Project Management of Retrofitting a Tablet Coating Machine in Pharmaceutical Industry

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Abstract: - Maintaining a state of compliance with Current Good Manufacturing Practices (CGMP) remains a challenge for manufacturing automated processes within pharmaceuticals industries. The challenge lies in dealing with integrated control systems and easy, user friendly and reliable monitoring approach that reduces the problem of manufacturing faults, which is costly to the organization. Mechatronic automated design is the integrated design of a mechanical system and its embedded control system. This paper presents the project management side for this mechatronic automated system of upgrading a tablet coating machine in a pharmaceutical plant, in order to achieve a powerful control processing system, process monitoring and reporting while concerning in increasing process productivity and quality. The approach used in the mechatronic automated system, to upgrade the tablets coating machine, based on investing in the power of two, relatively novel, technologies; Programmable Logic Controllers (PLC) and Supervisory Control And Data Acquisition (SCADA). The integration of both technologies provided a real powerful upgraded design that increases the efficiency, reliability and robustness of the control and monitoring process, and reduces time, cost and rework. The project management of a machine in-service is quite challenging since coordination with the different departments and scheduling production plans should be accommodated with a tight retrofitting plans.

Key-Words: - Retrofitting, Mechatronics, Pharmaceuticals, Project Management, PLC, SCADA

1 Introduction

This paper deals with the lack of control and the need of parameter optimization of a critical-to-compliance process in the pharmaceuticals industries, namely, the coating process. As the pharmaceutical's compliance restrictions and Current Good Manufacturing Practices (CGMP) requirements on quality control of the manufacturing processes are increasing proportionally, the need of a more automated process in each stage of drugs manufacturing becomes a critical requirement. Many researchers have identified the compliance and traceability issues and how does that impact productivity [1-3, 17-25].

Coating is considered to be the final production stage, for many pharmaceutical drugs, before packaging. This process improves the tablet functionality and stability, increases productivity (in the packaging stage) and increases the patients' compliance. The tablet coating is of immense importance and was shown to depend on a big number of parameters which can control its uniformity and amount [9-16]. Several Parameters play a role in tablet coating manufacturing process, which makes a manual process of such a stage susceptible to human error. Tracking and resolving such errors is difficult since admitting of committing these errors is rare due to fear for job security and effect on career advancement. Some organizations offer incentives of mistakes or error admittance, in order to save the product and reach a conclusive assignable cause for a fault within a manual process [2]. Many automated processes employ a large number of controls and checks during the process activities, but some possible fault occurrences are difficult to control or detect and results in non-conformities to CGMP compliance. The problems of non-compliance lie mostly in the original design of the manufacturing process or equipment. If the

actual failure is the product itself, then such a failure can be reproduced and confirmed by the proper procedure and methods of quality control testing and inspection [17-20]. On the other hand where the product failure is not real and it can be attributed to several possible faults such as equipment, method, measurements, environment, or human error, the current compliance control mechanism uses logical sequences and assumptions to investigate each process input parameter starting with the most likely and assume assignable cause. This investigation procedure is lengthy, costly and in many cases the outcome is inconclusive [1]. For Pharmaceutical products, it has been estimated that to manufacture one batch of a medical drug costs between $10,000 to $50,000 US dollars [3]. Many of these erroneous analysis data can be avoided if the used equipment or machine can save the batch actual manufacturing parameters throughout the whole process, so that the investigators can accurately know the environment in which the product was produced.

As a case study, we will work with a coating machine (Manesty, Accelacota 150) that is used in film and enteric tablet coating at Hikma Pharmaceuticals. The machine is considered as a productive machine, and it has a heavy duty mechanical design, but unfortunately it has an old control system that suffers from lack in both accuracy and process integration. Process traceability and the possibility of data acquisitioning are also considered as one of the machine main problems.

Several control parameters impact the final coated product, each parameter has a working range values that must be followed throughout the process. Having such a process makes the manual operation hard, complicated and poor from both control and monitoring points-of-view. On the other hand the well-skilled operators know the optimal set points for each parameter linked with the product type. They gain such knowledge through experience and time. However, this experience is not transformed into written know-how and procedures from which the industry can benefit and knowledge can be transferred to new hires. This is why the employees in the coating department are with a minimum of 7 years experience in the same operation, which will not be the case in other departments.

Hence, this paper primarily aims to develop and analyze different techniques to form a reliable and robust compliance automated process to retrofit Accelacota tablet-coating machine in order to come up with a new control system that provides a powerful control and processing capabilities to the pharmaceuticals regulatory standards at minimum cost and provide high quality coating process due to the finer tuning of the control parameters.

This project is an applied mechatronic application, namely, retrofitting a coating machine to be automated for the Pharmaceutical industry. Design of mechatronics systems in different fields is present in literature [4-8], but authors did not come across similar projects in the pharmaceutical industry. This work is motivated by the fact that mechatronic and automated systems can play a pivotal role in increasing pharmaceutical industries' productivity and quality, reducing process cycle time and process errors while maintaining quality standards and compliance.

2 Project Management

Project management is a methodical approach to planning and guiding project processes and resources from start to finish. The purpose is to control and monitor schedule, performance, and cost of the project tasks to insure finishing the project on time, according to client requirements and within budget. According to the Project Management Institute, the processes are guided through five stages: initiation, planning, executing, controlling, and closing (see Fig. 1). Project management can be applied to almost any type of project and is widely used to control the complex processes of hardware and software development projects.

Project Management was developed to save time on a project by planning it out and considering all relevant factors which may affect its outcome. The benefits are proven - it saves time and money, utilizes resources efficiently and generates a more successful outcome.

In this project, retrofitting the Accelacota machine project, as titled in the ongoing projects list at Hikma Pharmaceuticals, need to be planned well to achieve deliverables, otherwise project approvals are not granted. Good planning will lead to minimized machine downtime and lost production.

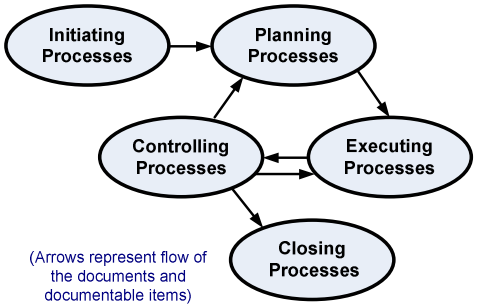

Fig.1. Links between processes stages

The Project Management in this project started from the company vision and mission and continued with the project deliverables, break down structure, network, time schedule, budgeting and human recourses management. The following few sections lay down the project description and structure.

3 Retrofitting Project Outline

This retrofitting project; such as most projects, has a number of project management components that are imperative to its success and should be defined clearly early on in the project and should attain the team approval before the kick-off of the project. These components are namely:

3.1 Project Objectives

This project has the following objectives:

a) Develop a control architecture based on Programmable Logic Controllers (PLC) and Supervisory Control and Data Acquisition (SCADA) technology for the integration of all additional hardware and software required to automate the production process on this particular machine.
b) Identify and integrate a system traceability mechanism with the developed techniques to measure and monitor process performance and capabilities as well as reporting quickly the non-compliance occurrences.
c) Develop a technique to ensure a fail-safe strategy within the process critical-to-compliance parameters, by establishing a method to verify that each parameter of the process is within its acceptable range.
d) Establish a process knowledge-base to enter, save and update products' recipes which will lead to a more efficient process operation and reduced errors rate.

3.2 Project Deliverables

The main deliverables of this project are:

a) Equip the machine with new control system based on PLC technology.
b) Provide the machine with a process monitoring system.
c) Enable process parameters archiving and backup abilities of the machine.
d) Describe the new system in a fully detailed report with a product manual.

3.3 Project Milestones

The project milestones of this retrofitting project are:

a) Understand machine current status
b) Conduct coating technology literature review
c) Implement the upgraded control and monitoring system
d) Conduct overall system installation and troubleshooting
e) Writing the report and documentation
f) Deliver final presentation to management

3.4 Project Requirements

In order to implement this retrofitting activity, the are a number of hardware and software components that should be acquired. These are listed below:
As for the hardware components, they are: Controller (PLC), display (monitor), sensors and actuators, printer and network connection, and mechanical and electrical equipment
As for the software needed by this project, they are the control and data acquisition software that is compatible with the controller and the display validation software, friendly man-machine interface, and database for the machine historical data.

3.5 Consulting Resources Needed

Since this project requires the approval of so many parties from standards to maintenance, the following is only a few who are needed to approve the retrofitting activity:
FDA and CGMP consultant
Computer consultation
Machine validation and calibration

3.6 Project Assumptions & Constraints

All the project team will be available to participate at the scheduled times.
The machine will be available (under maintenance) at the installation time as scheduled.
The design standard in this retrofitting task will be CFR part 12 (The latest FDA standards).
The Purchasing will be performed directly through the engineering purchasing department.

The installation of the machine requires a black-shutdown of the machine for about two weeks.

This project had significant improvements of this tablet coating automated process in terms of quality and monitoring. Furthermore, this success story within the organization led management, compliance group and engineering to consider automation as a viable choice for the manual processes residing in their operations. The retrofitting of manual processes to be automated and monitored enhances greatly compliance with different codes which impacts the industry productivity and quality.

4 Project Planning Elements

The basic element that guarantees the success of project is in proper planning and execution; hence the following sections illustrate this:

4.1 Project Breakdown Structure

Fig. 2 illustrates in details the project breakdown structure:

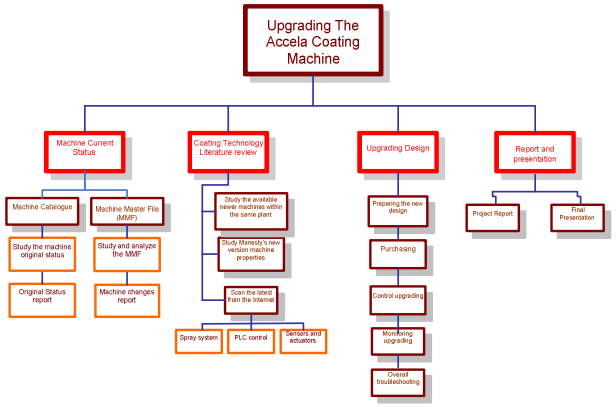

Fig.2. Project breakdown structure

4.2 Project Network Diagram

The project follows in its progress the network diagram shown in Fig. 3.

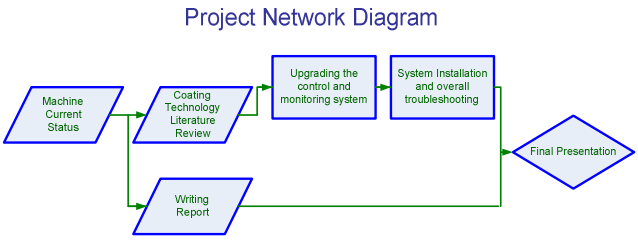

Fig. 3. Project Network Diagram

Each stage in the network diagram reflects more details or sub-network diagram.

4.3 Project Time Schedule

Project Evaluation and Review Technique (PERT) was used to calculate Project duration. The concept of this technique is illustrated in Fig. 4.

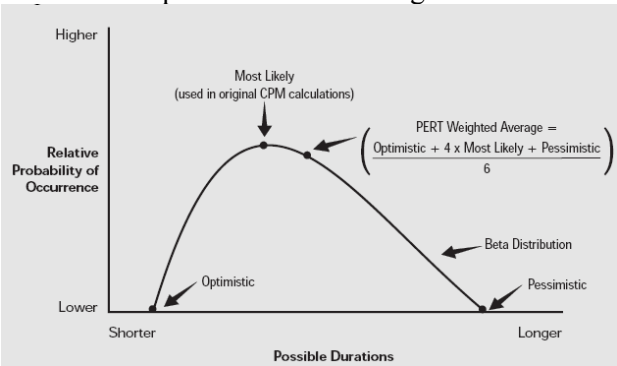

Fig. 4. PERT concept

4.4 Project Budget

Budgeting depends on two areas (Materials (Hardware and Software) and consultation.

Table 1 shows the summary budget of the main three areas of the project.

Table 1. Total Cost budgeting

no.	Item Description	Estimate cost (US$)
1	material cost / Hardware	14,000
2	material cost / Software	4,000
3	Consultation cost	2,000
Total		**20,000**

Project Human Resource Management, Project Communication Management and others were also discussed.

5 Conclusion

Using the mechatronic automated designs in the pharmaceutical industrial machines will add a real value to the process productivity and quality. PLC and SCADA technologies are one of the best solutions for the control and monitoring problems in the industries. These are systematic and standardized technologies to trace and control compliance within automated processes in regulated industries. Taking advantage of the latest reliable and capable hardware/software of advanced technology tools available today along with control tools; retrofitting

proofed to be feasible and one could easily adopt and build a robust and reliable compliance control system based on PLC and SCADA methodologies, such this one demonstrated in this paper.

In summary, automation in pharmaceutical industry enhances its competitiveness through productivity improvement, sustainability of high quality products, and availability and accessibility of data and information for problem root-cause traceability and product compliance.

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