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**This article presents an industry case study of the application of lean maintenance methodologies carried out at the Pfizer Biotech, Grange Castle Campus, Dublin.**

# Lean Maintenance – A Risk-Based Approach

by Gerard Clarke, Gerry Mulryan, and Padraig Liggan

## Introduction

Lean maintenance is defined as delivery of maintenance services to customers with as little waste as possible. This promotes achievement of a desirable maintenance outcome with fewest inputs possible.[1] Inputs include: labor, spare parts, tools, energy, capital, and management effort. The gains are improved plant reliability (availability) and improved repeatability of process (less variation).

The fundamental principles of lean are more frequently being applied to pharmaceutical asset maintenance. One of the most important aspects of lean maintenance is developing an understanding of the maintenance processes and applying a risk-based approach. This involves evaluating whether each element of maintenance practice used adds value to the product and benefits the customer. Lean maintenance drives efficiency and effectiveness and this ensures improved quality, equipment performance, and profitability.

Waste maintenance practices are associated with the following activities:

1. Unproductive work – efficiently doing work that does not increase equipment reliability.
2. Delays in motion – waiting for production equipment to be available to carry out preventive maintenance.
3. Unnecessary motion – unneeded travel, trips to parts stores, and looking for tools required to do a job.
4. Poor management of inventory – not having an adequate amount of the right parts at the right time.
5. Rework – having to repeat tasks due to poor workmanship.
6. Under-utilization of resources – maximizing resources available and harnessing the skill sets of the maintenance teams.
7. Ineffective data management – collecting data that is of no use or failure to collect data which is important.
8. Misapplication of machinery – incorrect operation or deliberate operational strategies leading to maintenance work being done when it needn't be.

It is important to note that lean maintenance is not simply an approach to do more with less resources.[2] It enables pharmaceutical companies to focus resources where they are needed to meet production and regulatory requirements.

## Why Choose Lean Maintenance?

Pharmaceutical companies recognize the need for change because of evolving regulatory requirements and competition in the marketplace. For example:

- The costs of product to market are rising and there are increased pressures from patent limitations and generic brands.
- Regulatory environment is continually evolving.
- The market is becoming increasingly competitive.
- Equipment is becoming increasingly specialized and automated. There are advantages to large scale production activities.

A lean maintenance approach mitigates against these factors and provides:

1. Consistent and coordinated approach across the plant.
2. Performance targets set through a combination of top-down aspirations and bottom-up site diagnostic assessments.
3. Accelerated timelines for implementation, because fast and efficient turnaround increases flexibility and profitability.

| Technique | Explanation |
|---|---|
| Value Mapping | A method of charting the transactions and processes required to satisfy a customer order with the aim of revealing opportunities for improvement in customer retention, productivity, lead time reduction, waste elimination, and reduced cash flow. |
| Criticality Analysis | An assessment of equipment and processes to identify the most critical areas, those with potential for human error and whose which impact the quality of service as a means of agreeing priorities and reducing risks. |
| Hidden Lost Cost Model | Defining the value of stabilizing/optimizing technology effectiveness and the cross functional agenda and techniques needed to deliver it. |
| Best Practice Development | A process for reviewing/refining existing working practices and standards to reduce accidents, breakdowns, contamination, and quality defect levels (ABCD). |
| Lean Maintenance Standards | Seven policy areas/standards which directly impact on reliability of equipment and the effectiveness of the maintenance department (preventive maintenance, servicing, technical information, planning, recording, budgetary control, spares management). |
| Focused Improvement | Tools to systematically address technology issues ad problem prevention techniques to secure breakthrough levels of equipment performance. |

Table A. Lean maintenance tools and techniques.

4. Increased quality and compliance through simpler systems/processes and focus on critical equipment and systems.
5. Better customer service by focusing on production needs.
7. Increased motivation of employees through true empowerment.
8. Linking individual contribution to overall business performance.
9. Faster response times to changing business and regulatory requirements.
10. Lower operation costs through rationalization of inventories along with less space and management requirements.

## Preparing for Lean Maintenance

A lean maintenance program begins with an assessment of the strengths and weaknesses of current maintenance practices (the current state). A major consideration is the demands placed on equipment by production needs and schedule. The reliability needs of the future state are identified and an action plan developed on how to achieve this. From there, improvement priorities are developed into a maintenance improvement project plan. This plan contains an analysis of equipment criticality to the process, optimization of maintenance, education of stakeholders, implementation of best practices and best fit of tasks to the appropriate functional area. Table A lists samples of the main lean tools used to support this activity.

The overall aim of the lean maintenance project at Grange Castle was to reduce non-value added maintenance activity and reduce cost 30% (stretch target). This was done by using lean maintenance principles and techniques. The key objectives identified after assessing the 'current state' were:

a. Optimizing the maintenance schedule by reducing preventive maintenance work by 30%.
b. Simplifying equipment maintenance documentation by reducing duplication in practices and complexity.
c. Implementing current best maintenance practices.

Table B summarizes what was identified as the current state at Grange Castle and the Lean Project Objectives. The objectives on the right were targeted during this phase of the project.

This article focuses on a number of these key areas targeted during the lean maintenance effort. The most effective way of engaging the workforce in the lean improvement agenda is to follow a growth strategy. In this project, one of the key drivers for lean was related to freeing up resources to support expansion projects in other areas of the plant. This added the flexibility to support a growing organization.

## Implementing the Lean Maintenance Process

### *Determination of Maintenance Strategy and Frequency for Process Equipment*

A formal engineering guideline document was written which enabled stakeholders, including the quality and engineering functions to review the current PM program with a view to agreeing the following:

- Identification and removal of non-value added maintenance tasks.
- A scientific and risk-based approach to revising and determining planned maintenance frequencies.
- Removal of duplication of tasks where these tasks were performed as part of procedural processes by Production Operations.

The approach was accepted across the site because it provided a

| Lean Maintenance Highpoints | |
|---|---|
| **Current Lean Maintenance Practices** | **Targeted Lean Maintenance Practices** |
| • Planning and Scheduling<br>• RCM<br>• Multi-Skilled Maintenance Technicians<br>• Work Order system<br>• CMMS System (SAP)<br>• Parts and Materials on a Just-in-Time Basis<br>• Maintenance Engineering and Reliability Engineering Group | • Proactive Maintenance<br>• Total Productive Maintenance (TPM)<br>• Empowered (self-directed) Action Teams<br>• SMED<br>• 6S – A method of workplace organization and visual controls<br>• Kaisen Improvement Events<br>• Autonomous Maintenance<br>• Distributed Lean Maintenance/MRO Stores |

Table B. Lean maintenance methodologies and current practices.

| | Weighting | 5 | 4 | 3 | 2 | 1 | |
|---|---|---|---|---|---|---|---|
| **Factor** | **Criterion** | **Catastrophic/ High Impact** | **Critical/ Will Impact** | **Marginal/Could Impact/Med Cost** | **Low Impact/ Low Cost** | **No Impact/ No Cost** | **Weight** |
| Quality | Contamination/ Batch Loss/ Production Impact | Multi-batch loss or production stopped for several weeks | Single batch loss but production able to continue once problem resolved | Could impact a batch if failure occurs during certain process step | Will have an impact if a second system were to fail | Product will not be contaminated, loss or production stopped | X50 |
| Safety | Degree of injury to a person or impact to the environment | Cause death or lose IPA license; shutdown for several weeks | Serious injury to people or could impact IPA license | Injury to people or recoverable impact to environment | Second system would have to fail before people or the environment are at risk | Failure will cause no injury to people or impact the environment | X70 |
| Maintainability | Inspection/Repair/ Maintenance downtime to be determined by area requirements | Downtime high with no standby system in place | Downtime low but no standby system in place | Downtime high with standby system in place | System seldom down and standby system in place | System is never down and low cost to repair and no production impact | X30 |
| Impact to Schedule | How manufacturing schedule is | Loss of multiple batches | Loss of batch (3 days) | Medium impact to schedule (a day and possibly recoverable) | Low impact to schedule (hours and recoverable) | No schedule impact | X40 |
| Cost (at time of production) | Cost of the reinstallation/ recovery and lost production days | Cost > 10M | Cost > 2M | Cost 100K to 500K | Cost 10K to 100K | No recovery cost | X20 |
| Idle Time | Turnaround Time | Idle Time 0 to 1 day | Idle Time 1 to 2 Days | Idle Time 2 to 3 Days | Idle Time 3 to 4 Days | Idle Time > 4+ Days | X35 |

Table C. Criticality assessment matrix grid.

clear and transparent decision making process that was based on a scientific and risk-based approach to support business and compliance needs. The approach provides a framework and mechanism for continuous improvement.

The document also assisted the stakeholders in determining, understanding, and communicating the rationale behind amending maintenance task lists and frequencies and was based on well recognized maintenance engineering standards and guidelines. The approach followed the following rationale and sequence:

**Equipment Criticality** – qualitative weighted compilation of the effect of equipment failure on product quality, personnel safety, and equipment downtime, cost and facility idle time. It provides the means for quantifying how important an equipment or system function is relative to the production process. Table C shows the criticality assessment grid used, it includes all the key areas considered and weightings that were applied.

**Strategy Decision Logic Tree** – this process uses equipment criticality and a review of maintenance task lists to determine what the best maintenance strategy is for the equipment and its application in the process. This tool can be used to assess each maintenance task and decide its eventual outcome. Figure 1 below shows the flow diagram used.

Using the decision logic diagram (Figure 1) ensured that all process equipment was subjected to the same standard approach. It allowed the maintenance engineer/maintenance technician to select from one of the following maintenance strategies.

- TBM – time base preventive maintenance – replacement irrespective of condition
- CBM – condition based or predictive maintenance
- DOM – design out maintenance (re-design where possible)
- OTF – operate to failure

**Frequency Decision Process** – a process for determining time-based maintenance intervals based on historical data (mean times between failure) and probability of equipment failure. Figure 2 shows the flow diagram used.

### *Production Operator Autonomous Maintenance*

When a number of maintenance tasks were brought through the decision trees, it was noticed that many activities were already or would more logically be completed by production operators. It was agreed with the operations function to move tasks that routinely already had been carried out as part of standard operating procedures or could have been more easily executed by operations technicians. These tasks were classified as 'autonomous maintenance tasks' and were incorporated into operations daily routine as part of the business process or as part of standard operating procedures depending on the criticality of the task and equipment. Examples are cleaning and lubrication of equipment as well as visual checks for leaks. The term 'autonomous maintenance' is also widely referred to in industry as 'operator care.'

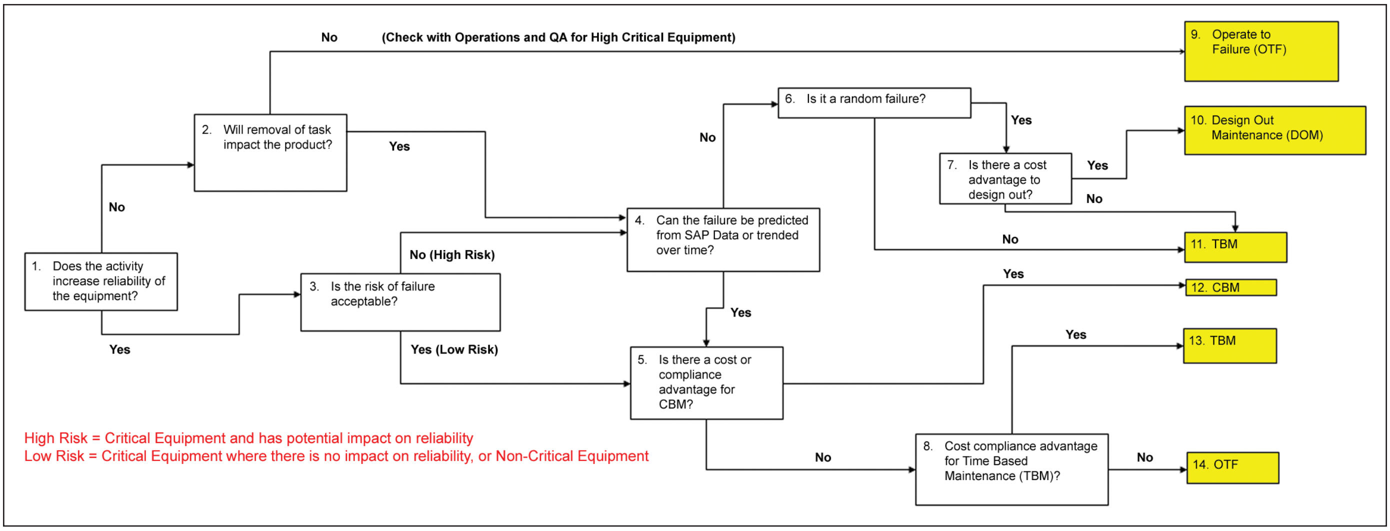


Figure 1. Strategic decision logic tree.

The operator accepts and shares responsibility (with maintenance engineering) for the performance and health of their equipment. The advantages are ownership and understanding of equipment and better use of existing resources.

As part of the business process, a check sheet was developed for each of the production areas called a "housekeeping list," which requested the operator to carry out basic checks prior to production. This list is similar to aircraft 'pre-flight checks' checks carried out by the pilot. Operators have a well-defined check list and a set of simple maintenance activities that can be performed during their shifts. Abnormalities are recorded and communicated to maintenance engineering. This ensures that appropriate resources and expertise are deployed where they are required to meet business needs and also allows prioritization of maintenance work.

As part of this process, basic checks such as look, touch, feel, and smell are explained to the operators by the equipment system matter expert. Operators are now more involved in root cause analysis programs to improve this understanding of failure modes and their elimination and improvements in the maintenance program.

## *Single Minute Exchange of Die (SMED)*

Single Minute Exchange of Die (SMED) is widely used in lean production. SMED was originally used in industry to streamline and reduce the time taken to change a die. Since then, it has been applied more generally to changing of tools, materials, and machines between repetitive jobs. The goal of

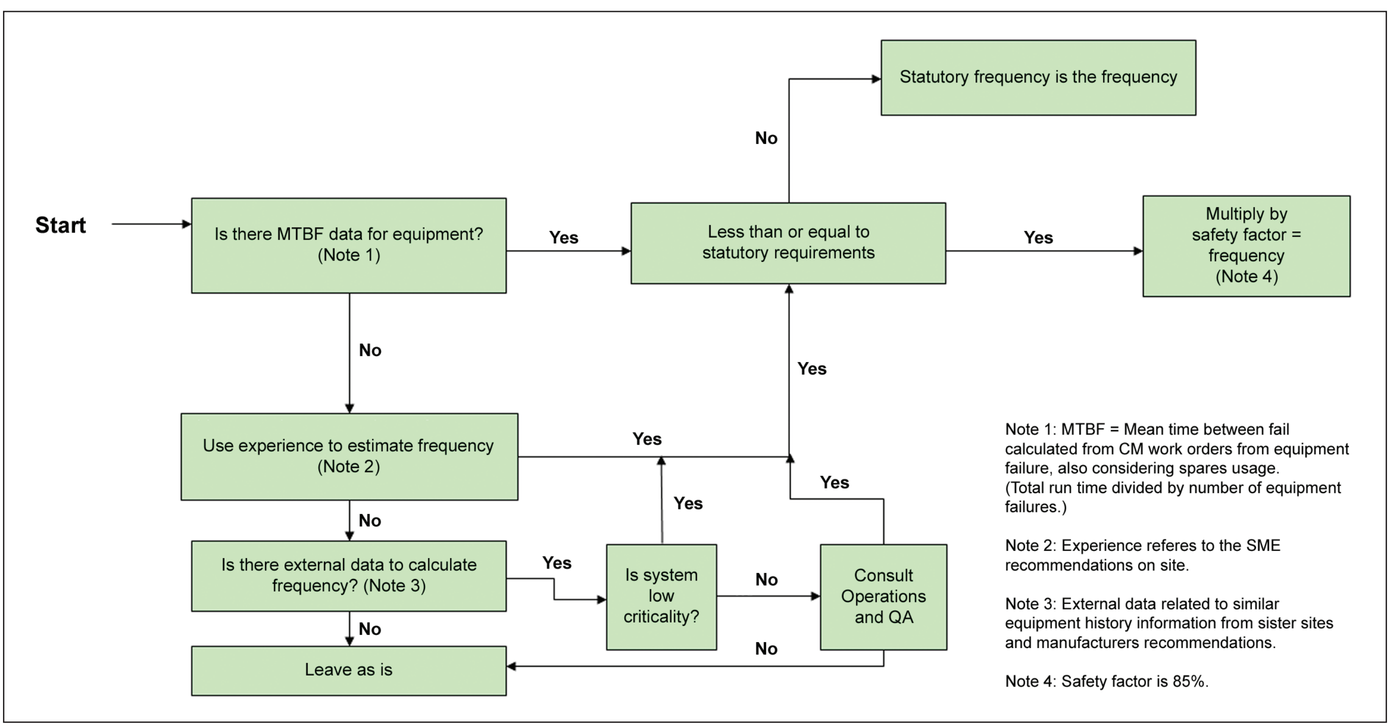


Figure 2. Frequency decision tree.

Figure 3.Process diaphragm valves.

SMED is to safely achieve the shortest possible change-over time. This is achieved by thoroughly examining all aspects of the task and removing wasteful activity.

During the lean maintenance project at Pfizer Biotech, Grange Castle, the SMED process was used effectively to minimize downtimes for scheduled Elastomer Change Outs (ECO) on bioreactors. In a biotechnology facility, diaphragm valves (Figure 3) are widely used, the sizes vary from ½ inch up to 4 inch diaphragm valves with the diaphragm material used being either Ethylene Polymer Diene Monomer (EPDM) or Polytetrafluroethylene (PTFE). The diaphragm valves targeted for the SMED process are located on bioreactors; they are subject to high process use and regular steaming cycles which require the internal diaphragms to be changed out on an annual basis.

The change management program known as Elastomer Change Out (ECO) involves a complete disassembly of the valves and diaphragms. This involves the following:

- isolation of system (for safety reasons)
- disassembly of the valve housing and building valve with new diaphragm

The SMED process was used to divide the steps involved in elastomer change out maintenance into three types, as follows:

- Waste – steps which did not add any value
- Internal – steps which could only be done within the maintenance task
- External – steps that could be performed prior to the maintenance task

Video was used to record a number of elastomer change-out activities. This helped categorize the steps required to complete the task. ECO's performed on different shifts were recorded by different people. This showed a huge variation in the steps taken and in the time needed to complete each step. By analyzing the steps into waste, internal, and external the maintenance technicians evaluated their own performance and identified inefficiencies. The outcome of the SMED process was a reduction in bioreactor downtime by 25% through greater preparation and simplification of the tasks.

## Results of the Lean Maintenance Program

Figure 4 summarizes the initial results of the lean maintenance program. The project yielded a 22% reduction in maintenance man-hours required. The following original goals and objectives were achieved:

1. Non-value activity was removed from the preventative maintenance program.
2. A risk-based structured process was created to remove non-value added maintenance activities and to allow for consideration for the addition of future maintenance tasks.
3. Technician resources were released to support other projects or focus resources where they were most needed.
4. Autonomous maintenance was introduced.
5. Using the main lean principle Single Minute Exchange of Die (SMED) the time to complete elastomer change outs in production areas was significantly reduced.
5. Lean maintenance projects are now ongoing as part of a continuous improvement program.

The reduction in planned maintenance activity has reduced the amount of corrective maintenance required significantly since its implementation 12 months ago. There has been no negative impact on equipment performance, availability, and reliability.

## Summary and Conclusions

Before lean maintenance was introduced, the company suffered from "iatrogenic failures," i.e., failures caused by over maintaining or not focusing on critical activities. Symptoms of this included:

1. **Over production:** the maintenance technicians completed tasks more times than needed.

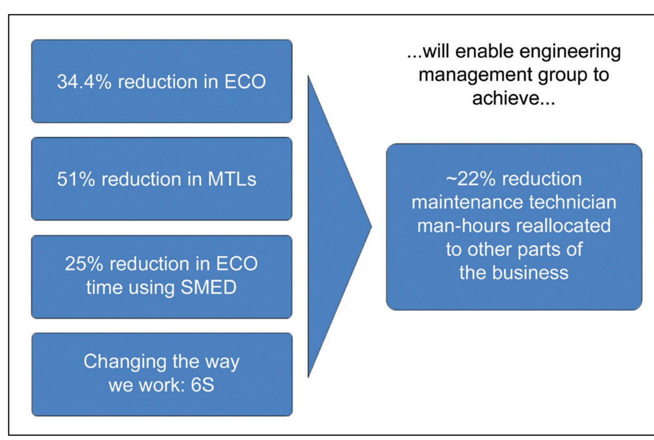


Figure 4. Overall results from the lean maintenance transformation.

2. **Inventory:** the store room had to unnecessarily stock more spare parts. For example elastomers, gaskets.
3. **Motion:** the maintenance technicians misused their time by moving back and forth looking for tools.
4. **Waiting:** excessive production downtime required for maintenance.
5. **Transportation:** additional preparation for conducting the maintenance was done which was not needed.
6. **Over processing:** extra maintenance work orders were created that needed to be audited and verified by maintenance technicians, supervisors, and final approvers.
7. **Not right the first time:** provided the opportunity for "not getting it right" more times than was needed.
8. **Under-utilization of people:** technician doing non value added work.

These areas were targeted as part of this project and significant progress has been made in eliminating or significantly reducing the associated impact. The process of improvement is continuous and has resulted in a positive cultural change around maintenance and its objectives.

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