Electrical and Controls Maintenance Strategy

Bryan A. Sanchez Marcum, PE
Graduate Program of Engineering Management
Héctor J. Cruzado, PhD, PE
Department of Civil & Environmental Engineering and Land Surveying
Polytechnic University of Puerto Rico

Abstract — *Keeping an automated manufacturing line in the pharmaceutical industry competitive through the end of life is challenging. The total cost of ownership starts increasing with the amount of new problems that arise as individual components start to fail. It was found that automated manufacturing facilities need a strategy that can be easily implemented to lead the direction of tactical decisions that affect the competitiveness of these assets. A case study is presented where the strategy developed was deployed for the filling equipment inside the diabetes care filling line of XYZ pharmaceutical, which was near the disposal phase of its life cycle. The tactical implementation of the strategy provided the organization with a re-manufacturing plan of obsolete components and a Ticket Management System to keep track of electrical and control system outages.*

Key Terms — *Control Systems, Corrective Maintenance, Preventative Maintenance, Total Life-Cycle Asset Management.*

INTRODUCTION

This project takes place in the diabetes care filling line of XYZ pharmaceutical company. The filling line is composed of several assets, which include a vial washer, a depyrogenation tunnel, a filling and stoppering machine, a capping machine and a tray loading machine. The project will mainly focus around the filling and stoppering machine as it is located in a clean room, restricting access to provide corrective maintenance, making preventative maintenance the desirable option.

The goal of this technical report is to provide a strategic framework that can be applied to any facility while providing a case study example of a near end-of-life equipment. The framework was developed within the current stage in the life-cycle the asset is in, as no capital expenditures are to be planned for an asset that will not be in service for a long term.

The case study presents the application of this strategy to an aseptic vial filling line that will reach end of life in 2024. Based on current literature, the line is in between the modify and dispose stages, as shown in Figure 1[1].

Figure 1
Total Life Cycle Asset Management

Just like any other technology, automation and computerized control systems become obsolete over time. The pace of obsolescence of this equipment can be faster than the pace of the asset's lifespan. In the case for an asset in the pharmaceutical industry, bringing any technology into service, including retrofits and upgrades, will have to follow the Good Automation Manufacturing Practices (GAMP) V-Model shown in Figure 2 [2]. As shown in the figure, each activity from the right-hand side is used to validate the deliverable or activity on the left-hand side [2]. This process is time consuming and critical to ensure compliance with regulatory agency across the world. Making capital intensive modifications that impacts the validation/qualification of the asset, would require to re-qualify the asset with the new equipment, depending on the asset this could feasible or not.

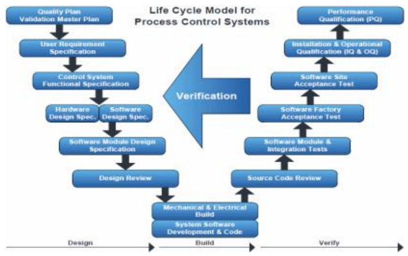

Figure 2
GAMP V-Model

The paper will start by discussing the overall framework of the strategy for all electrical and controls equipment. Once the strategy is developed it is deployed to the filler, as it is the most critical asset of the line. The application of the strategy consists of the implementation of each tactical pillar with the decisions making process aligned with the mission, vision and values in order to achieve competitiveness in the industry. Decisions on weather update or re-manufacture obsolete components are presented as the main problem while an improvement in the how data and information is collected regarding these assets is implemented for future assessments.

LITERATURE REVIEW

The development of a strategy will serve as the basis for the tactical implementation. Once developed, it should include the following components: Mission, Vision, Tactics, Target Timing and Values [3].

Decisions to utilize preventative or predictive maintenance plans are not strategies but are tactical choices within an overall strategy [4]. The problem from most maintenance strategies is that they solely focus on these tactical aspects, which are not inclusive or holistic per our strategy definition. Additionally, when employing this tactical measure, the manager must understand the equipment's reliability [5].

Equipment life cycle failure rate are typically depicted by the Bath Tube curve, also known as the life cycle curve or failure rate curve, shown in figure 3 [6]. The curve is comprised of three stages:

- Infant Mortality
- Chance Failure
- Wear-Out Phase

Also, it is important to understand that although, Figure 3 presents the systems failure rate curve, each component within a system will have its own failure rate curve, as shown in Figure 4 [7]. As technology used in a control system becomes obsolete, reliability is not the only thing to consider that could impact the operation. As shown in Figure 4 (b), as the time goes by the electrical components of the control system start to fail.

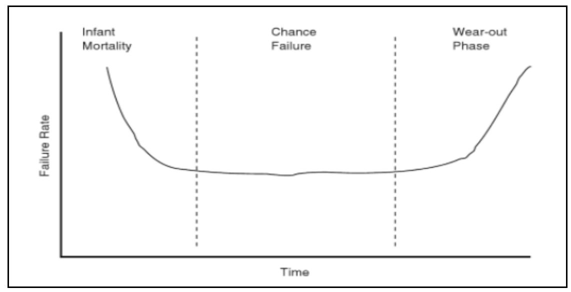

Figure 3
Bathtub Curve

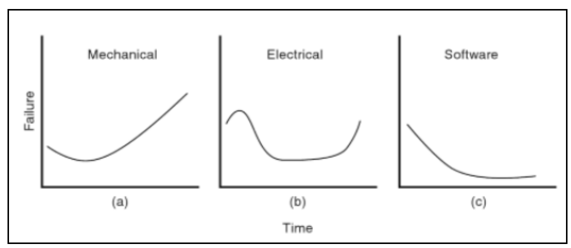

Figure 4
Characteristic Failure Rate Curves

An option becoming popular is to develop a migration plan for near end of life components. When compared with other capital expenditures on more tangible and easily understood return-on-investment (ROI) projects, control system migrations are considered less priorities, which often results in repeated delays in funding them [6].

STRATEGY DEVELOPMENT

Defining a Mission, Vision, Tactics, Target Timing and Values are essential for strategy development. They will set the overall direction of the organization and influence decision making. The strategy developed in this technical paper is tailored for a filling line in a pharmaceutical setting near the end of life (2 years prior to the disposal phase shown in Figure 1), but the steps for strategy development will be the same for any other asset. Note that this describes the target timing as it will not be discussed to a further extent.

The mission statement of the strategy will provide a simple common and clear purpose for the organization being led by the strategy. For this reason, the mission statement for the strategy has been selected as follows: "Achieve competitive advantage throughout the lifecycle of the assets".

The vision is a simple statement of what the organization is trying to achieve with the maintenance strategy. It is written as if the organization is already there [8]. Considering the maturity of the assets, process and the employees, the vision is "Zero Downtime caused by Control System Outages". Although this is almost impossible, it will drive excellence and a spirit of continuous improvement.

Next the strategy focuses on the tactics that will get the organization there. These pillars the projects and initiatives that will be put in place to achieve the strategic goals of the organization [8]. To achieve the strategic goals, the following tactical initiatives have to take place on the assets of interest:

- Leverage existing Predictive, Preventative and corrective Maintenance Programs
- Elimination of the Main Problem
- Obsolescence plan and standardization of components
- Use Information Systems to generate knowledge, and drive business decisions

Values will serve as the foundation of the strategy and will focused on the organization's most valuable asset, people. Therefore, the foundation and the values that the strategy will be placed upon will be an "Engaged Team in Making Medicine with a safety first and quality always culture". Figure 5 can be used to communicate the strategy to the entire organization.

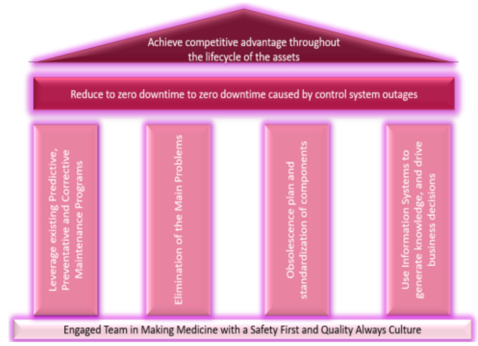

Figure 5
Electrical and Controls Maintenance Strategy

The resulting strategy house will help people understand the foundation of the strategy, the pillars that will hold it in place as well as the direction the organization will be headed over the life span of the asset. Since the implementation of such strategy is outside of the scope of this paper, a case study will be used to depict its implementation.

RESULTS FROM STRATEGY IMPLEMENTATION

Elimination of Main Problems

In order to prioritize, an asset was selected based on the potential risk it poses to the facility. Figure 6 and additional knowledge from the process supported that the filler should be the focus as it difficult to maintain due to its accessibility and potential near end-of-life components.

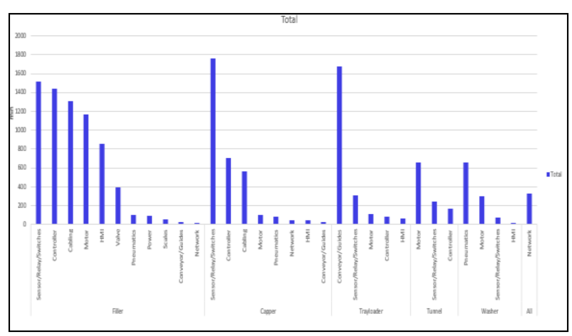

Figure 6
Downtime Histogram Related to Control Systems

Further categorizing the assets components was the next step for successfully determining priority. In doing so it was discovered that the motion control system for the filler, depicted in Figure 7, was becoming obsolete and no longer supported after June 2021.

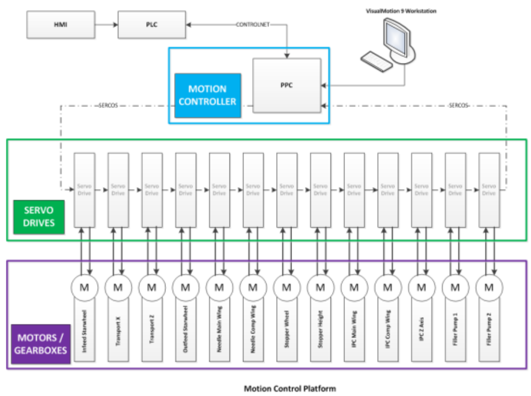

Figure 7
Filler Motion Control System

Obsolescence Plan and Component Standardization

In general, there are four options that can address control system components obsolescence problems, these are:

1. Pre-Stock additional spares in-house [8]
2. Coordinate with a distributer or third-party vendor to stock additional spares [8]
3. Find a refurbish parts dealer as an alternate supplier [8]
4. Migrate the component to a newer equivalent

Options 1 and 2 require overstocking, which represents an infant mortality risk. Option 4 has a lead time over 10 weeks at a cost $250,000 to complete the work. Finally, option 3 and the one selected will guarantee through a service agreement the re-manufacturing of these units at a cost of $80,000 in between PM’s.

Use of Information Systems

During the initial deployment of the strategy, it was discovered that obtaining information related to control system issues was challenging. A database system with integrated Form was developed to capture control system outages, what was done to recover from the specific outage and how much time it took to recover. The solution implemented is shown in Figure 8.

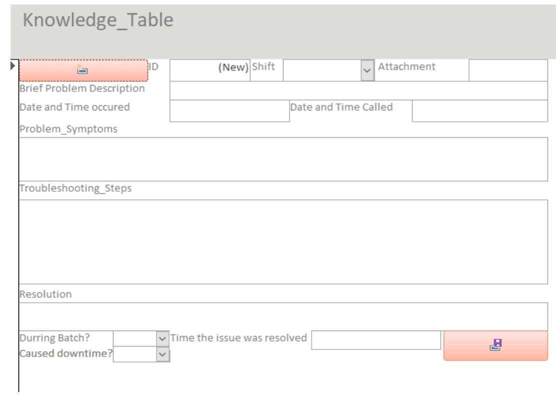

Figure 8
Ticket Management System Form

Leverage Current Preventative and Predictive Maintenance plans Programs

The filler motion control system relies on two type of maintenance programs. One is the preventative maintenance, which consists in maintaining the components on a time interval basis [9]. The other program consists of a run to failure plan, which is known as Corrective Maintenance (CM).

The Preventative Maintenance (PM) program for the filler motion control system includes the replacement of the servomotors every 12 months, while the servo drives are on a run to failure plan. The reasoning behind the selection on which components go on which program is risk based. Servo Motors are an electrotechnical as they have bearing, shaft and other moving parts they have wear and tear. On the other hand, servo drives have no moving parts as all internal electronics are solid state, hence no wear and tear are expected from this equipment if installed under the right environmental conditions.

Another consideration when selecting which program this component should be on, is the impact or risk caused by one of them failing. Replacing a servo motor is a highly involved process as it is located in an aseptic environment. Once a servo motor is replaced, the entire area must be cleaned and sterilized so that production can resumed. Servo drives are located outside of the aseptic environment and replacing them is relatively simple process. All this risk and impacts must be evaluated on a case-by-case basis to determine what Maintenance program they should be on.

From Figure 9, the life-cycle of these motion control components used to go from the OEM all the way to being installed and then disposed after usage. Figure 10 provides the new life-cycle that these motion control components will go through, as they will be refurbished after usage.

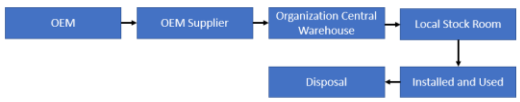

Figure 9
Initial Motion Control Components Life Cycle

Figure 10
Initial Motion Control Components Life Cycle

Servo motors will be replaced during the 12-month interval and sent to the repair center where they get refurbished in order to be available for re-ordering again. An automatic trigger from the CMMS will occur to replenish the servo motor that was used during the PM. Per contract with the refurbishing company, the servo motors will be re-delivered in a 6 weeks' time frame back to the main warehouse where they wait the next PM cycle to be used. For the servo drives the process is the same except that they are not routinely replaced.

DISCUSSIONS

The strategy presented in this technical paper can be applied to any assets, yet specific tactical decisions should be evaluated on a case-by-case basis. Note that the case study presented for implementation is an asset that will be entering the disposal phase in 2024, and capital investments are scrutinized. The risk still exists of the asset being utilized passed 2024, but this was not aligned with the overall business strategy. Finally, the deployment of the strategy identified and addressed problems around information systems.

CONCLUSION

During the implementation of the strategy an end-of-life motion control system was found. Support for the components was limited and they were no longer manufactured. From the options available and presented in this technical report, a refurbishing agreement was selected with an OEM partner to remanufacture these obsolete components until 2025, extending one year pass the facility entering the disposal phase. This solution provides an additional year of contingency if the plan for disposal of the asset is changed over time.

Another challenged solved through the strategy deployment was the stablishing of Information Systems to track electrical and control system maintenance.

The success of this project entails in applying it throughout the entire production line an address issues using a risk-based approach. As each equipment goes through each pillar, new findings will arise and with the mission and vision presented in the strategy a long term and sustainable solution can be developed that will provide the competitive niche that will be later benchmarked in the industry.

REFERENCES

[1] John D. Campbell, Andrew K.S. Jardine, Joel McGlyn, "Asset Classes and the World of Life-Cycle Asset Management", *Asset Management Excellence: Optimizing Equipment Life-Cycle Decisions*, Second Edition, 2019, Page 16.

[2] *Instruments Engineers' Handbook: Process Software and Digital Networks*, ISA, Research Triagle Park, NC, 2012, Pages 803-808.

[3] John D. Campbell, James V. Reyes-Picknell, "Building a Maintenance Strategy", *Uptime: Strategies for Excellence in Maintenance Management*, 2016, Third Edition, Pages 8-10

[4] John D. Campbell, James V. Reyes-Picknell, "Building a Maintenance Strategy", *Uptime: Strategies for Excellence in Maintenance Management*, 2016, Third Edition, Page 4

[5] Matthew P. Stephens, "Statistical Applications", *Productivity and Reliability-Based Maintenance Management*, first edition, page 26.

[6] Daniel Rossler, “Migration Project Justification”, *Control System Migrations: A Practical Project Management Handbook,* page 1.

[7] Matthew P. Stephens, “Statistical Applications”, *Productivity and Reliability-Based Maintenance Management*, first edition, pages 33-35.

[8] Daniel Rossler, “Migration Project Justification”, *Control System Migrations: A Practical Project Management Handbook,* page 8

[9] Matthew P. Stephens, “Preventative Maintenance”, *Productivity and Reliability-Based Maintenance Management*, first edition, pages 63-82