyzed and all the raw data is converted into meaningful information, this also include identifying causes of the defects or problems.
- **Improve –** In this step solutions of problems are developed, results of process changed are seen and also it is decided if the change is beneficial or if any other change is necessary.
- **Control –** In this final step of DMAIC, the process is monitored to assure no unexpected changes occur, if the process after this analysis is performing as desired it can be said is under control.

METHODOLOGY

DMAIC approach will be used as the project's methodology; each step of DMAIC will be explained with the necessary tools that will be used and how each one can be defined from the IT standpoint. "The five phases of **DMAIC** are not rigid, in principle; there is no sharp delineation separating one phase from the preceding and/or the following. The phases of a specific project are shaped and determined by the project champion." [3]

- **Define;** During the Define phase it is expected to define a clear scope of the project. A project charter will be developed in order to state: Project Goal, Project Participants, Stakeholders, Requirements, Constraints, Milestones, Communication methods and Deliverables.
- **Measure;** This Measure phase will include a Voice of the Customer (VOC) with the objective of identifying real output from the customer as well as requirements. With that information obtained and gathered from the customer a Critical to Quality (CTQ) tree or analysis will be conducted. Here, business requirements will be defined. In this project the customer represents one of the plants or sites where the solution will be implemented. This will include a team of engineering, Information Technology (IT) and management.
- **Analyze**; At the Analyze phase, all the data and information obtained from the Measure phase will be studied so it can be established the necessary approach for implementation. This phase will help how to focus the efforts and the personnel available in order to accomplish deliverables of the project. Weekly meetings will be scheduled including representatives from the site as well as the core team of the global solution.
- **Improve**; At this improving phase, the implementation of the project will occur. At this moment of the project it will be expected to have a decided pilot plant or site for the implementation of the global solution for engineering drawings. The coordination will occur between engineering and Information Technology teams. It will be expected during this phase: Updated validation package, Tested new global solution and the Transition from old system to new system.
- **Control/Support**; Since this project is from the perspective of Information Technology (IT), Control phase can be called Control/Support and that is because after implementing IT's is accountable for the support of the process. For this phase, the site or plant should expect: Seamless transition, Support from IT and Report Capabilities.

RESULTS AND DISCUSSION

The implementation of this project was completed using DMAIC approach. Including the development of a strategy for a deployment and standardization of a global Drawing Management Solution for Manufacturing Pharmaceutical Company X. Over the next few pages each of the steps from the methodology used on this design project will be discussed and results will be presented.

Define

An Engineering Drawing Management System has capabilities of storing electronically documents and it is specially designed to support engineering drawings. These drawings can be created with software like AutoCAD, as well as, scanned drawings or other images. Manufacturing Pharmaceutical Company X has to invest, as any other pharmaceutical company, in the means to comply with all the regulations and in order to comply with them in this implementation, different modules have to be incorporated to the main system's functionality. Some of these functionalities includes Electronic Records/ Electronic Signatures (ER/ES), audit trails of all modifications, approval workflows based on drawing's criticality or preconfigured definitions.

By the time this design project started three existing software solutions (Engineering Drawings Management) were already implemented in Manufacturing Pharmaceutical Company X and its different sites across globe. For different reasons, that was the approach and their current state, in the part maybe driven by limitations in technology and by new global acquisitions of small companies or new sites. In the following *Table 1*, you can see how it was distributed, the three solutions and the different zones, without explaining details on the sites:

Table 1
Software Solution Distribution

Zone	Solution
America	Software Solution A
Europe and Asia	Software Solution B
Small Sites	Software Solution C

In place there was also a fourth "solution" and it is commonly referred to as: Paper Based. These sites (The minority) at the moment do not have implemented an electronic solution for the management of engineering drawings but it is also in the scope of this project, meaning, eventually there are going to be migrated into the new global solution.

Measure

A very common, and powerful at the same time, tool was used as part of this stage (Measure) of DMAIC. This tool is known was Voice of the Customer (VOC) and it minimizes effort in the design phase. Not only from the IT aspects on this design project, but anywhere or in any project where a customer exists. When input from the customer is received, most of the basic needs and necessary characteristics are obtained at a time where they can be incorporated as part of the final product without incurring in redesign or additional costs.

On *Table 2* results from the VOC conducted as part of this design Project are shown:

Table 2
VOC Results

Voice of the Customer
• Projects are transitioning to primary usage of Revit with more selective usage of AutoCAD and verticals. • Release of Revit Model is becoming more commonplace with clients that are Building Information Modeling (BIM) focused. • Establishment and implementation of BIM Guidelines. Leverage software and collaboration tools such as previously discussed. • Use of best practices, templates, etc. to allow improved turnover and project deliverable development. • Become more aligned with Industry standards. • Utilize industry standard symbols included in software editing tools and not maintain many customize tools.

Analyze

By using all the data collected on previous steps from DMAIC methodology, it was possible organizing a strategy or a project plan for this design project. In this case services from Project Managers (PM) were required at a higher percentage of involvement. They were always involved since the beginning, but it was at this time where it made more sense to conduct a workshop to have established tasks, dependencies, roles required, and all the theory from the PM field.

Critical Chain Project Management (CCPM) was used as the method of planning for this Project. CCPM emphasizes in the use of resources and the

people in charge of each activity, having in mind different sub-teams and critical tasks essential to accomplish and finish the project on time. This method has as the base theory that each person should only be focused in one activity at a time, that way when all the tasks are identified and assigned a possible need for personnel can be discovered. Other aspect covered by the CCPM method is the buffer.

The buffer in CCPM can be defined as additional time separated for each activity, or for the whole project with the objective of covering possible delays during the project. For this CCPM run a very common value was used; 50% of buffer (i.e. A project having an estimate duration of 10 days, after adding a 50% of buffer a project manager will safely say that the project estimated duration will now be 15 days), that way, the project will be secured against regular delays in project tasks or any other event that might occur over the course of the project. It even opens the possibility of ending early the project while minimizing overpassing established end date.

A tool or chart used to measure the consumption of buffer through a project is called a Fever Chart, basically it represents a Cartesian Plane (X, Y coordinates) color coded the project progress versus the buffer consumed at that time.

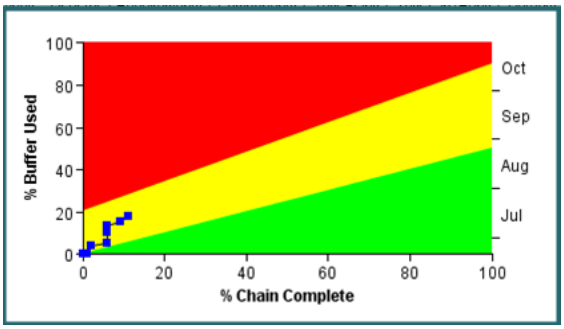

Figure 2
Fever Chart Update Example

A project will initiate at (0, 0) on a Fever Chart, and hopefully it will move northeast as time passes residing in the yellow portion of the chart, this region is expected. Being on the green zone will imply the end date of the project will end before initially estimated without consuming to much of that buffer. On the other hand, being on the red zone will indicate a trending or a projection of finishing the project after the expected date. On *Figure 2* a Fever Chart from this project can be seen.

Improve

During the Improve step of DMAIC, the work on the validation documentation was started. Some of the documentation that was created in order to have global procedures and business processes were: System Overview, Test Plan, Test Strategy, User Guide, Security Plan, Disaster Recovery Plan, System Admin, Security SOP.

Also as part of this improvement step, the Core Team of this project conducted a workshop with the main objective of establishing basic requirements of the application of the future global software solution for Engineering Drawing Management. These requirements are called user requirements and they are written in "business language". After having the user requirements, they can be used as a base to obtain technical requirements of the system at the level of configuration, architecture and development. All of the requirements were presented to the vendor of the COTS application so they can configure and customize according to the requirements. Locally in Manufacturing Pharmaceutical Company X, the requirements were stored in Application Life Cycle Management (ALM) 12.5 or as its commonly referred: Quality Center (QC). This web based tool is a solution from Hewlett Packard which brings to a team or a company a comprehensive test management tool. That way when the Engineering Drawing Management System is configured it can be tested against the requirements in an environment (ALM 12.5) in an effective, global and with high quality.

Control/Support

As it was mentioned earlier, this design project has a focus on IT, that it why Control step of DMAC was named Control/Support. Every application from the IT standpoint requires some level of support to guarantees the quality of the

product, to keep it up to date and to manage any kind of issue or possible incident.

This project will count on the services from an external contractor for the Tier 1/Tier 2 support, which means that first and second line of defense on possible incidents on the users while using the solution. Also this external contractor will support future change control processes that may occur (Change Request, Service Requests) as well as upgrades of the application.

The support will also have the collaboration of IT from Manufacturing Pharmaceutical Company X in a team effort with the external contractor but working more at the coordination level and serving as liaison between the business and the users.

CONCLUSION

Using correctly Lean Six Sigma as part of a project can guarantee optimization of all the available resources and it can provide a continuous improvement way of thinking. On the other hand, Information Technology supports manufacturing and can leverage Enterprise Asset Management. When it is combined and Lean Six Sigma methodologies are applied in Information Technology projects the end product or deliverables is one of high quality.

Through the implementation of this design project in Manufacturing Pharmaceutical Company X, we able to complete all of the objectives; System requirements as well as user requirements were defined and handover to the vendor of the Global Drawing Management Solution. Also the project strategy was defined using the knowledge of experts from project management and developing Critical Chain.

Applying Lean Six Sigma concepts and DMAIC methodology significantly improves the manner of implementing this kind of projects. Usually it is seen this type of concepts applied more on manufacturing directly and not in Information Technology, but reality is that Lean Six Sigma is a way of thinking and an organized method of accomplishing an objective reducing different types of waste or steps that do not add any kind of value to your project.

As part of next steps; it was explained this is a global initiative and just a part of a bigger effort. It can be considered as phase one and where next steps will include continuing validating the whole system, following project schedule and according to the Critical Chain, without consuming all the buffer in order to have it completed by the end of Q2 2017 and ready to deploy globally.

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