IMPLEMENTING LEAN METHODOLOGIES WITHIN A MAINTENANCE ORGANIZATION

By

Dana Ari Levine

S.B. 2002 Brain and Cognitive Science
Massachusetts Institute of Technology

Submitted to the MIT Sloan School of Management and the Department of Biological Engineering in Partial Fulfillment of the Requirements for the Degrees of

Master of Business Administration

and

Master of Science in Biological Engineering

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Signature of Author _____
Department of Biological Engineering, MIT Sloan School of Management
May 8, 2009

Certified by _____
Alexander M. Klibanov, Thesis Supervisor
Novartis Professor of Chemistry and Bioengineering

Certified by _____
Roy Welsch, Thesis Supervisor
Professor of Statistics & Management Science

Accepted by _____
Alan Grodzinsky, Graduate Committee Chairman
Department of Biological Engineering

Accepted by _____
Debbie Berechman, Executive Director of MBA Program
MIT Sloan School of Management

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ABSTRACT

The primary goal of the project was to make the machine maintenance process more efficient. In order to do this, we conducted a 3-day Value Stream Mapping workshop, during which we generated a map of the present value stream. We identified shortcomings and inefficiencies within this value stream, and then mapped out a future state Value Stream, creating a 90-day action plan to move towards that desired future state. This action plan relied heavily upon measuring and improving key performance indicators, which allowed us to make objective measures of our progress.

A second internship objective was to reduce the number of clean room re-sanitizations. Currently, clean rooms undergo a costly and time-consuming re-sanitization whenever an air handler is shut down for a brief period of time. It is likely that some of these cleanings are unnecessary, and eliminating extraneous cleanings could reduce maintenance costs significantly.

In order to reduce unnecessary clean room re-sanitizations, we designed and conducted a study to measure environmental standards during an air handler shutdown. Genzyme's Validation and Quality Control Departments approved this experimental plan prior to execution. We shut down an air handler that supplied a clean room, and monitored the air for viable and non-viable particles for several hours. Viable particulate levels did not exceed action limits during a four-hour shutdown, and non-viable particulates dropped to pre-experiment levels as soon as we re-started the air handler. Based on these results, we conclude that air-handler shutdowns should not require room re-sanitization.

Thesis Supervisor: Alexander M. Klibanov
Title: Novartis Professor of Chemistry and Bioengineering

Thesis Supervisor: Roy Welsch
Title: Professor of Statistics & Management Science, MIT Sloan School of Management

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TABLE OF CONTENTS

Table of Contents

LIST OF FIGURES

GLOSSARY

KPI: Key Performance Indicator

WO: Work Order. There are two different types of work orders at Genzyme. We will refer to Corrective Action Work Orders as Work Orders, while we consider Preventative Maintenance tasks separately.

Corrective Maintenance: Unanticipated maintenance work to correct an equipment malfunction or failure.

Preventative Maintenance: Regularly scheduled maintenance work to prevent equipment failure. This may include inspection and replacement of any worn or used parts.

PM: Preventative Maintenance Task.

End-User: Any Genzyme employee who relies on the machine or facilities that are being serviced by Facilities Management. Typically, we will refer to the end-user as the person who is responsible for said machine or facility.

ISO Clean Room: A room that meets specified standards for levels of particulate matter. Each clean room classification limits the maximum density of particles greater than or equal to several specified sizes.

Action Notice: Notice that a room or piece of equipment will be shut down for maintenance work.

Re-Sanitization: When a clean room needs to be taken down for a maintenance task, the room must be cleaned before normal activity can recommence within that clean room. This involves cleaning all surfaces in order to remove any particulate matter that may have accumulated.

1 Introduction

1.1 Project Background and Overview

As the biotechnology industry has matured over the past several decades, Wall Street has come to expect greater profitability and increased efficiency. Despite earning astronomical revenues over the past 40 years, the biotech industry has lost over $100 billion since the early 1970s, and the industry as a whole did not achieve profitability until 2008[1] [2]. Since it takes eight to twelve years to get a new product through the FDA approval pipeline, and sales of existing products tend to ramp slowly, often the only option for increasing a company's profitability over the short term is to decrease its costs for biopharmaceutical production. This has led to widespread adoption of operational improvement methodologies among biotechnology companies.

Tools such as Lean and Six Sigma originated in the manufacturing industries, but over time they have expanded to cover all types of business operations. Biotech companies have applied some lean tools to their actual manufacturing processes, but these tools can also improve all aspects of their operation. Tools such as value stream mapping and kaizen events have helped to improve any portion of business workflow.

Founded in Boston in 1981, Genzyme has grown from a small start-up to a large-scale enterprise with annual revenues of nearly $4 billion and over 10,000 employees. Genzyme is headquartered in Cambridge, MA, and has manufacturing locations around the globe.

Genzyme's primary mission involves creating drugs that meet previously unmet medical needs, and this has lead it to develop a number of novel drugs and diagnostics. Genzyme focuses on rare inherited disorders, kidney disease, orthopedics, transplant, cancer, and diagnostic testing, and has helped patients in over 90 countries. Its commitment to innovation continues today with a

[1] http://www.nytimes.com/2008/12/10/business/10biobail.html

[2] http://www.fiercebiotech.com/press-releases/biotech-industry-turns-profit-first-time-milestone-overshadowed-companies-struggle-su

substantial research and development program focused on creating new treatments for these conditions, as well as immune disease, infectious disease, and other areas of unmet medical need.

Over the past few years, Genzyme has focused heavily on Operational Excellence, and management has made this a key focus. In 2007, the company created a dedicated Business Process Improvement group to spread operational improvement through the company. This group has facilitated a number of trainings and value stream mapping events, with the aim of driving improvement and cost savings.

Genzyme's Facilities Maintenance group serves to support its manufacturing process, providing critical utilities such as refrigeration, water for injection, and air filtration. Genzyme's Framingham facilities have expanded drastically since the site began operations, and they now fill 14 buildings. Over time, a facilities group of nearly constant size has taken on responsibility for maintaining an increasing number of buildings. The facilities group has attempted to increase operational efficiency in the past, and it even hired a consulting firm to assess its operations. Prior to the beginning of this project, total operating cost was the only regularly measured number that Facilities Maintenance could use to assess its performance. In an attempt to suggest some operationally relevant metrics, the consultants recommended that Genzyme facilities implement 35 Key Performance Indicators (KPIs), which aimed to gauge the health of the facilities operation and to drive improvement. Unfortunately, no one ever implemented measurement or analysis of these KPIs. Genzyme facilities management has dealt with a constant series of high-priority projects, and no one ever attributed this condition to a lack of metrics. Furthermore, implementing the KPIs required significant data entry and customization of the Computerized Maintenance Management System, and this work did not happen until recently.

One of Genzyme's goals is to move to a defined, measurable process for facilities maintenance. Parts ordering and job scheduling will be performed by dedicated personnel, and these processes will be regimented and standardized. Genzyme aims to use a structured approach for reforming its process, involving industry best practices such as Value Stream Mapping. In doing this, Genzyme will reduce both the cost to perform work and the time required to complete it. Finally, it hopes to begin measuring and assessing Key Performance Indicators, which should enable continuous improvement.

1.2 Problem Statement

As a cost center, Facilities Management aims to maintain or to decrease operating expenses, even as it provides a greater level of service to its clients. Maintenance technicians spend a significant portion of their time performing tasks that do not involve actually doing maintenance work. Facilities Management has attempted to increase "wrench time" by hiring dedicated personnel to handle the planning and scheduling aspects of work order processing. In order to integrate the aptly named "Planner" and "Scheduler" into the work order process, group management devised new workflows that integrated these functions. However, informal assessment has quickly revealed many more potential improvements to the workflow process. As facilities makes changes to its workflows, it is important to have a process for gauging the actual effects of those changes, and the lack of metrics makes it impossible to do so. A set of well-designed metrics will give insight into the effects of any process changes.

Facilities Management aims to reduce operational costs by eliminating unnecessary maintenance procedures. ISO Class 8 clean rooms undergo two different types of cleaning – a nightly cleaning and a more stringent weekly cleaning. Whenever facilities personnel shut an air handler down for maintenance, standard practice dictates that the clean rooms serviced by that air handler undergo an additional weekly cleaning. Based on anecdotal evidence, we have inferred that some of these cleanings are unnecessary, and believe that eliminating extraneous cleanings could reduce maintenance costs significantly.

1.3 Thesis Overview

This thesis is designed to study the effects of applying lean principles and tools to Genzyme's Facilities Management organization. We do this in two ways; the first involves performing a value stream mapping event and using this to implement metrics and kick off a number of process improvements. The second involves conducting a validated experiment where we assess the impact of an air handler shutdown on the environmental conditions within a clean room that it services.

Chapter 2 provides background information that details the legacy maintenance procedures at Genzyme. It walks through the Work Order execution process, giving insight into some of the steps involved and highlighting some of the inefficiencies in this process. In addition, it discusses the cleaning policies currently applied to Genzyme's ISO Class 8 clean rooms.

Chapter 3 overviews the general approach that we use in improving the machine maintenance procedure. It discusses the methodology that we use, and discusses the value stream mapping process, including the present-state, future-state, and action plan. Finally, it outlines the specific follow-up plans that we lay out during the workshop.

Chapter 4 discusses the follow-up to the value stream analysis process. It discusses actions that we take in the months following the value-stream analysis, and details the short-term results. Furthermore, it makes recommendations for further actions and improvements.

Chapter 5 discusses the air handler shutdown experiment. It overviews the development and validation process, goes over the experiment procedure, and outlines the data that we collected from the experiment. It then presents results and recommendations, and suggests a course of action for future study.

Chapter 6 presents some of the lessons learned during this project, and makes recommendations for some future actions that could increase the success of future initiatives.

2 Background

2.1 Legacy Work Order Process Overview

Facilities Management has defined a formalized process for executing work orders. The work order process has six different steps: **Work Order Entry, Work Order Review, Planning, Parts and Scheduling, Work Execution**, and **Closeout**. Both Corrective Work Orders (WOs) and Preventative Maintenance tasks (PMs) follow a similar process. The main difference is that PMs are performed periodically, and are automatically scheduled to kick off at preset intervals (eliminating the need for manual entry). Corrective WOs are manually entered into the system when a user files a work request. In this document, we will describe Corrective WOs, even though our actual improvement efforts focus more on PMs.

In order to track and route WOs, Genzyme uses a Computerized Maintenance Management System (CMMS). This CMMS allows Facilities Management to keep track of work orders, as well as the associated machines, labor, and parts. At every point in the workflow process, a work order is assigned to a specific person, and that person may view the status and history of that work order. As the assignee completes his work, he enters information into the CMMS, and the Work Order passes to the next phase.

The following description covers the work order process at the time that we began our comprehensive value-stream improvement.

2.1.1 Work Order Entry

The corrective work order process begins whenever an end-user wants to have facilities perform a task. This could be because something is broken, needs to be cleaned, moved, or procured. The requestor, who could be any Genzyme employee, enters the request into a form on Genzyme's corporate portal. They enter their *name, phone extension, building, room number, asset number (optional), work order type (optional)* and *description.*

Submitting this form sends an email to a special email account, which is periodically checked by an administrative assistant. She manually copies and pastes the information into the CMMS, creating a

new work request. She prioritizes the work order, and it is routed to the appropriate building supervisor. She then manually sends an email to the requestor, telling them the work order number, their building number, a brief description of the WO, and the building supervisor's name. There are about 250-350 Work Orders routed through this system each month, constituting about 10-20% of the 20,000 annual WOs. Most of the remaining WOs (including the highest priority Work Orders) are manually entered into the system by a technician or a supervisor, and a few users have the ability to enter WOs directly into the system. Genzyme is currently implementing a service request system that will allow end users to enter work requests directly into the CMMS, but this may not be implemented for several months to a year.

2.1.2 Work Order Assignment

The work order is then sent to the appropriate Cost Center Front Line Supervisor, of whom there are six. The CCFLS is below the building manager, and supervises the work. The CCFLS verifies the Asset number and location, which can be done using the asset list in the CMMS. If the Asset number is not included, it must be manually determined and then entered. The status in the CMMS is then set to "verified." The supervisor will typically call the client, and verify the WO's priority (sometimes the work is not truly urgent). At this point, he will assign it to a technician.

The CCFLS then determines whether or not action is to be taken (99% of the time, action is taken). Sometimes, the request is sent to IT, security, or another group, and it is closed out in this system. Each group within Genzyme has its own ticketing process, necessitating the creation of a new ticket in the corresponding system.

2.1.3 Planning

The job is sent to the planner, who determines what needs to happen prior to and during execution of the work. Genzyme Facilities performs a large number of different types of work, so each work order needs to be handled differently. For example, parts may need to be ordered or permits may need to be approved. It is much easier to do planning for preventative maintenance tasks, since they are scheduled at regular intervals and can be planned a few weeks ahead of time. Currently, there is

not much formal planning for corrective work. The planning process for preventative maintenance tasks has improved drastically since a planner and an RCM engineer were added to the group, but is still in its infancy.

2.1.4 Parts Ordering and Stocking

Genzyme keeps a storeroom, which stocks parts for Preventative Maintenance and Corrective Work Orders. Parts generally are only stocked for a subset of Corrective Work Orders, although work with critical parts and planning may ensure that parts are stocked for all high-probability and high criticality Work Orders. The parts ordering process involves a number of distinct steps.

When a part needs to be purchased, the technician first gets quotes from several sources. The order is then put into the eProcurement system, and is approved by the appropriate authority (currently the building manager). The purchasing department then creates a PO in the purchasing system, and the PO is then approved. The part is ordered, and a confirmation is put on the purchasing order. Eventually, the part is received, and can be used for the required maintenance task.

Currently, parts are ordered for PMs and stored in the storeroom. However, the current plan is to deliver PM parts to a predetermined location in the appropriate building. The parts will generally be delivered two weeks in advance of the PM due date.

2.1.5 Work Order Execution

The work is routed to one of three groups.

- Building Technicians – This group consists of both general-purpose workers, who perform general mechanical installations and repairs, and of licensed technicians, such as electricians, plumbers, and HVAC repair.
- Building Vendor – Some work is not performed by Genzyme personnel, but is outsourced to a vendor. A special group within facilities that performs this work.
- Project Group – Larger (time intensive/expensive) projects are sent to the project group, who plans and executes them. This could include renovations and equipment replacement.

Each of these groups performs a slightly different workflow process. Since the Building Vendor and Project Groups were out of the scope of this project, these workflows will not be covered. The workflows for the Building Technicians and Trade groups are the same, since both report through the same structure. The groups originally were split by function, but this caused too many logistical and organizational problems, and now a dedicated group of building technicians and trades people services each building group (as of the beginning of 2008). Technicians are generally responsible for a single building, while trades people are responsible for a few buildings. The supervisors do assign some general maintenance tasks to trades people, in an attempt to better round their skill set.

The supervisor then determines the due date and routes the work order to the appropriate technician. The technician has a large amount of discretion over how the work is completed. The projects are prioritized by the CCFLS, although the technician is ultimately responsible for choosing which work to execute. Each WO is given a deadline of about two weeks, and if that deadline is missed, it can be extended until completed. Preventative maintenance tasks are rarely given extensions, as FDA regulations govern the execution of PM tasks.

There is a fair amount of variance in the number of work orders that the technicians have assigned in the CMMS at any point. The building technicians have about 10-12 WOs assigned at a time, and about 20 PM tasks. The specialists may have 30-40 WOs at a given time (since they are responsible for several buildings at once). Some of the PM tasks could involve taking daily or weekly readings, while some are much more complex. Since each task translates into a different amount of work, the number of WOs assigned to each technician will not always be equal. However, the supervisors ensure that every technician has a fairly equal workload, and attempt to make sure that each technician has about two weeks of work assigned at any point. Improvement in the planning and scheduling functions could help to standardize the amount of work that each technician has assigned.

The technicians are at liberty to schedule the work, order parts, and file an action notice if the project has potential impact on operations. For any Work Order, the requestor may need to order the part, which could cause the WO to be placed in an Awaiting Parts status). Scheduling any

significant work in some of the facilities can be difficult, since these facilities are constantly manufacturing product. Furthermore, any work could require clean room re-sanitization. Often workarounds need to be found to reduce downtime to critical equipment.

2.1.6 Close Out

When the work is completed, the technician documents it in Genzyme's CMMS. The description includes his employee ID, the amount of time that he worked on it (used to track labor costs), and a summary of the work performed. He changes the status to "Technician Complete." There is significant variation in the detail level of the description entered when a WO is closed. Some technicians are meticulous in describing the work performed and root causes, while others just put "complete" in the field. The CCFLS then reviews the WO for completeness and other requirements, and then closes it out within the CMMS.

2.2 Discussion of the Planning and Scheduling Roles

About two years ago, the Facilities Group decided to offload some of the work that was normally assigned to maintenance technicians. This mostly involved planning for jobs and attempting to schedule the work with end-users. Although technicians were able to plan jobs and order parts, certain technicians became experts on certain jobs, and most of the knowledge was not publicly documented. In addition, Genzyme did not have complete bills of materials for many of their machines, and maintenance procedures may be dependent on time-based and traditional maintenance practices. Although the maintenance procedures were based on manufacturer recommendations, not all procedures incorporate predictive maintenance or condition monitoring.

From the scheduling perspective, the technicians were doing a significant of repetitive and unnecessary administrative work. When it came to getting permits signed, the technicians often had to make multiple trips to track down the person responsible for the equipment. Furthermore, it is fairly inefficient to have multiple people scheduling shutdowns, as it would be possible for the same equipment to be taken down more than needed if maintenance efforts are not coordinated.

2.2.1 Planning

Genzyme added the planning role in order to help regiment the process of preparing for maintenance tasks. Genzyme has always had formal maintenance procedures, and these procedures identify the tasks and materials required to perform the PM tasks. However all of the required materials in the procedure are not reflected in the CMMS. This makes planning jobs beforehand more difficult. Technicians may perform additional or non-value added maintenance or checks that supplement the official procedure, and until recently there was no official feedback loop to allow technicians to note that the maintenance procedures could be improved. In addition, Facilities does not have complete Bills of Materials for many pieces of equipment. As parts need replacement, they are added to the Bill of Materials, but some critical parts that never require replacement may never be identified and entered into the CMMS.

In some cases, the inspections required are subjective in nature and lead to PM actions being performed more often than needed. This could lead to over-ordering of parts. For example, Air Handler belts do not need to be replaced every time the machine is inspected, and ordering a belt every time has led to a surplus of inventory.

In response to this, Genzyme hired a planner around 2006. The planner's job is to make sure that all parts and procedures are correct, and that the necessary parts are ordered for preventative maintenance tasks. If the actual task varies from what is documented, the planner will receive feedback and update the relevant documentation. Facilities also hired a Reliability Centered Maintenance (RCM) engineer in early 2008. The RCM engineer's job is to perform technical analyses of the maintenance procedures, and to determine which parts are critical for machine operation. After reviewing the procedures, he updates them based on current equipment use and maintenance practices.

2.2.2 Scheduling

The scheduler's primary job is to handle scheduling any work with the end users. Genzyme is moving away from a system where technicians schedule their own work, and is moving towards placing all work on a formalized schedule. Each PM action currently has a specified due date, and the task must be completed by this date. Under the new system, PM actions will be done on a scheduled date and time. The scheduler takes care of all permits and shutdown notifications, and can

coordinate multiple preventative maintenance tasks to be performed during a single equipment shutdown. After getting sign-off from the end-users, the scheduler generates a schedule for when all work is to be performed, and the supervisors can then assign these scheduled jobs to the technicians. All parts and materials are delivered to the work site ahead of time, and the schedule is finalized the week prior to when the work is performed. All that is left for the technician is to show up, perform the work, and to document that it has been completed.

Genzyme hired its first scheduler in mid-2008, and so this role was not operational when we began working on this project. Scheduling of preventative maintenance tasks was scheduled to go live in fall of 2008.

2.3 The Storeroom

Genzyme recently set up a storeroom, which keeps parts used by the facilities organization. This includes all parts used for preventative maintenance and corrective work orders, with the exception of small parts, which are stored in each building. The storeroom management process consists of four steps:

Purchasing – Parts need to be purchased from a vendor and shipped to Genzyme. The purchasing process is detailed elsewhere in this document. When parts are ordered for stock, they must go through the same approval process as corrective parts.

Receiving – Once a part is purchased, it needs to be received and accounted for.

Storing – Parts need to be stored so that they can be retrieved and used later on. The storeroom recently installed six automated parts shuttles, which facilitate the storage and retrieval of small parts. The location of each part is stored within the CMMS. In addition, Genzyme has a series of racks, which can be used to store parts that will not fit inside the shuttles. The storeroom manager would like to implement a min/max system for stocking parts, where the inventory is tracked over time, and stock is ordered to the max level whenever it reaches the min level. This could reduce overstocks of air handler belts, which are currently ordered for each PM procedure.

Maintaining – Some of the parts are complex systems that need to be periodically maintained, even if they are not in use. For example, bearings may need to be replaced, even if the part is not installed, since they will eventually deform if they sit in one position for too long.

2.4 Air Handler Shutdown Background

Genzyme operates four types of clean rooms within their facilities. These include ISO Class 5, ISO Class 7, and ISO Class 8. The ISO standards specify maximum concentration limits for the particles within the air of a clean room (detailed below).

ISO classification Number (N)	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below.					
	0.1 um	0.2 um	0.3 um	0.5 um	1 um`	5 um
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000

Table 1: Maximum Allowed Particulate Levels for ISO Classes

Genzyme maintenance procedures specify that the ISO Class 8 rooms need to be cleaned every day, and a more thorough cleaning needs to be performed every week. If the air handler needs to be shut down for any reason, the weekly cleaning needs to be performed before the clean room can be used for any purpose. This both reduces the amount of time that the rooms can be used (since the cleaning usually can not be performed until that night) and adds significant cost in the case that a cleaning is not already scheduled (since each additional cleaning bears additional costs).

If the clean room remains sealed and no activity occurred during the shutdown, it is unlikely that the space will be contaminated by biological or non-viable particles (particularly in the case of ISO Class 8 rooms).

In late 2007, another Genzyme manufacturing facility did some work to validate ISO Class 8 rooms for up to a 12-hour air handler shutdown. This work was successful, and we decided to leverage this work in running our own study.

3 Process Improvement Procedure

In order to improve operations within Facilities, we performed a value-stream mapping event. We ran a three-day workshop to generate maps of the present state and to devise a transition plan for getting to the desired future state. We implemented metrics to measure our progress, and used these to assess progress towards our goals. Then we set out to systematically address each item on our action plan, and held regular meetings to assess progress towards our goals.

3.1 Value Stream Mapping

The first step in the process involves constructing a value stream map for the current facilities workflow process. Value Stream Mapping, which was originally designed and implemented by Toyota, is a Lean tool used to analyze the flow of materials and information required to bring a product or service to the end-user[3]. In building a value stream map, you create a visual representation for every piece of the process flow. You then map out your goals, as well as a set of actions required to get to those goals. Value stream mapping involves improving a process holistically, rather than just focusing on individual components. It allows you to see the flow, and any steps that may limit or divert that flow. The tool was originally created to allow visualization of the current and future states, which enables development of an implementation plan for transitioning to the ideal state.

The steps in value stream mapping are mapping the current state, identifying shortcomings and inefficiencies in the current state, using this to map the future state, designing an implementation plan, and executing upon that execution plan. The Lean Enterprise Institute recommends a three-day value stream mapping workshop. Before the workshop, it is necessary to do some pre-work to define which processes will be mapped, and who will be in attendance. The first day involves mapping out the present state and identifying problems with that current state. The second day involves mapping out an ideal future state, which addresses and fixes the problems present n the current state. Finally, the third day involves designing a well-defined plan for transitioning between the two states, and beginning to execute upon that implementation plan.

[3] Learning to See. Mike Rother and John Shook.

3.1.1 Workshop Preparation

In order to prepare for the workshop, we met with a number of members of the pilot group for the value stream optimization process. We prepared the Value Proposition template, which we titled "Improving Maintenance Process Execution." The processes to be examined were the PMs and WOs performed by the pilot group. Our primary objectives in this process were to *increase wrench time, to spend less time dealing with action notices, to spend less time trying to find parts, to improve the quality of work order data entered, to improve planning and scheduling, and to identify ineffective or inefficient preventative maintenance procedures.* The goals were *better on-time execution of work orders, reduced overtime, end-user buy-in, more effective preventative maintenance procedures, less urgent work, fewer rescheduled WOs, eliminate rescheduled PMs, and more effective feedback for modifying PMs and SOPs.* We defined the process inputs as maintenance procedures, end-user requests, and spare parts. The services provided are supplying utilities to manufacturing process, asset management, and minimal downtime. We decided to invite a wide range of personnel to the value stream mapping workshop, including employees from the director level down to the maintenance technicians. The owner of the process was the manager for the pilot facility.

3.1.2 Present State Mapping

In order to map out the present state, we ran through the machine maintenance process, laying out the steps involved in work order creation, assignment, planning, scheduling, execution, and closeout. Once we had these steps, we placed them in order, and drew process flow arrows between the steps. This included rework, waiting time, and any buffers. We then identified any data that are collected (or that we would like to collect) during this process, as well as any process issues or problems involved with work order processing. Any steps that involved inefficiencies were labeled with red dots.

Once we had the process laid out, we split the steps into the various process stages. We then put a time estimate on each process step, and added up the times to determine the waiting time for each stage. Finally, we identified the value-add time for the entire process. Overall, we identified the work order creation phase as taking one day, involving about eight minutes of value-added time. Review and assignment took another day, and about 20 minutes of this was value-add. The planning process took 8 days, and involved 2.15 hours of value-added time. Parts and scheduling took another two

days, and four hours of this added value. Execution took another day, including about two hours of value-added time. Finally, closeout lasted for two days, providing about 40 minutes of value-added time. Overall, the process takes about 15 days, and the value-added time involved was only seven hours and 30 minutes. Examination of historical Work Order data in the CMMS indicated that actual process time was around 18 business days.

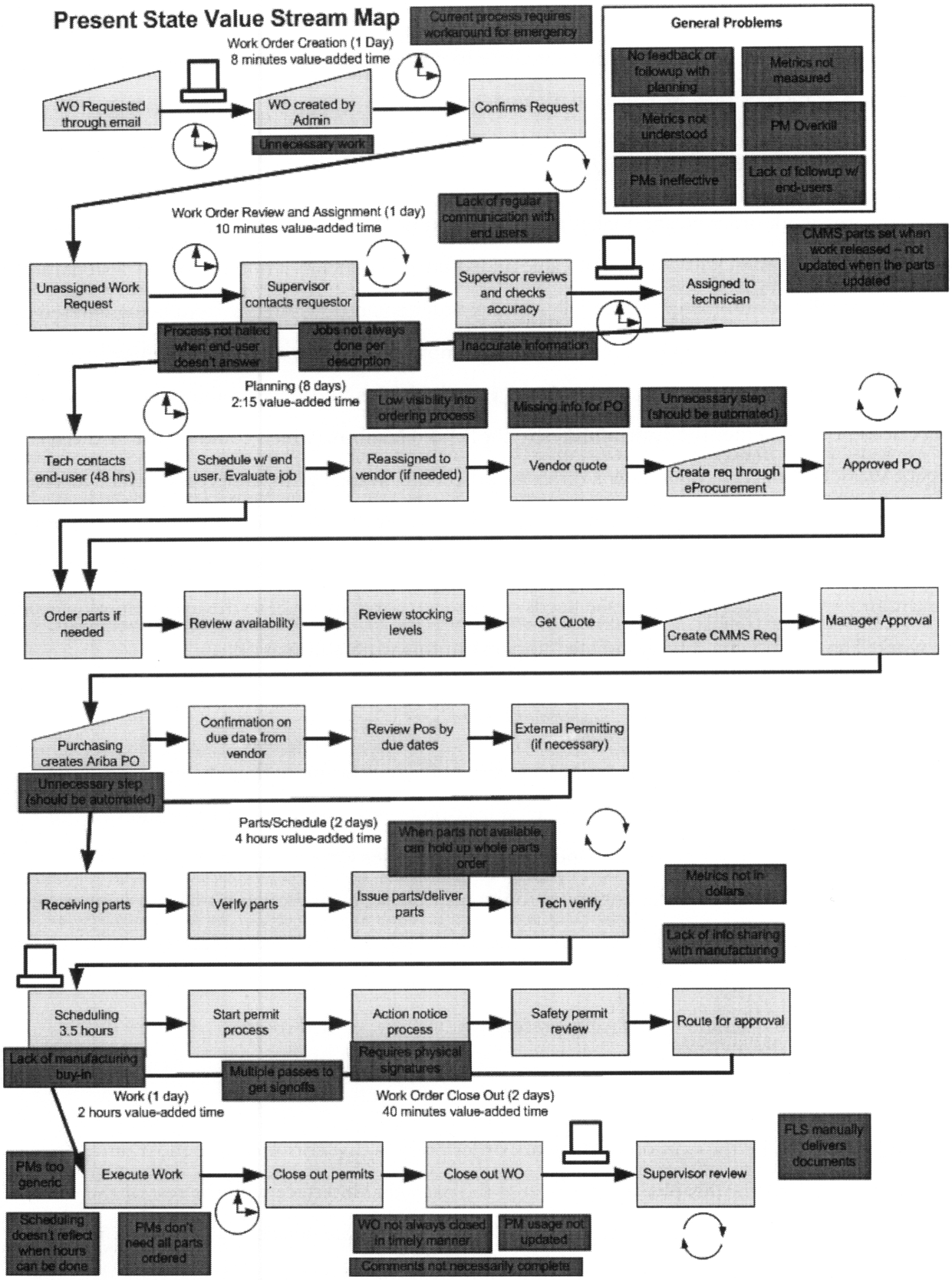

Figure 1: Present State Value Stream Map

One important consideration is that there are little to no metrics collected during work order execution. Any metrics that are collected are underutilized.

3.1.2.1 Work Order Creation Analysis

In general, the work order creation takes far longer than needed. A process that takes on average one day only has about eight minutes of value-added time. It contains a number of extra steps, and it could be completely automated. Potentially, a work order could flow directly from being entered by an end-user to being reviewed by a supervisor. Right now, it is necessary for an administrative assistant to manually retrieve work orders from a mailbox. This introduces waiting time, as the work order does not even enter the system until she checks the mailbox (which could be the next day). Urgent Work orders currently follow a different procedure, and it seems unnecessary to have a separate entry process for urgent and non-urgent work. Furthermore, entering the work order into the CMMS requires manual data entry. A human must copy the information from the mailbox and paste it into a work order, and then she needs to manually send an email to the user who requested the work. The CMMS could be automated to perform this work automatically.

3.1.2.2 Work Order Review and Assignment Analysis

The work order review and assignment process also consumes far more time than needed. Work order review currently requires about one day of lead-time, and only includes 10 minutes of value-added time. The supervisor needs to manually contact the user who requested the work. If the user does not respond, the work order continues to the next phase, even though it may not contain all of the needed information. When the job gets to the supervisor, it may contain incorrect or incomplete information, even though it should be possible to automatically verify that the information is correct (for example, that a machine is physically present within the specified room).

3.1.2.3 Planning Analysis

Planning appears to be the portion of the work order process that consumes the most time. The value stream analysis for this phase only covered the parts that interface with the rest of the work order process; it would be possible to generate a significantly more detailed value stream map for parts ordering, stocking, and maintenance procedures. Planning takes an estimated eight days, and just over 2 hours of this is actual value-added work. If parts need to be ordered, or a vendor needs

to be used to complete the job, up to 12 additional steps could be involved in the process. Any time that something needs to be purchased from an external source, a purchase order is needed. In the past, parts could be ordered via standing purchase orders, but the requisition/approval process was added in an attempt to control costs.

The current purchasing process involves requesting a quote and then creating a requisition in the eProcurement system, an entirely separate system used for approving purchase requests. This requires data to be manually copied from the CMMS into the eProcurement system. Once the cost center manager approves the purchase order, the goods or services may finally be ordered. When parts are ordered, the vendor commits to a due date, although there are no built-in checks to ensure that they hit this due date.

3.1.2.4 Parts and Scheduling

The parts and scheduling process takes about two days, and about four hours of this is value-added time. The parts receiving process has been streamlined and improved significantly since early 2008. The main opportunity for improvement with this process lies in scheduling. There is a lack of buy-in from the end-user; manufacturing often does not cooperate with facilities, and will make it extremely difficult to schedule a shutdown. Sometimes they will choose to postpone a scheduled shutdown at the last minute, which can make scheduling work extremely difficult. Finally, action notices require a physical signature, requiring a technician or the scheduler to make a visit to the end-user. Moving to an electronic signature process could save a non-trivial amount of time.

3.1.2.5 Work Execution

Work execution takes about one day, and involves an average of about two hours of value-added time. Work order execution is fairly straightforward. The main issues that came up regarding this are that the preventative maintenance procedures are too generic. Genzyme sometimes has multiple machines within a single equipment class, and one PM procedure may cover maintenance for all machines. In addition, not all PM parts are always used, creating excess inventories. Finally, the scheduling does not reflect the hours when work can be done. If the work requires a shutdown, it may only be able to be performed during a specific time period. Improved scheduling could alleviate some of these concerns.

3.1.2.6 Work Order Close Out

Once the actual work is completed, the work order needs to be closed out before the process can end. Work Orders are not always closed out in a timely manner; sometimes technicians take a few days to close out their work orders. Furthermore, technicians' comments are not necessarily complete in all cases. The current process has technicians enter the number of hours worked and then fill out their comments in a freeform text field, which allows for a lot of variability. Some technicians enter detailed feedback, while others may simply mark "complete" on the work order. This means that work details are not entered in a standardized format. The RCM engineer has been working on standardized fault codes, which could be useful in standardizing work order feedback. The feedback loop for work orders also appears to be incomplete. There is not a clear way for technicians to communicate issues with procedures or planning back to the planner. An easy feedback mechanism would probably facilitate this communication. There is also a lack of follow-up and feedback with end users. Supervisors do not follow-up with end users in any consistent fashion. Individual supervisors may follow up with specific end-users, but there is no procedure for surveying users to determine whether they were satisfied by the work that was performed.

3.1.3 Future State Mapping

On the second day of the workshop, we used the lessons that we learned from the present state mapping exercise to create an optimal future state map. We already had a future state process that was set up by Facilities management, which may have affected the outcome of the VSA in unintended ways. This made it fairly difficult to get people to look beyond the existing plans to create their optimal map. This section details the future-state map that we devised.

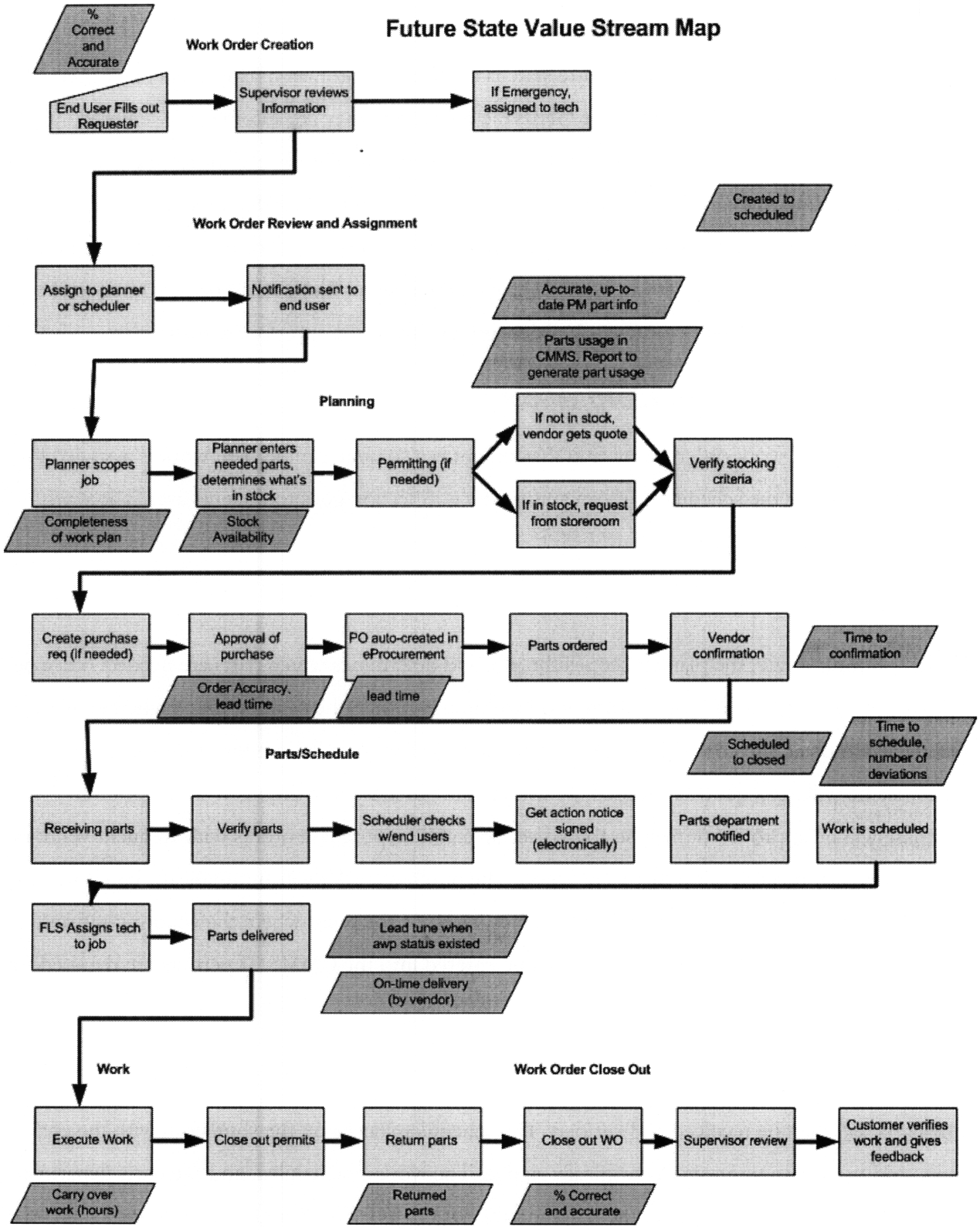

Figure 2: Future State Value Stream Map

3.1.3.1 Work Order Entry

The work order entry process in the future state is completely automated. End users enter their work order requests directly through the Genzyme portal, and they are automatically entered into the CMMS and routed to the appropriated front line supervisor. The supervisor reviews the information, and it is assigned to a planner or scheduler. Due to the fact that there is no delay between the times when the work order is entered and when the supervisor receives it, extremely high-priority work orders can also be routed through the system. Rather than being routed to the planner and scheduler, high-priority work orders go directly to the appropriate technician.

3.1.3.2 Work Order Review and Assignment

In the future state, work order review and assignment is also quite simple. The work is assigned to the planner and/or the scheduler, and an automated notification goes to the end-user. The work then enters the planning stage.

3.1.3.3 Planning

Under the future state, the planner scopes the job, and determines which parts are needed. Since he has accurate and up-to-date parts information within the CMMS, he can determine whether all of the needed parts are in stock. If the part is in stock, he will request it from the storeroom, and otherwise he will get a quote. If needed, he will get the purchase requisition, at which point the purchase will be approved (it may be able to set up standing purchase orders with frequent vendors, which could significantly simplify this process). The purchase order will automatically be created in the eProcurement system, and the parts can be ordered. At the point where the vendor confirms receipt of the order, tracking information can be entered into the CMMS. If permits are required for the process, they can be ordered.

3.1.3.4 Parts and Scheduling

The parts will then be received and verified. The scheduler checks on the shutdown with the end-users, and the action notice is electronically signed. The work is scheduled, and the parts department is notified so that they can deliver the parts in time for the job. The front line supervisor assigns a technician to the job, and the parts are delivered.

3.1.3.5 Work Execution

The work is then executed. The technician is able to perform any shutdowns and do the required maintenance work.

3.1.3.6 Work Order Close Out

When he finished the work, the technician will immediately close out any permits and return the unused parts. He can then close out the work order in the CMMS. The supervisor can review the work order, and may route it back to the technician for further details. It may also be necessary to route the work order to the planner or scheduler for feedback if the work that was done differs significantly from what was planned or scheduled (for example, the hours were incorrect or the maintenance procedure needs to be updated). Finally, the end-user has the opportunity to verify the work and give feedback.

3.1.3.7 Metrics

During future state mapping, we identified a number of metrics that we would like to track and use to benchmark ourselves. Some of these would be difficult to measure with the current CMMS, but hopefully the next revision of the software will incorporate the needed functionality.

Work Order Entry Percent Correct and Accurate – We would like to know what percentage of work orders are entered correctly by the end-user. If the supervisor needs to request clarification or to correct any information that the end-user entered, a work order would be marked as incorrect.

Created to Scheduled – Facilities currently does not have good metrics for how long a work order takes to go from creation to the point where it is scheduled.

Work Plan Accuracy – It would be extremely useful to be able to assess the completeness of a job's work plan (were the right parts ordered?).

Stock Availability – The storeroom does perform cycle counting, but these reports are not 100% correct. Parts are still stocked for machines that Genzyme no longer uses, and the storeroom does not yet have a complete list of all critical parts that should be stocked.

Order Accuracy – Orders are not always accurately entered correctly.

Approval Lead Time, eProcurement Lead Time

Time to Vendor Confirmation – An important vendor metric is the time that it takes for them to confirm that they have received an order and to promise a delivery schedule.

Scheduled to Closed – How long it takes from the time a work order is scheduled until when it is actually closed.

Schedule Compliance – Corrective Work Orders can still be considered on time if the schedule is repeatedly adjusted. We would like to know how often the schedule date moves.

On-Time Delivery By Vendor – How often is a vendor able to deliver parts on or before the promised delivery date?

Average Time Spent in Awaiting Parts Status – Right now, we have no way to distinguish at a high level between work orders where parts needed to be orders and ones where all parts were present. Work orders that do not need parts (and could be scheduled within a few days) may be masking long lead times when parts need to be ordered. We would like to know what percentage of work orders enter Awaiting Parts Status, and how long on average they spend in that status.

Carry-Over Work – How much scheduled work do technicians carry over from one day to the next?

Returned Parts – What parts are being returned by the technicians, and how many? Knowing which parts are not being used could help preventative maintenance planning and in parts ordering, and could prevent buildup of excess inventory

Work Order Closeout Percent Correct and Accurate – Are technicians entering complete information into work order closeout forms. If the information is incomplete, it should be routed back to the technician.

3.2 Transition Plan

After we devised the present and future states, the next action was to generate a transition plan. The VSA team made a list of potential actions that could be taken to improve upon the future state, and then rank-ordered and prioritized this list. In the end, we decided to focus on 12 different actions. The recommendations were as follows:

Fix Status Changes in the CMMS – The CMMS automatically gives the work order different statuses (such as "awaiting parts" or "complete") as it flows through the process. Some of the statuses were not being set correctly when the work order hit the appropriate step.

Create a Min/Max System – In order for the storeroom to have an appropriate amount of each part in stock at any given point, it needs a minimum and maximum stocking level for each part.

When the inventory hits the minimum level, enough will be ordered to return to the maximum level. Facilities does not have min/max levels set for all parts, and the min/max levels that are currently set may not be adequate. Another problem is that the storeroom does not even have a complete list of all parts that need to be ordered. A min/max needs to be established and then periodically refined as needs change.

Improve Purchasing Process – The purchasing process is extremely time-consuming, taking up over half of the estimated in-process time for a work order. There are clearly opportunities for improving the purchasing process – a first step would be to set up standing orders for some frequently purchased parts. More analysis will be needed to determine detailed action – likely a kaizen event or a series of meetings.

Regular Communication between the Scheduler and End Users – One of the reasons it is difficult to schedule jobs is that the scheduler does not have regular in-person communication with end users. The scheduler does communicate with end-users via email, but it would be more productive for the scheduler to have a physical presence at production meetings.

Have End Users Stop Calling Technicians – End users regular make calls directly to technicians when they have problems. This is disruptive to technicians, who may be performing other work, and also subverts the planned work order process. End users should be directed not to call technicians directly, and technicians should route all requests to supervisors.

Critical Spare Parts – Certain parts should always be in stock in the storeroom in order to minimize machine downtime. This will minimize the possibility that machine failure could have a negative impact on the production schedule. Facilities management needs to come up with a policy for what is considered to be a "critical spare," and then use this to generate a list of all the critical spares. A further meeting or series of meetings is probably needed to follow up on this.

Improve Portal Work Order Homepage – The portal work order homepage does not contain a detailed explanation of what the priority codes mean, including service level agreements for each priority code. This information needs to be added.

Implement Customer Feedback – Facilities needs a formal process for determining how to get feedback from end users. This could include sending a survey to a randomized sample of end users, or the supervisors could each be responsible for calling a certain number of users each month. A meeting is needed to plan out the specifics of this action.

Add Information To The CMMS for Work Order Closeout – The current work order closeout process requires technicians to enter the hours worked and a freeform text description. Work order closeout should allow technicians to select the failure codes that the RCM engineer is currently generating. This would standardize data entry, and would make it easier to analyze past work orders. Furthermore, there is no good way to route work orders back to the planner and scheduler if feedback is needed. Work orders should allow for a "feedback" step post closeout.

Form Implementation Team – In order to make sure that this value stream mapping event generates definitive actions, we need to form an implementation team that will be responsible for defining metrics, creating a process board to hold the metrics graphs, and periodically analyzing the progress made towards the future state. This implementation team will take responsibility for making sure that implementation is on-schedule.

Each item in the action plan was given a due date and assigned to one or more stakeholders in the facilities organization.

In order to follow up on this action plan, we agreed on the flowing steps:

- Send out a weekly status email, alerting all relevant people about any progress made over the past week and exposing any issues that have arisen.
- Post the transition plan status on the action board
- Hold biweekly meetings to discuss the status of the transition plan. These would include facilities management as well as the planner, scheduler, storeroom manager, the building manager, and the maintenance supervisor. It could also include anyone else whose input is needed.
- Generate and send out a concrete implementation plan by the beginning of September (the event was held in late August).

4 Implementation and Results

In the weeks following the Value Stream Analysis event, we began to implement the recommendations generated from the mapping process. Progress went fairly slowly at first, due in part to high priority projects that occurred during the late summer and early fall. These included bringing a new building online and establishment of a corporate facilities group. Since each of the VSA stakeholders had other responsibilities, it was fairly difficult to expect people to achieve the tasks without tracking and guidance. In our follow up plan, we intended to send out weekly update emails, and to keep track of progress through regular correspondence. We found that emails worked well for communicating information, but it could be somewhat difficult to get people to respond to emails in a consistent or timely manner. It quickly became apparent that the best way to track progress was to hold regular implementation team meetings. We scheduled a weekly meeting at a time that all of the stakeholders could make, and went through the implementation plan, item by item. Notes were compiled and sent out to all relevant people.

4.1 Metrics Implementation

In addition, we came up with a list of metrics that we wanted to track, and figured out how to aggregate these in the CMMS. We started with the metrics list from the Value Stream Mapping process as well as the KPIs from the previous analysis, but decided to implement only a few metrics. It is likely that the facilities group failed to implement the previous recommendations because it can be time-consuming to do the data entry and CMMS reconfiguration necessary to begin measuring 30 or 40 metrics. We attempted to start with a small set of metrics that would give us insight into the process without being cumbersome to implement. Since planning and scheduling will apply to preventative maintenance tasks first, we decided to choose metrics that measured preventative maintenance only. We settled on the following metrics:

PM Schedule Compliance – This measures the percentage of PM tasks that are completed on time. We defined on time as being completed within one day (ahead or behind) of the scheduled date.

PM Extensions – How often were preventative maintenance tasks extended beyond the original due date? We measured the total number of extensions to PM tasks.

Each metric was measured using a seven-day moving average. So the data captured on a particular day are actually the average of the past seven days. Since there are some periodic variations in the data throughout the week, this smoothes out some of that effect.

We also discussed implementing a number of metrics that tracked storeroom progress. These included:

On-Time Cycle Counts – One of the measures of an efficient storeroom having an accurate and up-to-date list of the materials in stock. The on-time cycle count metric is currently at 80%, even though the storeroom recently completed a complete cycle count. Apparently, a lot of non-existent parts are currently being tracked.

Awaiting Parts – There is a metric to show how many work orders are awaiting parts.

Stock Outs – How often is the storeroom running out of parts?

Percentage of Critical Parts In Stock – This measures the percentage of the critical parts that the storeroom has in stock at any time. It should optimally be at 100%. In order to measure this, the storeroom needs a complete list of critical parts.

On-time cycle counts, Stock Outs, and Awaiting parts are currently being tracked. Percentage of critical parts in stock is not yet being tracked.

4.2 Planning and Scheduling

One of the major initiatives with regards to implementing the scheduling involved setting up better communication between the scheduler and end users. The scheduler started sending out PM tasks one to two months in advanced, and asked manufacturing for a list of times that worked. He received positive feedback from this change from both facilities and the end-users. It gave the supervisors more time to manage their reports, and it gave technicians more advance notice when work needed to be done. The technicians were also pleased that they were no longer responsible for performing much of the administrative work involved with scheduling PMs. The scheduler set up regular meetings with the end-users, which could be used to review the schedule and to get signatures on action notices. We also discussed using synergies, such as being able to complete multiple WOs (or PMs and WOs) in the same room at the same time.

The scheduler also began to schedule all PMs. He started out by only hard-scheduling a portion of PMs, but moved towards putting a specified schedule date on all PMs. He also began to schedule some of the work performed by outside vendors. The next step is to begin scheduling low priority WOs; the scheduler will eventually schedule all non-urgent Work Orders. The short-term goal is to schedule four hours of time per day for each technician. Each job will be assigned one hour, but this can be updated using the feedback process.

A feedback status was added to the CMMS, and technicians or the supervisors can select this status at closeout time. This status allows a completed work order to be sent back to the planner and scheduler for feedback (in the case that the planned or scheduled work differed from what was actually done). At first, the feedback loop was used for scheduling, but this could later be used for all types of feedback. One suggestion was to use the feedback loop to flag non-value added PMs. Technicians and supervisors were trained on the use of the feedback loop.

4.3 Inventory Management

During the value stream improvement event, the storeroom manager mentioned that he was not able to get an accurate list of parts usage. We investigated this, and he was able to get parts usage directly from the CMMS with a usage report. This report was not 100% accurate, but gave more insight than did the previous strategy.

The storeroom was also able to generate a stock low report, which when coupled with a min/max list, made it possible to determine what to order.

In terms of critical spare parts, the RCM engineer performed RCM analyses on some of the machines. This involved the likelihood and impact of various equipment failures, and allowed facilities to determine which parts needed to be stocked. The RCM engineer has scanned in manuals for many of the machines, and it may be possible to download the bill of materials for each machine directly from these scanned manuals.

In order to stock the correct number of critical spares, all of the machines need to be entered into the CMMS, which is a time and labor-intensive process. A process for entering equipment on a regular basis needs to be defined.

4.4 Other Initiatives

Facilities management spoke with site management, letting them know that end users were no longer supposed to call technicians directly. A site-wide email was also sent out at to the Framingham campus. Additionally, the technicians were coached on how to respond to requests from end users. We did not create a reporting system or metrics to track this, so we were unable to directly assess compliance.

In order to improve work order entry, explanations of priority codes were put in the FAQ on the order entry page. This helped end-users to properly prioritize their jobs.

The correct drop-down codes for equipment failures were put in the CMMS, although the closeout form does not incorporate these yet. At the end of this project, that remained on the to do list.

In order to speed the purchasing process, the number of people able to approve purchases for each cost center was increased to at least two. The approval limit was also increased significantly. A meeting was planned to scope out further improvements to the purchasing process, but we were unable to complete that within the timeframe of this project.

We discussed ways to implement customer feedback. One suggestion was that each supervisor makes 12 calls each year to end-users (for a total of 50 each year). We also discussed creating a regimented feedback form, with five to ten questions. Technicians could leave a card or survey, or the users could be directed to a website with the survey. Due to time constraints, we were unable to develop a finalized process for obtaining feedback. We expect that facilities management will make progress on this initiative in the future.

We also discussed additional metrics that we might want to measure. These include determining how much work carries the highest priority code, and a metric for equipment availability.

4.5 Metrics Tracking and Results

We began to track metrics and to generate a weekly graph that was discussed at regular meetings. This graph incorporated all metrics into a single graph. While we did not put a process board up,

this was accomplished shortly after the internship ended. The metrics graphs were reviewed regularly, and fluctuations in the metrics could be traced directly to particular events.

PM extensions started at about eight, but it soon dropped to zero. Since it is not mandated that Corrective Work Orders are completed by a particular due date (PMs are FDA regulated), tracking the number of rescheduled Work Orders would probably offer more insight into the process.

When we began tracking metrics, PM schedule compliance was at about 2% (the schedule date is prior to the due date), although it quickly rose to 20%. Over time, it gradually rose to nearly 100%. There were several fluctuations due to high-priority work, but the numbers quickly returned to normal (and facilities was able to give a detailed reason for each dip). By tracking this metric and noting any changes, facilities was able to drastically improve schedule compliance.

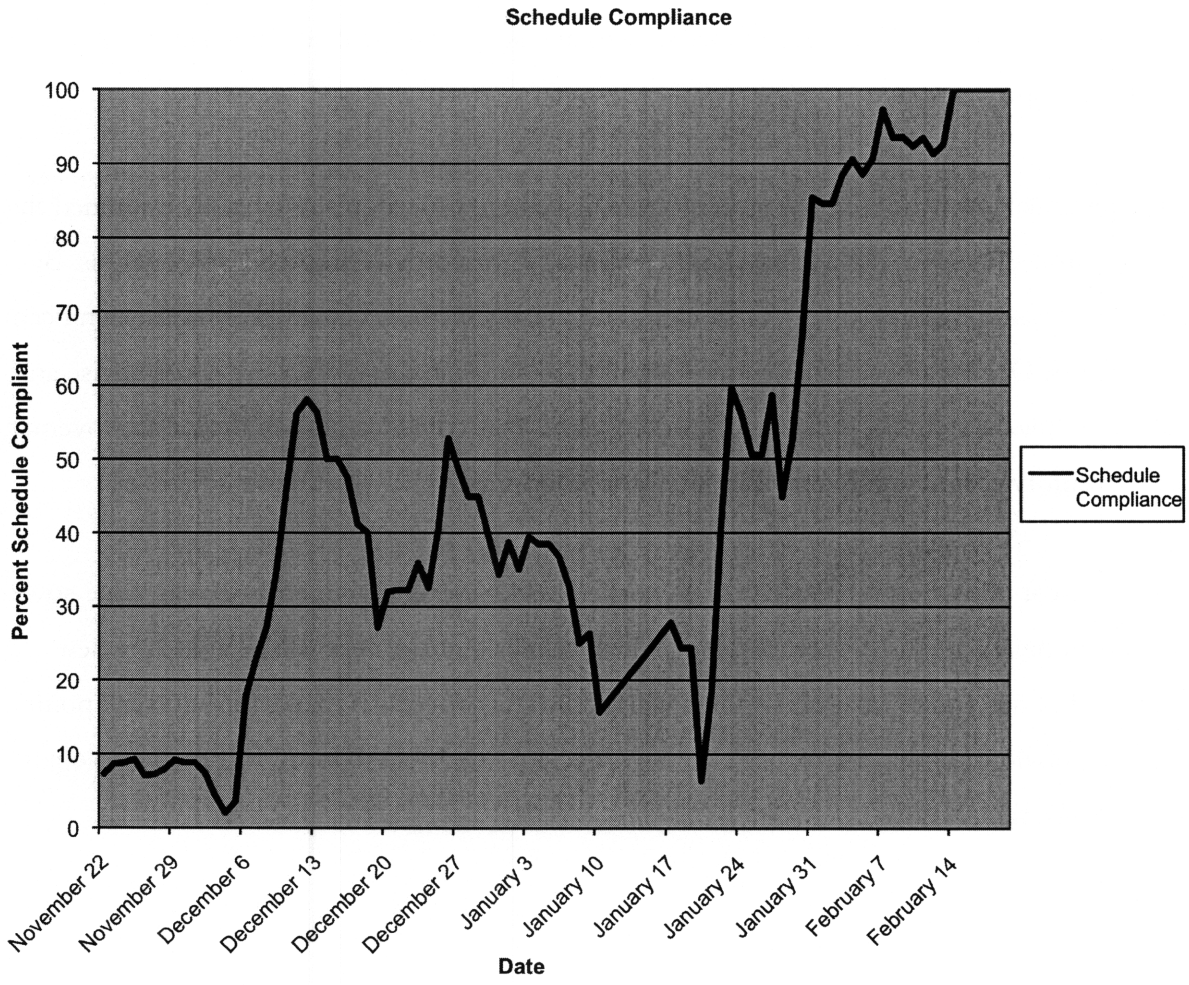

Figure 3: PM Schedule Compliance

Regular review of the metrics graphs actually led to a number of process improvements. For example, the schedule week was moved to Wednesday-Tuesday (from Monday-Sunday), and the due date for unscheduled work was set to Friday (since overtime work is the only thing that is done on weekends).

Recently, facilities began to schedule corrective work orders in addition to preventative maintenance, and will begin to track those as well. Over time, this will lead to all non-emergency work orders (defined as having priority code lower than 4) being placed on the schedule.

4.6 Further Work

There are a number of areas that Genzyme could target for future improvements to the machine maintenance value stream. The first area that we would recommend targeting is the process for purchasing parts. Even with the changes that have been made so far, the purchasing process is still suboptimal. Right now, purchase orders need to be entered into and tracked in multiple systems, and require per-item approval. Time and money savings are likely possible if additional effort is put into value stream improvement.

Another potential area would be the storeroom management procedures. We briefly examined the storeroom procedures, but did not have sufficient time to perform a comprehensive analysis. By looking at the workflows for inventory stocking and management, we could likely make significant improvements. Once we have accurate tracking of parts usage in the CMMS, we could devise an efficient min/max system for critical and stocked parts. This could lead to significant improvements in both inventory cost and potential lead times for work orders.

One of the most important pieces of further work involves continuing to have regular value stream improvement meetings. Just by meeting regularly, Facilities management will be able to review progress and to determine what needs to be worked on. As progress is made, further weak points will become obvious. By having regular meetings, Facilities can help to instill BPI methodologies into its organizational culture.

5 AHU Shutdown Study

5.1 Previous Work

Shortly after we began working on designing the AHU shutdown experiment, we discovered that another Genzyme manufacturing plant conducted a similar project in late 2007 to validate shutdowns of greater than 30 minutes. Their experimental procedure involved shutting down an air handler that serviced an ISO Class 8 area. The room was sealed for the duration of the procedure, and continuous nonviable monitoring equipment put in place (they did not test for viable microbial particles). After the air handler was shut down, non-viable particles did not exceed ISO standards for two hours. After 12 hours, the air handler was restarted, and environmental monitoring was performed to determine how quickly particulate levels would recover. Within 20 minutes, the non-viable particulates within the rooms recovered to their pre-experiment levels. The conclusion from this study was that air handler shutdowns are permitted within the ISO Class 8 rooms, so long as there is no open product in the room during the shutdown and one enters or exits during the procedure.

5.2 Hypothesis

Based on this work as well as some previous precedent, we initially believed that some of the clean room re-sanitizations are unnecessary. We decided to validate a four-hour shutdown window, which should give facilities sufficient time to perform many common air handler maintenance tasks. The window was also chosen to give us maximum flexibility with our monitoring equipment. In order to test this, we created a validated study to test the following hypothesis:

Hypothesis: *If the Air Handler Unit that services an ISO Class 8 clean room is shut down for four hours and then restarted, the clean room will have low enough biological and non-biological loads to pass environmental monitoring standards so long as no activity occurs within the room and no one enters or exits.*

In order to test the hypothesis, we generated a plan for conducting the study, and had this plan validated by Genzyme's validation department. We then executed the study three times, and compiled the data to generate conclusions.

5.3 Study Procedure

5.3.1 Purpose and Introduction

The purpose of the experiment was to determine how quickly clean rooms become contaminated when air-handling systems are shut off. Currently, clean rooms have to be re-sanitized every time that an air handler is shut down for maintenance. However, formal tests had not been conducted to determine whether this is actually necessary. We proposed running periodic air quality tests to determine how long a clean room can have its air handlers shut off before it becomes contaminated.

5.3.2 Definitions

Action Level: An action level is any test site result that exceeds its established action limit.
Activity Level: The level of activity going on in a clean room during testing procedures
Static: No activity is going on in the clean room during testing
Dynamic: Regular activity is going on in the clean room during testing (personnel may be present, equipment in place, operations ongoing)

5.3.3 Scope

This procedure applies to the ISO Class 8 Framingham manufacturing area clean rooms. It defines the methodology for testing clean room air quality when the air handlers have been shut down. It only includes testing under static conditions, which occur when no activity is going on inside the clean room and no personnel enter or exit the clean room during the test. In the future, testing may also be conducted under dynamic activity levels.

5.3.4 Responsibilities

It is the responsibility of Quality Control / Quality Assurance to ensure that all personnel performing this procedure are properly trained. The QC Microbiology Department executed the testing as described. It is the responsibility of the Quality Control Personnel to update and revise this procedure as appropriate. It is the responsibility of Quality Control to ensure that a method has been verified per this document.
It is the responsibility of Quality Control Personnel to ensure data security. Data from the particulate sampler was contained in an open file, and Quality Control Personnel needed to ensure that this data were not tampered with or modified.

Manufacturing was responsible for providing clean rooms for the testing procedures, and for making sure that activity in the clean room is at the appropriate activity level during testing. The clean rooms needed to have a single site, which reduced the area to be monitored.
Facilities was responsible for drafting and posting an action notice that prevented all operations in the clean room during the test procedure. Any personnel who entered the test rooms needed to wear a second layer of protective clothing in order to avoid contamination to the adjacent hallways.

5.3.5 Safety

The air sampler is an intrinsically safe instrument for use in the appropriate areas.
Observe and adhere to all precautions posted in areas that testing is required.
It is the responsibility of the Quality Control Department to be familiar with all emergency exit routes at all testing locations.
Air handler shutdowns must be performed at a time when it would be safe to do so. It is important to avoid shutting down air handlers when processes like ethanol transfers and other hazardous operations are taking place.

5.3.6 Procedure

Air Handler Shutdown: In order to test air quality, we shut off the air handlers in ISO Class 8 clean rooms (ISO Class 7 clean rooms may be tested in the future). Immediately prior and subsequent to the air handler shutdown, we tested the air to make sure that the clean room passed the tests.

5.3.6.1 Monitoring of Non-Viable Particles

The procedures for testing for non-viable particulates are detailed in Genzyme's Quality Control procedures. The particulate test involved pulling a specified volume of air through a particle counter, and determining the size and number of particles within that sample. After taking and initial sample, the air sampling machines were put on continuous monitoring for the duration of the test. They were then shut off during the viable sampling process, and restarted when the AHU came back up.

5.3.6.2 Monitoring of Viable Particles

The procedures for testing for viable particulates are detailed in the quality control documents covering environmental monitoring. We took viable particulate samples before the AHU was shut down, immediately before it was restarted, and then again 30 minutes after airflow was restored.

5.3.6.3 Monitoring with settling plates

In order to assess viable conditions during the test, QC put down settling plates at the beginning of the experiment. These plates collected particles during the static portion of the experiment.

5.3.6.4 Monitoring with RODAC

Due to the environmental standards in ISO Class 8 clean rooms, we did not perform any Replicate Organism Detection and Counting (RODAC) sampling for the purpose of this study. If testing is extended to ISO Class 7 clean rooms, then RODAC may be necessary.

5.3.6.5 Experimental Results

Due to the nature of these tests, the viable particle samples needed to be incubated for 5 to 7 days to allow colonies to grow. In some cases, it may be possible to determine the nature of viable particles, which may help with their abatement.

5.3.6.6 Testing Conditions

The clean room tests were run under static conditions. During the tests, no activity occurred within the clean rooms between the time that the air handlers were shut down and the time that they were restarted. QC personnel entered the room immediately prior to restart in order to measure the viable particles and to collect the settling places. Future tests may involve conditions where activity occurs within the clean rooms during testing.

In addition, tests were run immediately before the regularly scheduled weekly cleaning. This maximized the variation in pre-test room environmental conditions, as the rooms had not been cleaned in almost a week.

5.3.6.7 Testing Procedures

The test procedure was as follows:

- QC first performed baseline viable and non-viable testing
- QC then set the non-viable sampler to perform continuous monitoring.
- QC put down settling plates in the room.
- QC then left the room, and the room was sealed at this point.
- Facilities then shut down the Air Handler that supplies the room (for four hours)
- Just before the four-hour point, QC personnel reentered the room.
- QC stopped and marked the non-viable testing equipment. This caused a small but unavoidable pause in nonviable monitoring.
- QC closed off the settling plates.
- QC performed viable monitoring.
- QC then left the room.
- Facilities then turned on the Air Handler.
- The non-viable sampler restarted.
- After 30 minutes, facilities reentered the room.
- Finally, QC performed baseline viable testing and non-viable testing to determine whether particulate levels had recovered.

5.3.6.8 Reproducibility

In order to assess reproducibility of results, we ran the test three times on three different days. The clean room received a full weekly cleaning between runs, as well as several days of normal usage.

5.3.7 Analysis

In order to analyze the results, we averaged the particulate levels across the three tests. We made sure that the data for each run are fairly close – if the data varied significantly between runs, we may have needed to rerun the test until we had a number of similar results. We then graphed the results (for viable, non-viable, and combined particle totals), and determined how long the air handlers could be shut off before environmental monitoring tests failed.

5.4 Description of Findings

The tests were run on three consecutive Wednesdays. We collected viable samples by placing settling plates in three locations in the room, and exposing them for 3 hours 55 minutes. We also collected viable samples by sampling air before, after, and during the test. We also sampled Non-viable

particles before and after the test – we measured the number of particles greater than 0.5 um and greater than 5.0 um in each foot of air. Continuous data were collected before and after the test – we measured particles greater than 0.5 um, greater than 1.0 um, and greater than 5.0 um in each foot. During each study, we collected 45 samples using continuous particulate sampling, each taken 5 minutes and 40 seconds apart. The continuous results included data for particles greater than 0.5 um, greater than 1.0 um, and greater than 5.0 um in each cubic foot. Since the ISO specifications for Class 8 clean rooms do not consider the concentration of particles smaller than 0.5 um, we disregarded any data for particles of size 0.3 um. We averaged the results from each run to come up with an aggregated result sets for all runs. We also found the standard deviation between runs, and used this to calculate confidence intervals for the predicted air quality.

5.4.1 Maximum Particulate Levels for ISO Clean Rooms

The following chart shows selected airborne particulate cleanliness classes for clean rooms of the specified classes. The concentration of each particle within a clean room must be below the specified limit. The clean room that we study corresponds to ISO Class 8.

ISO classification Number (N)	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below.					
	0.1 um	0.2 um	0.3 um	0.5 um	1 um`	5 um
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000

Table 2: Maximum Particulate Levels for ISO Class 8[4]

[4] ISO-14644-1, Cleanrooms and associated controlled environments – Part 1: Classification of Air Cleanliness. International Organization for Standardization (1999).

5.4.2 Results with Viable Particles

The air-sampling methods showed no growth before or after the test, and growth in only one of the three mid-test trials. The settling plates showed on average 1 (total) mold colony-forming unit (CFU) during each trial. This was well below the 16 CFU per plate limit specified in the study protocol.

5.4.3 Results with Non-Viable Particles

The non-viable results showed low levels of particulates both before and after the test. The particle counts following the test were higher than those before the test, but were still well below the limits. We assumed normal distribution for the results. Given that we only performed three trials, it can be extremely difficult to analyze the fit of the data to a distribution, so we assumed normality. If we look at the particulate level three standard deviations above the mean, which would be the upper bound in 99.9% of such trials, the particulate levels are still well below the action limits (the number of particles > 0.5 um per cubic meter would be 32043, which is about 1% of the action limit). The average particulate counts (averaged across the three runs) and standard deviations are shown below:

Non-Viable Sampling	**particles > 0.5 um per cubic meter**				
Trial	**Count 1**	**Count 2**	**Count 3**	**Average**	**Std Dev**
Pre	10900	18200	13000	14000	6000
Post	27100	20000	13500	20200	11300

Non-Viable Sampling	**particles > 5.0 um per cubic meter**				
Trial	**Count 1**	**Count 2**	**Count 3**	**Average**	**Std Dev**
Pre	153	436	141	243	91
Post	200	106	118	141	42

Table 3: Pre and Post-Test Non-Viable Sampling

5.4.4 Continuous Results

The continuous sampling results included three samples taken before the test began, as well as three taken after the test was completed. The results immediately post-test were somewhat higher than the pre-test results, although the post-test results fall well within the specified limits. At three standard deviations above the mean (which covers 99.9% of such trials), the particulates are also well within action limits (34886 for the 0.5 um samples, which is again about 1% of the action limit).

Pre-Test Non-Viable	particles per cubic meter		
Sample	**0.5 um**	**1 um**	**5 um**
1	14000	4940	200
2	21700	6710	506
3	18300	5650	153
Average	18000	5770	286
Std Dev	2200	1650	27

Post-Test Non-Viable	particles per cubic meter		
Time	**0.5 um**	**1 um**	**5 um**
1	32100	10500	188
2	26400	7530	82
3	18500	5690	94
Average	25700	7900	122
Std Dev	3070	775	48

Table 4: Pre and Post-Test Continuous Sampling Results

The continuous monitoring yielded the following graphs, which show the change in particulate levels over the course of the test (particulate levels for all three runs are averaged for each data point). Particulate levels quickly increased to a steady-state level, and then remained at that level for the duration of the test. It is likely that particulate levels did not increase past the steady-state because no activity occurred in the room and the room was sealed for the duration of the test.

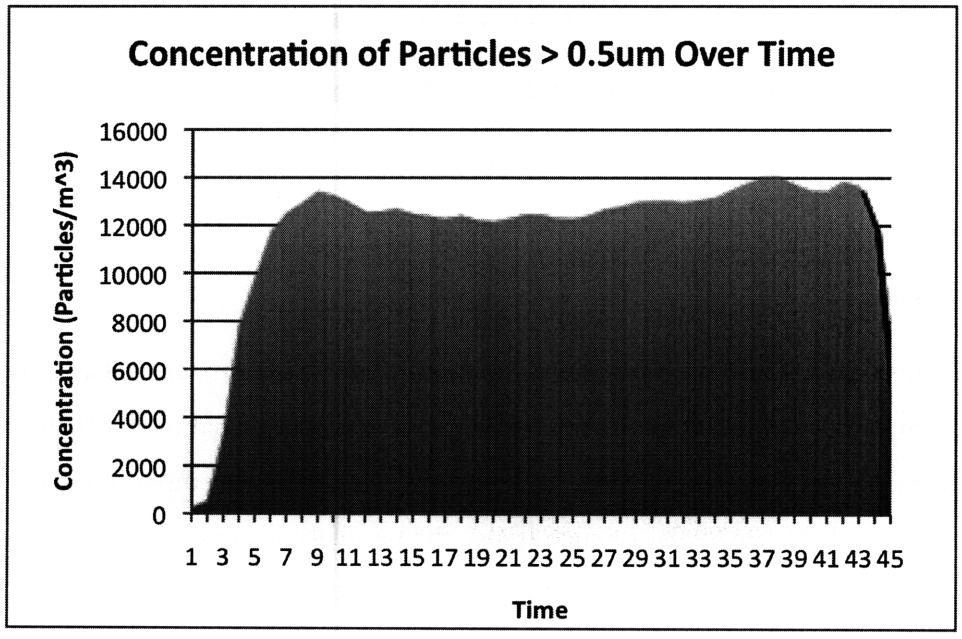

Figure 4: Concentration of particles greater than 0.5 um over time

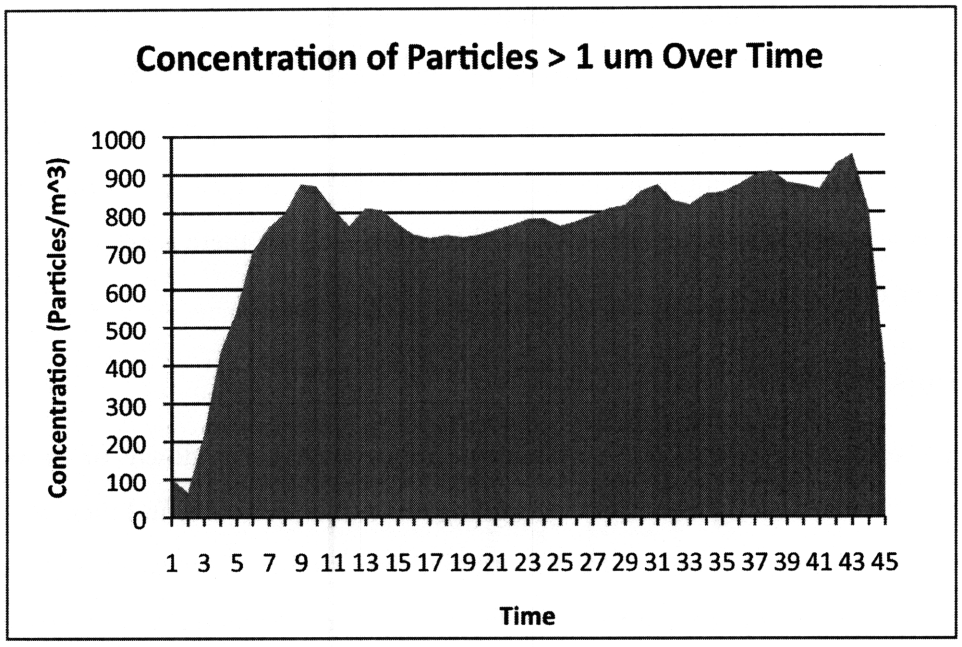

Figure 6: Concentration of particles greater than 1 um over time

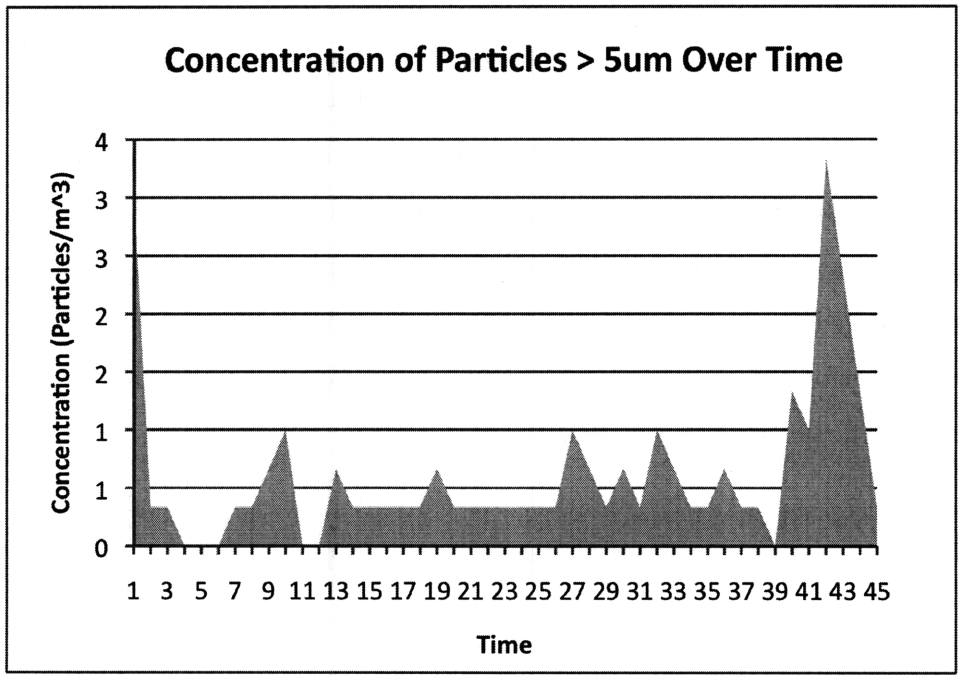

Figure 7: Concentration of particles greater than 5 um over time

All of these levels were well below the specified action limits for ISO Class 8.

One interesting consideration is that the concentrations of particles greater than 0.5 um varied between trials. During one of the trials, the average concentration across all non-viable samples was 24000 particles/ft^3. For the other two trials, the average concentration was 5-6000 particles/ft^3. This is likely the result of having different conditions in the clean rooms when the test started. However, the maximal observed level was significantly less than 1% of the action limit, so there is no significant concern over this discrepancy.

5.5 Recommendations and Potential Savings

Based on the results of the study, we recommend that Genzyme approve AHU shutdowns of up to four hours under static conditions. So long as no activity is going on within the room, and there is no entry or exit from the room during the course of the shutdown, a four-hour shutdown should be acceptable. Based on our calculations, there were 86 additional sanitizations required between 1/07 and 9/08 as the result of shutdowns. The total savings per year from cleanings alone would be nearly $92,000 per year.

5.6 Further Work

We would recommend that Genzyme do further work to validate shutdowns of longer than four hours. It would be interesting to see whether the non-viable particulates rise above the four-hour steady-state value if the AHU is shut down for 12 hours or more. In addition, studies with dynamic activity and where Genzyme personnel enter and exit the room a specified number of times could be used to validate conditions where it is necessary to have activity in the room during a shutdown. Finally, it may make sense to perform this study in an ISO Class 7 clean room as well, although there would be significantly more difficulty in approving this sort of shutdown.

6 Conclusions

Based on the results of the Value Stream Analysis and AHU shutdown, we have drawn a number of conclusions.

6.1 Value Stream Improvement and Buy In

We were able to make a number of improvements to the facilities value stream. However, the biggest challenges involved bringing about cultural change within a Facilities organization that was used to the maintenance traditional practices. The maintenance staff seemed to resist the notion that over 90 percent of the time involved in processing work orders is not value-added, and initially seemed skeptical that this could be reduced. In order to get buy-in, it was important to emphasize that this was not about pointing fingers, but about figuring out what is broken so that it can be fixed. Once they began to see that this process yielded improvements, they began to gradually come around to supporting it. Once we had buy-in, it is much easier to implement future changes. The most important lesson is that it is imperative to get buy-in from personnel at all levels of the organization. In many cases, organizational change is driven from the top-down.

Genzyme management appears to have some level of commitment to BPI initiatives, as evidenced by the creation of a BPI group. This is important, as it is necessary to begin the process by educating people on BPI and by making the first few improvements. However, this is not enough to create lasting change. In order to make this a permanent cultural shift, everyone must take responsibility for suggesting and making improvements to his or her own work process. BPI must become part of every division, rather than a separate division. Genzyme would benefit a long-term goal for integrating BPI into its operational culture. Some companies actually require employees to make suggestions, while others have programs designed to give rewards to employees who make and implement suggestions. Within the maintenance group, it is important to solicit feedback from the technicians, many of whom have worked at other biotech companies and have seen other examples of best practices.

6.2 Metrics

Another important lesson was that it is important to choose a few well-targeted metrics when undertaking a BPI effort. The prior attempts at implementing metrics failed for a number of

reasons. First of all, they were externally imposed. Genzyme hired a consulting firm to come in and to suggest measurements. The firm based its recommendations on industry best practices. However, these metrics were not particularly salient to Facilities group management. If they had been linked to solving particular problems, they might have been relevant, but they seem to be more preventative than anything else.

Another problem is that there were too many metrics recommended. Any improvement project should have multiple phases – each phase should involve completing a single, coherent piece of work that solves a particular problem. At any point, you should have a good idea of what you are trying to complete and what problem that addresses. When you start with a few metrics, you can get a mile-high overview of the project before diving deep into the specifics. Once you can assess the overall health of the project, you can start diving deeper and measuring more specific metrics that give you insight into particular problems.

A third problem is that the metrics did not accompany a structured improvement effort. Once we defined a particular set of problems (for example, scheduling work orders) and came up with a metric for measuring that process (schedule compliance), it made sense to begin tracking the metric and then making efforts to improve on that metric. Without the improvement efforts

By tracking a few metrics, it was possible to get a surprising amount of insight into the process. Facilities management spent hours looking at the metrics and at the specific reasons for any drops or fluctuations in performance. "I can't believe how one metric that meant something to us has spurred so much discussion," one of the managers within Facilities said.

Now that Genzyme has managed to improve the initial few metrics to 100%, they can either choose more sensitive metrics or start to work on additional processes. Currently, they are in the process of beginning to schedule and measure performance for all corrective work orders.

6.3 Review of Existing Standards

Another important lesson is that it is important to periodically review existing standards and procedures. A lot of organizations continue to follow traditional policies and practices without ever questioning them or researching updated practices. While some processes were deliberately determined and continue to be relevant, others were either arbitrary in the first place or are out of

date and need to be revised. It makes sense to go through all procedures on some fixed schedule, reviewing them and potentially testing for obsolescence.

For example, Genzyme has a number of preventative maintenance procedures that may be adding unnecessary costs. Clean room re-sanitization following an AHU shutdown is probably unnecessary, and costs the company $100,000 per year in additional cleaning costs. There are likely many other actions that are unnecessary, and there may be some necessary actions that are not being performed frequently enough.

By re-examining these procedures and potentially eliminating or reducing these actions, we may be able to realize significant cost savings. In addition, it may be possible to free up technicians to work on other jobs that are more critical to the organization's success. Furthermore, it may be possible to increase the frequency of some other preventative maintenance procedures that would reduce the amount of work done when there is an inspection.

APPENDIX

Data From AHU Shutdown Trial 1

Settling Plates

Site	CFU
1	0
2	0
3	0

Viable Sampling

Trial	CFU
Pre	0
Mid	0
Post	0

Non-Viable Sampling 0.5 um/ft

Trial	Count 1	Count 2	Count 3	Average
Pre	426	549	659	545
Post	689	792	549	677

Non-Viable Sampling 5.0 um/ft

Trial	Count 1	Count 2	Count 3	Average
Pre	6	13	4	7.7
Post	4	2	2	2.7

Pre-Test Nonviables

Time	0.3	0.5	1	5
13:52	996	426	157	6

13:53	1300	549	204	13
13:54	1946	659	210	4
Average	1410	545	190	7.7

Post-Test Non-Viable

Time	**0.3**	**0.5**	**1**	**5**
18:16	3455	689	262	4
18:17	3204	792	253	2
18:18	2003	549	194	2
Average	2890	677	236	2.7

Continuous Monitoring During Test

Sample	**0.5**	**1**	**5**
1	476	231	6
2	102	52	1
3	6729	395	1
4	19746	1015	0
5	24460	1238	0
6	26486	1403	0
7	27126	1442	1
8	27159	1424	0
9	28658	1599	1
10	28431	1614	1
11	27423	1456	0
12	26293	1310	0
13	25795	1330	1
14	26187	1348	0
15	25730	1298	0
16	25557	1246	0
17	25342	1224	0
18	25501	1213	0
19	25167	1228	0

	20	25136	1234	0
	21	25405	1260	0
	22	25432	1266	0
	23	25186	1266	0
	24	25292	1295	0
	25	25521	1292	0
	26	25848	1315	0
	27	26146	1310	0
	28	26314	1370	0
	29	26476	1378	0
	30	26243	1399	1
	31	26243	1370	0
	32	26457	1368	0
	33	27012	1392	0
	34	27594	1437	0
	35	28588	1456	0
	36	29410	1515	0
	37	29298	1523	0
	38	29019	1504	0
	39	28451	1480	0
	40	27928	1439	0
	41	27431	1411	0
	42	27440	1526	4
	43	26792	1486	3
	44	25538	1366	1
	45	8523	465	0
Average		24500	1270	0.5

Data From AHU Shutdown Trial 2

Settling Plates

Site	CFU
1	1
2	1
3	0

Viable Sampling

Trial	CFU
Pre	0
Mid	1
Post	0

Non-Viable Sampling **0.5 um/ft**

Trial	Count 1	Count 2	Count 3	Average
Pre	167	254	214	211.7
Post	266	252	120	212.7

Non-Viable Sampling **5.0 um/ft**

Trial	Count 1	Count 2	Count 3	Average
Pre	2	7	3	4.0
Post	5	4	4	4.3

Pre-Test Non-Viable

Time	0.3	0.5	1	5
13:52	996	426	157	6
13:53	1300	549	204	13
13:54	1946	659	210	4
Average	1410.0	545	190	7.7

Post-Test Non-Viable

Time	0.3	0.5	1	5
18:16	3455	689	262	4
18:17	3204	792	253	2
18:18	2003	549	194	2
Average	2890	677	236	2.7

Continuous Monitoring During Test

Sample	0.5	1	5
1	93	33	1
2	1422	128	0
3	3127	260	0
4	3701	285	0
5	4279	336	0
6	4466	330	0
7	4471	334	0
8	4708	364	0
9	4978	401	0
10	4937	406	1
11	5031	387	0
12	5125	388	0
13	5116	386	0
14	5134	369	0
15	5170	370	0
16	5112	369	0
17	5015	360	0
18	5048	356	0
19	4976	342	0
20	4787	326	0
21	4860	327	0
22	5090	352	0

	23	5132	370	0
	24	5128	372	0
	25	5047	354	0
	26	5040	359	0
	27	5440	378	1
	28	5702	388	1
	29	5902	392	0
	30	5989	403	0
	31	5969	429	0
	32	5938	427	1
	33	5737	407	1
	34	5520	405	0
	35	5613	408	0
	36	5710	438	1
	37	6224	501	0
	38	6489	549	1
	39	6147	499	0
	40	5636	459	2
	41	5871	467	1
	42	6798	547	3
	43	7171	710	3
	44	3442	379	2
	45	410	47	0
Average		4950	376	0.4

Data From AHU Shutdown Trial 3

Settling Plates

Site	CFU
1	0
2	1
3	0

Viable Sampling

Trial	CFU
Pre	0
Mid	0
Post	0

Non-Viable Sampling **0.5 um/ft**

Trial	Count 1	Count 2	Count 3	Average
Pre	334	742	234	437
Post	1350	656	476	827

Non-Viable Sampling **5.0 um/ft**

Trial	Count 1	Count 2	Count 3	Average
Pre	5	17	5	9.0
Post	8	3	4	5.0

Pre-Test Non-Viable

Time	0.3	0.5	1	5
13:52	1272	334	106	5
13:53	1585	742	162	17
13:54	542	234	60	5
Average	1130	437	109	9.0

Post-Test Non-Viable

Time	0.3	0.5	1	5
18:16	5407	1350	366	8
18:17	4193	656	134	3
18:18	2715	476	95	4
Average	4110	827	198	5.0

Continuous Monitoring During Test

Sample	0.5	1	5
1	130	44	2
2	29	11	0
3	3	2	0
4	0	0	0
5	649	57	0
6	4179	363	0
7	5974	511	0
8	6977	606	1
9	6646	625	1
10	6400	587	1
11	6396	593	0
12	6269	597	0
13	6879	719	1
14	6753	705	1
15	6532	645	1
16	6497	612	1
17	6473	616	1
18	6677	653	1
19	6502	638	2
20	6544	663	1
21	6603	675	1
22	6867	680	1

	23	7027	710	1
	24	6498	685	1
	25	6278	646	1
	26	6377	655	1
	27	6460	687	2
	28	6352	672	1
	29	6577	684	1
	30	6820	763	1
	31	6859	816	1
	32	6545	693	2
	33	6415	659	1
	34	6386	700	1
	35	6227	691	1
	36	6213	660	1
	37	6529	665	1
	38	6581	668	0
	39	6558	653	0
	40	6817	712	2
	41	6996	700	2
	42	7320	703	3
	43	7003	661	1
	44	6788	664	1
	45	6785	638	1
Average		5830	586	1.0