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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.

Introduction

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. Just like any other technology, automation and computerized control systems become obsolete over time. 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 be feasible or not.

Background

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 [1].

Decisions to utilize preventative or predictive maintenance plans are not strategies but are tactical choices within an overall strategy [2]. 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.

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 [3]. Additionally, these migrations should be considered during the modify stage of the Lifecycle of the asset, not near end of life.

Problem

- Not having a defined Electrical and Controls Maintenance Strategy to keep the vial line competitive for four more years.
- Apply the strategy to the most critical asset: The Filler and Stopping equipment

Methodology

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.



Figure 1: Total Life-Cycle Asset Management

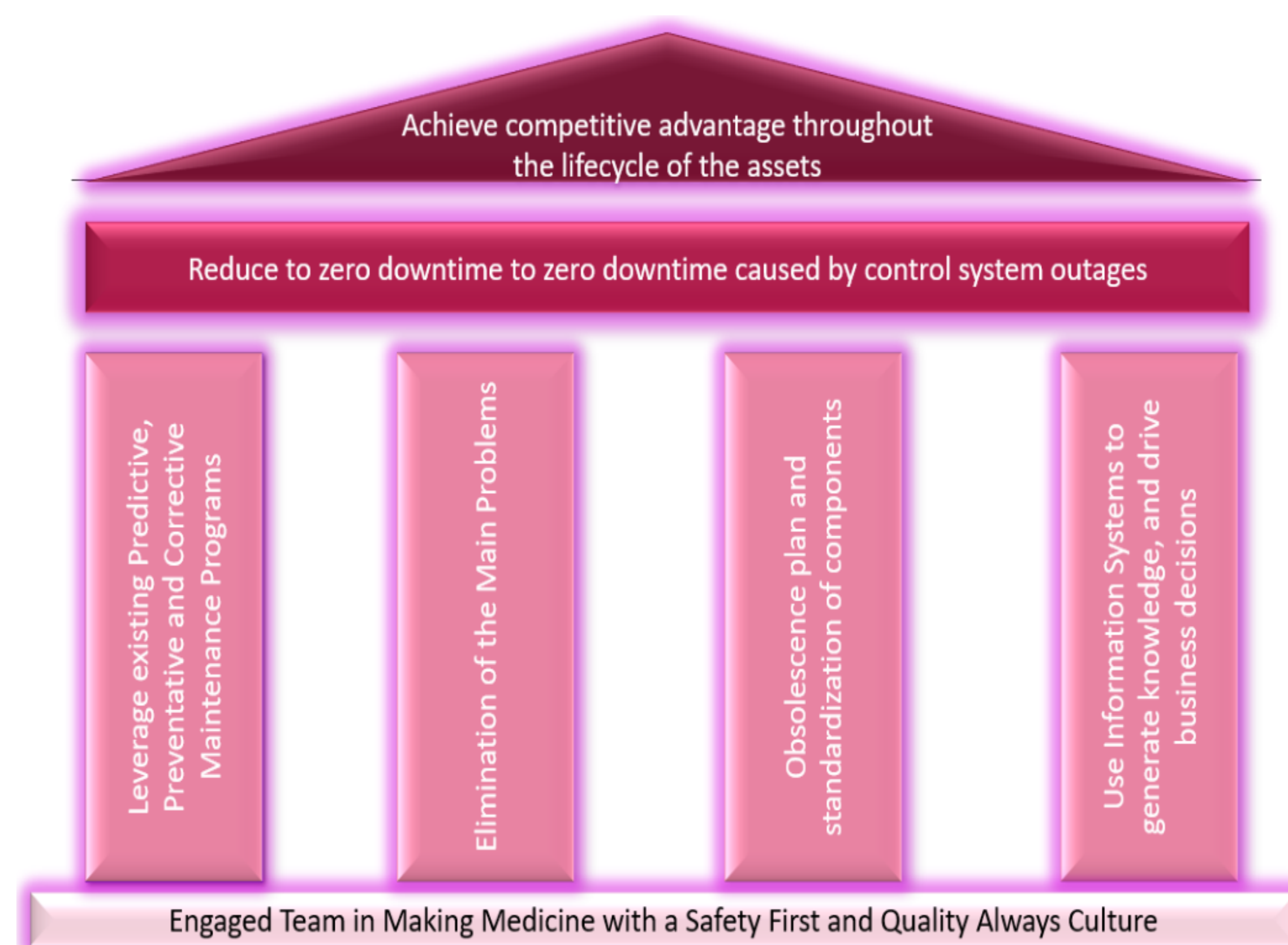


Figure 2: Electrical and Controls Maintenance Strategy

Results and Discussion

This section presents the results of the research, the analysis of the data including the most important statistical analyses performed and discusses the implications of these results regarding the research objectives. It must include only the results relevant to the research and how the conclusions were reached.

• Elimination of the Main Problem

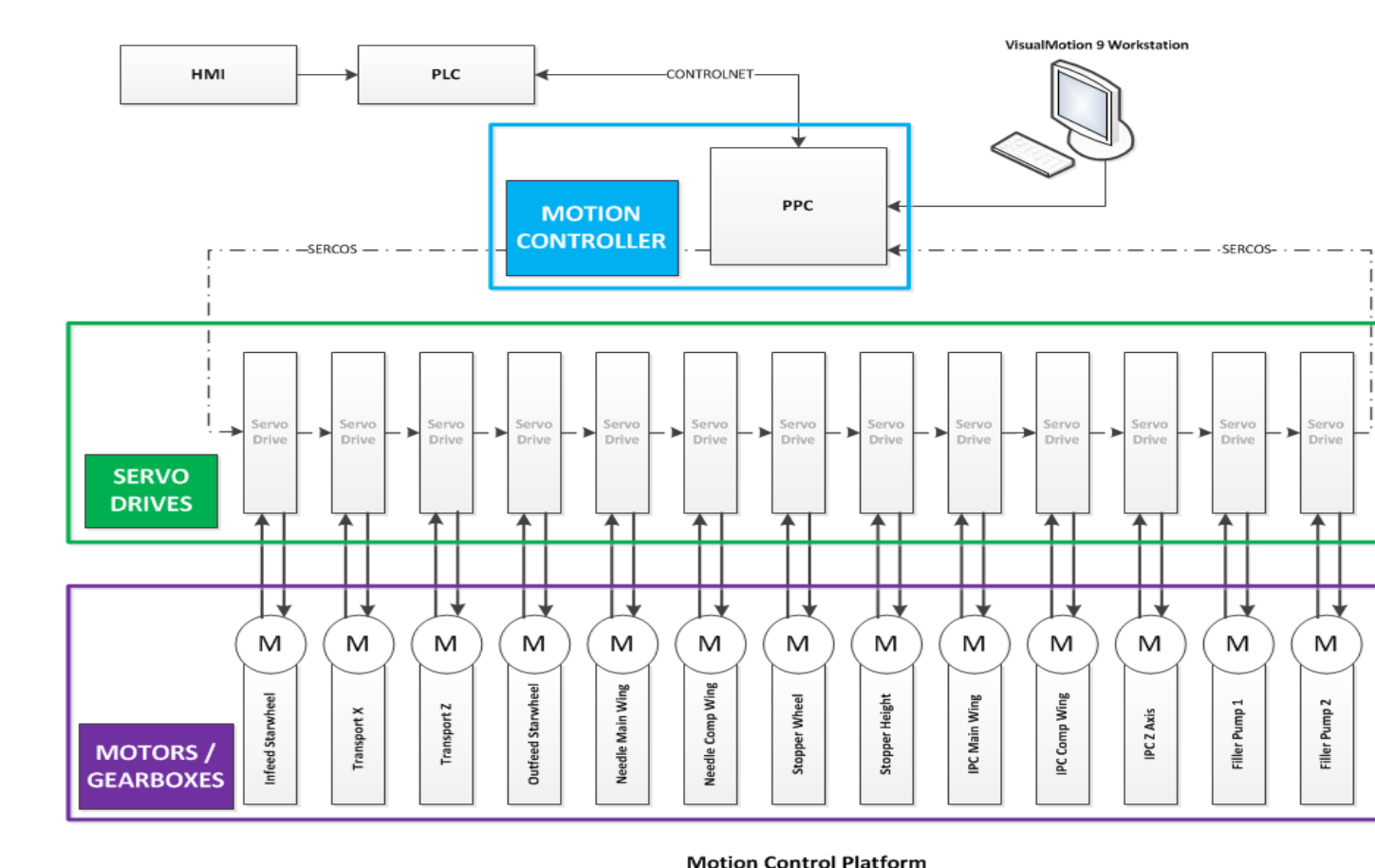


Figure 3: Filler Motion Control System

• Obsolescence Plan and Component Standardization

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

• Use of Information Systems

Figure 4: Ticket Management System

• Leverage Current Preventative and Predictive Maintenance

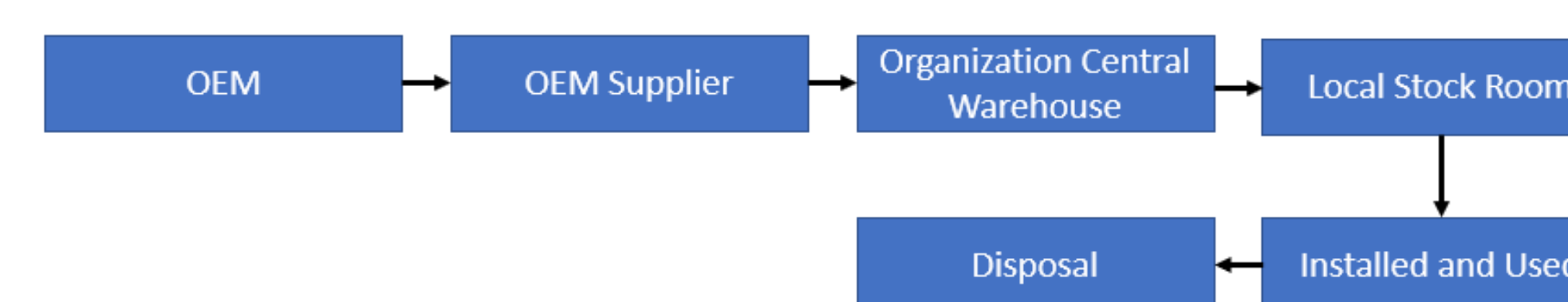


Figure 5: Initial Components Life Cycle

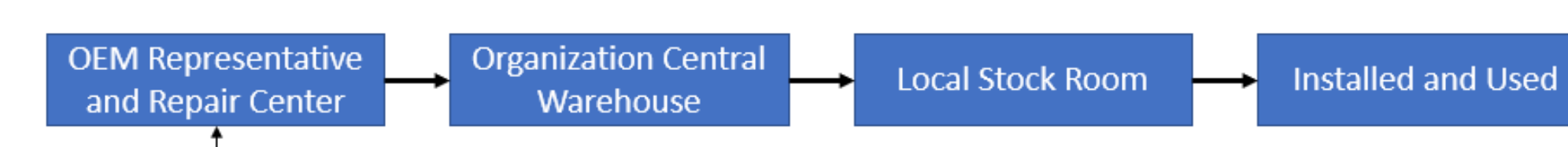


Figure 6: New Components Life Cycle

Conclusions

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 past 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 challenge solved through the strategy deployment was the establishing of Information Systems to track electrical and control system problems. The information can then be used to make business decisions that will increase the asset competitiveness.

Future Work

The success of this project entails in applying it throughout the entire production line to 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.

Acknowledgements

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References

- [1] John D. Campbell, James V. Reyes-Picknell, "Building a Maintenance Strategy", *Uptime: Strategies for Excellence in Maintenance Management*, 2016, Third Edition, Pages 8-10
- [2] John D. Campbell, James V. Reyes-Picknell, "Building a Maintenance Strategy", *Uptime: Strategies for Excellence in Maintenance Management*, 2016, Third Edition, Page 4
- [3] Daniel Rossler, "Migration Project Justification", *Control System Migrations: A Practical Project Management Handbook*, page 1.
- [4] Daniel Rossler, "Migration Project Justification", *Control System Migrations: A Practical Project Management Handbook*, page 8