Opticap XL Output and Workflow Improvement- Examining Production Line Dedication

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Abstract

Insufficient production capacity and backorder buildup motivated EMD Millipore to examine its Opticap XL filter encapsulation process. Through analyzing this process and interviews with key stakeholders our team confirmed the changeover process as a production bottleneck. One way to potentially reduce changeover time is through line dedication by product characteristics. In this project, we built a discrete-event simulation model to evaluate different dedication scenarios and ultimately recommended dedication by capsule size.

Acknowledgements

Authorship

The three students listed on the cover of this report contributed equally to its content and revision.

Executive Summary

EMD Millipore is a global leader in the life sciences industry and its primary business activity is the production of filters for the pharmaceutical and beverage industries. EMD Millipore has over 10,000 employees across 67 countries and a portfolio of more than 40,000 products.

 The manufacturing of single-use filters is an important strategic choice for EMD Millipore. Single-use filters eliminate the maintenance associated with stainless steel housings used in multi-use filters. The focus of this project is on the manufacturing process of the Opticap XL product line, one such single-use filter, specifically the final process step referred to as encapsulation process.

The encapsulation process consists of placing a filter cartridge into a capsule, welding the capsule to a cap, adding two vents and packaging of the final product. There are over 3,000 Opticap XL products available in EMD Millipore's catalog. This wide array of product types result in production line changeovers, which are known to be lengthy non-valued added processes requiring significant time and effort.

The lengthy changeovers and growth in demand have lead to insufficient capacity and an increase in backorders. Moreover, EMD Millipore forecasts a 16% annual growth in demand for the Opticap XL filter line. Consequently, the goal of this project is to improve the workflow and output of the Opticap XL filter encapsulation process to better satisfy customer demand.

Research Methodology

To identify potential improvements in the workflow and output of the Opticap XL filter encapsulation process at EMD Millipore, we analyzed the production and changeover processes, conducted time studies and performed interviews with key stakeholders.

We built a discrete-event simulation model of the current process in the commercially available software package Rockwell Arena. This model was used to

determine the impact of dedicating production lines by product characteristics through scenario analyses of alternative production schedules.

To ensure that the model was working as expected and that it matched EMD Millipore's filter encapsulation process operations, we conducted verification and validation studies. Verification consisted of scripted test cases while validation was done by using animation to visually examine model logic and through interviews with process stakeholders at EMD Millipore. As in any analytical approach, assumptions were made during the modeling process, which may limit the accuracy of our recommendations.

We hypothesized that line dedication would require fewer steps in the changeover process which in turn would reduce the changeover time. We analyzed three scenarios that the Opticap XL encapsulation area could possibly implement:

1. Dedicating production lines by filter size,
2. Dedicating production lines by capsule cap type,
3. Dedicating production lines by material type (gamma or non-gamma).

A line dedicated to a specific filter size would reduce the changeover time for two machines: the bonder and the vibe welder. A line dedicated to a particular cap type will have a shorter changeover time for the tester machine. A line dedicated to one material type will reduce the bonder machine changeover time.

We were interested in quantifying the changeover time reduction that can be achieved through each of the three line dedication scenario. Three performance metrics were used to assess the results of each scenario in each set and ultimately determine how lines should be dedicated. These metrics were:

1. Average vibe welder and tester changeover time,
2. Average bonder changeover time,
3. Total average changeover time.

Results and Conclusions

Using actual production demand data, we analyzed all the possible combinations for the three scenarios. Results from a preliminary analysis found that dedicating by size and cap type was clearly better than dedicating by material type for all three metrics. A second, more in-depth analysis determined that dedicating by size was better that dedicating by cap type.

For this reason, we **recommend** EMD Millipore **dedicate production lines by size**. This means that 2" and 4" filters should be assigned to one line, 3" and 5" inch filters should be assigned to a second line, and 10" filters should be assigned to a third line. After dedicating lines by size, lots should be first organized by cap type and then by material type. It is important to note that lines should be balanced before starting production to have a similar number of filters being produced in each line.

Our final deliverable for this project is a set of best practice guidelines that could potentially be of use to production leads when organizing the production schedule. Using these guidelines promotes standardization and reduces the risk of inefficient scheduling should the production lead be absent.

Future considerations

The simulation model developed for this project was used to analyze the impact of production scheduling on the encapsulation process; however, this model can be used for other analyses. For example, an analysis could be performed to assess the impact on output of factors such as operators' scheduling, lower production times or addition of new machines. Furthermore, the model is flexible enough so that it can be modified to reflect any changes that take place in the actual process.

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1 Introduction

Production processes in the pharmaceutical and life sciences industries are highly regulated. Because pharmaceutical and life science end products must be safe for consumers, products undergo a cleansing process several times throughout the manufacturing cycle. This cleansing process is referred to as sterile filtration and is designed to separate the desired fluid from impure particles. A variety of sterile filters are used for this purpose differing in size, filtration type, and membrane type, among other characteristics.

EMD Millipore is a division of Merck KGaA and a global leader in the life sciences industry. EMD Millipore's primary business activity is the production of filters for the pharmaceutical and beverage industries. A wide assortment of filters is produced to meet customer needs, each requiring a distinct manufacturing process. This project focuses on the manufacturing of the Opticap XL sterile filters, specifically the final step, referred to as encapsulation process. In this step, the filter is placed inside a disposable capsule, also known as housing that varies in design and functionality.

EMD Millipore has made the business decision to heavily emphasize the commercialization of single-use manufacturing devices. Opticap XL is a line of disposable filters that eliminates the need for maintenance associated with stainless steel housings. These disposable filters are composed of a cartridge containing a pleaded membrane and a capsule in which the cartridge is placed. Based on the combination of the membrane, cartridge and capsule type, there are over 3,000 Opticap XL products available in EMD Millipore's catalog. Figure 1 shows and image of one of these products.

Figure 1 - Opticap XL Filter (EMD Millipore)

1.1. Problem Statement

Opticap XL encapsulation process is currently facing two significant production challenges: insufficient capacity and backorder buildup. EMD Millipore's wide array of product types results in lengthy production line changeovers. Each changeover lasts over 30 minutes and entails documenting the previous and upcoming lot, as well as testing the machines. This somewhat lengthy changeover has contributed to production lines being at capacity. At full line utilization, the number of backorders has grown, having a direct impact on customer satisfaction and negatively impacting the company's reputation. At the same time, forecasts indicate that there will be a 16% yearly growth in demand for the Opticap XL filter line. EMD Millipore is planning to implement a new Opticap XL encapsulation cell to address this increase in demand in Q1 2015.

In addition to these capacity challenges, the Opticap XL manufacturing area will be replacing its enterprise resource planning system in the summer of 2014. Consequently, production must plan to build inventory to make up for planned downtime. This extra production represents around 10,000 units and is the equivalent of producing thirteen months' worth of inventory in twelve months.

This project aims to address EMD Millipore's Opticap XL filter encapsulation production challenges at specifically the insufficient capacity and increasing backorders.

1.2. Project Goals and Objectives

Considering insufficient capacity and requirement for back stocking, the goal of this project is to improve the workflow and output of the Opticap XL filter encapsulation process. To accomplish this goal we set the following six objectives:

1. Gain an in depth understanding of the Opticap XL encapsulation lines,
2. Comprehend the current state of production scheduling of the Opticap XL encapsulation lines,
3. Collect data on the current state of the changeover process through time studies,
4. Build a discrete-event simulation (DES) model of the current Opticap XL encapsulation process,
5. Determine the impact of dedicating lines to product characteristics by conducting scenario analyses in the DES model,
6. Analyze the results from the different scenarios and provide recommendations regarding line dedication.

1.3. Project Deliverables

Our team achieved the above-mentioned objectives by creating a DES model of the current process in a commercially available software package Arena by Rockwell Automation and through scenario analyses of alternative production schedules recommended a course of action. We studied the current encapsulation process through observation, interviews, time studies and data analysis. From these studies and input from the production team, our first deliverable was the DES model and the associated scenario analyses. Building on our findings from the first deliverable, our second deliverable was a set of guidelines/best practices for scheduling. These

guidelines will provide production leads a more standard way of preparing production schedules.

1.4.   Project Scope

Table 1 lists the scope of the project

Table 1 - Scope of the Project

In Scope	Out of Scope
Product: Opticap XL filters Process: Encapsulation - Focus on Changeovers Daily Production Scheduling	Product: Opticap XLT filters Process: Pre-encapsulation and packaging Manufacturing line layout Machine performance Standard Operating Procedures

2 Background

2.1 EMD Millipore

Merck KGaA is a multinational corporation in the pharmaceutical, chemical and life sciences industries headquartered in Darmstadt, Germany. In the United States, Merck KGaA is composed of three divisions: EMD Millipore, EMD Serono and EMD Chemicals. EMD Millipore is Merck's life sciences division, originally founded in 1954 as Millipore Corporation and acquired by Merck KGaA in 2010 (EMD Millipore, 2013c). EMD Millipore is composed of three business units: Bioscience, Lab Solutions and Process Solutions. These three units serve pharmaceuticals and research laboratories in a variety of needs. Figure 2 below shows an organizational chart of Merck's divisions and EMD Millipore's business units.
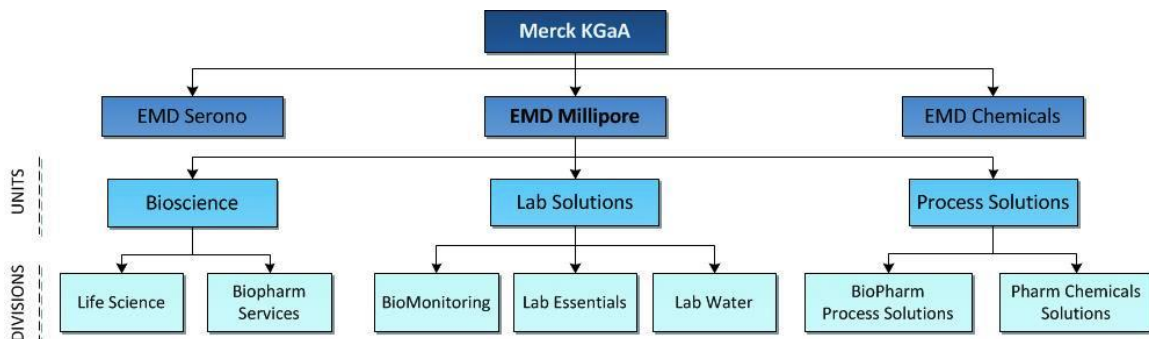
Figure 2 - Merck KGaA's Business Organizational Chart (EMD Millipore, 2013b)

The Bioscience unit focuses on supporting pharmaceutical companies and researchers by providing them with new technologies and work solutions. In this unit, EMD Millipore provides resources for third parties to conduct research as well as conducting its own research in the areas of genomic, proteomic and cellular analysis. The Bioscience unit is composed of two business fields: Life Science and Biopharm Services. Some of the main products and services in Bioscience include Multiplex instruments and kits, flow cytometers, antibodies and reagents, and drug discovery and development services (EMD Millipore, 2013e).

The Lab Solutions unit manufactures lab products and equipment for pharmaceuticals and researchers. It is comprised of three business fields: BioMonitoring, Lab Essentials and Lab Water. This unit offers water purification systems, control products for pharmaceutical and food and beverage processes, and analytical services for different industry products. Test kits, chemicals and reagents for analytics, and lab water purification equipment are among the key products in Lab Solutions (EMD Millipore, 2013e).

The Process Solutions unit provides products, services and solutions to improve pharmaceutical and biopharmaceutical manufacturing processes, focusing on therapeutic molecules. The two fields forming this unit are BioPharm Process Solutions and Pharm Chemicals Solutions. Some of the key products in Process Solutions are single-use manufacturing equipment, chromatography and purification devices, pharma and biopharma raw materials, and sterile filtration devices (EMD Millipore, 2013e).

EMD Millipore has several facilities and offices in 67 countries around the world with more than 10,000 employees. In the United States, EMD Millipore is headquartered in Billerica, MA and runs research facilities in Bedford, MA; Temecula, CA; St. Charles, MO; San Diego, CA and Seattle, WA. It also owns logistics and manufacturing sites in Kankakee, IL; Burlington, MA and Jaffrey, NH. Additionally, EMD operates a facility dedicated to customer service, the Bioprocess Technology Center, in Billerica, MA (EMD Millipore, 2013d).

Project Location

This project takes place at EMD Millipore's Manufacturing Center of Excellence located in Jaffrey, NH. This site manufactures different products for all of the company's business units worldwide. For this reason, the Jaffrey site is designated as a Foreign Trade Zone. As a production facility for the healthcare industry, the Jaffrey Manufacturing Center of Excellence complies with FDA regulations and is ISO 9001:2008 certified. Additionally, their manufacturing processes adhere to Lean and Six Sigma principles, making operational excellence and continuous

improvement a great area of focus. The Manufacturing Center of Excellence is also committed to making a positive impact on the environment through several initiatives such as water and electricity consumption reduction. The New Hampshire Governor's Award for Pollution Prevention received in the past years speaks to their environmentally friendly practices (EMD Millipore, 2013a).

A variety of BioProcess Solutions products are manufactured at the Jaffrey plant. These products are separated into two categories: normal-flow filtration (NFF) and tangential-flow filtration (TFF) devices. NFF devices include Durapore, Aerex, Aervent, Express, Millidisk, Millipak and Optiscale filters among others. TFF devices are filters such as the Pellicon 2, Pellicon 3, Prostak, Viresolve, Spirals and Prepscale (Gifford, 2013). Normal-flow filters retain the unwanted particles and let the fluid pass whereas tangential-flow filters retain the desired fluid, letting the contaminating particles pass (Gifford, 2013). Additionally, Jaffrey manufactures and pleats the membrane that composes the cartridges that are placed in the capsules.

The Manufacturing Center of Excellence employs over 800 employees, most of whom work in manufacturing and lab quality control activities. The facility is divided into six operation areas, which include UF Membrane Casting Plant, Pellicon/Prostak Devices manufacturing, Durapore/Opticap Devices manufacturing, Millidisk/Millipak Devices manufacturing, Viresolve/V-Pro manufacturing, and Warehouse(Gifford, 2013).

The Durapore/Opticap area in particular runs 24 hours a day from Monday to Friday, with occasional Saturdays. Operators work three different shifts: A, B and C. The A-shift runs from 7:00 AM to 3:00 PM the B-shift starts at 3:00 PM and ends at 11: 00 PM, and the C-shift operates from 11:00 PM to 7:00 AM. Each shift has different staffing levels according to production needs and staff availability.

2.2 Disposable Capsule Filters

Disposable sterile filters, such as the Opticap XL products, represent one of the main areas of production in the Jaffrey plant, accounting for 28% of the total site production. Demand for disposable sterile filters has grown considerably over the

past few years. The end-to-end manufacturing process of these filters takes place at the Jaffrey, NH facility.

Cartridge, capsule housings, and membranes for Opticap XL filters come in various sizes and types. Opticap XL capsule housings are available in 2", 4", 5", and 10" for sizes and Standard and Gamma for types. Additionally, the membranes could be Durapore or Express. For instance, Figure 3 shows filters with the following characteristics: 5" and 10" capsules, non-gamma material type, and Durapore membrane. The different possible combinations result in over 3000 different catalog products customers could order, leading to frequent changeovers in production.

Figure 3 - Opticap XL Filter (EMD Millipore)

2.2.1. Normal-Flow Filtration Filters Manufacturing Process

The production process of NFF filters starts with the manufacturing of membrane in the UF Membrane Casting Plant. Membrane is laminated and pleated to form the cartridges. A cartridge then undergoes ultrasonic seaming, serial number labeling and encapsulation to obtain the final disposable filter. In addition, housing integrity testing is performed on every unit and some samples from each lot are sent to a more in depth quality control test (Gifford, 2013). The end-to-end manufacturing process is shown in Figure 4 below. The darker boxes represent the steps of the encapsulation process.
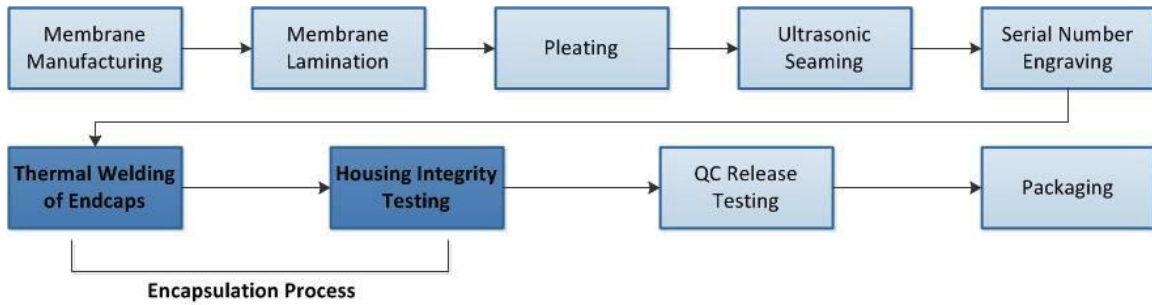
Figure 4 - NFF Filters Manufacturing Process (Gifford, 2013)

2.2.2. Encapsulation Process

Currently there are three production lines for the Opticap XL filter encapsulation process, referred to as XL1, XL2, and XL4. The inconsistency in the numbering sequence is due to the future plan of implementing a fourth line, which will be physically located between XL2 and XL4.

Within each production line, there are four steps that must be completed to encapsulate the cartridges. These steps, described below, are done by following a single-piece flow approach and include bonding and cooling, vibration welding, housing integrity testing, and bagging (Figure 5).
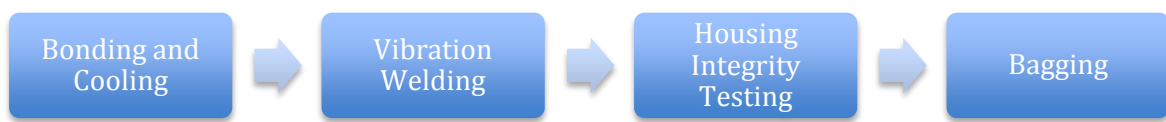
Figure 5 - Encapsulation Process Steps

Step 1 – Bonding and Cooling: each cartridge is thermally bonded to the "endcap" and then retained in the machine for the appropriate cooling time.

Step 2 – Vibration Welding: the cartridge and cap are bonded to the capsule housing of the filter through vibration. For both steps, while the Vibration Welding machine is performing the core activity, the operator must set up the process, move the materials from one machine to the next, and place unit labels on the capsule housings.

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Step 3 – Housing Integrity Testing: two vents are manually added to each capsule and then a test is performed to checks for the integrity of the housing, including the capsule weld and the vents. If the test fails the operator checks the vents and re-tests. If it fails a second time, the operator changes the vents and re-tests. If a third failure occurs, the product is considered to be a reject. When a product passes the housing integrity test, it is moved to the fourth and final step.

Step 4 – Bagging: each product must be packaged in a first layer of plastic bag, labeled and vacuum-sealed and then repackaged in a second layer of plastic bag and re-sealed. All final products are transferred through a window to an adjacent room where they are boxed and become ready for storage or delivery.

2.2.3. Changeovers

The set-up of a system before starting a manufacturing process is an essential part of production lead time (Singh & Khanduja, 2009). Since throughput is directly affected by production lead time, reducing the time taken by changeovers could significantly increase throughput. Additionally, faster changeovers are a requisite for increased flexibility and responsive manufacturing (Mileham, Culley, Owen, & McIntosh, 1999).

Changeover steps for the encapsulation process of Opticap XL filters are shown in Figure 6. The first step includes cleaning up from the previous batch and setting up for the upcoming one. Clean up is performed by operators in the production line and requires disinfecting all machines and stations (tables, bins, labeling equipment) with the provided disinfecting wipes. The set-up involves completion of paperwork, machine setup and batch testing.
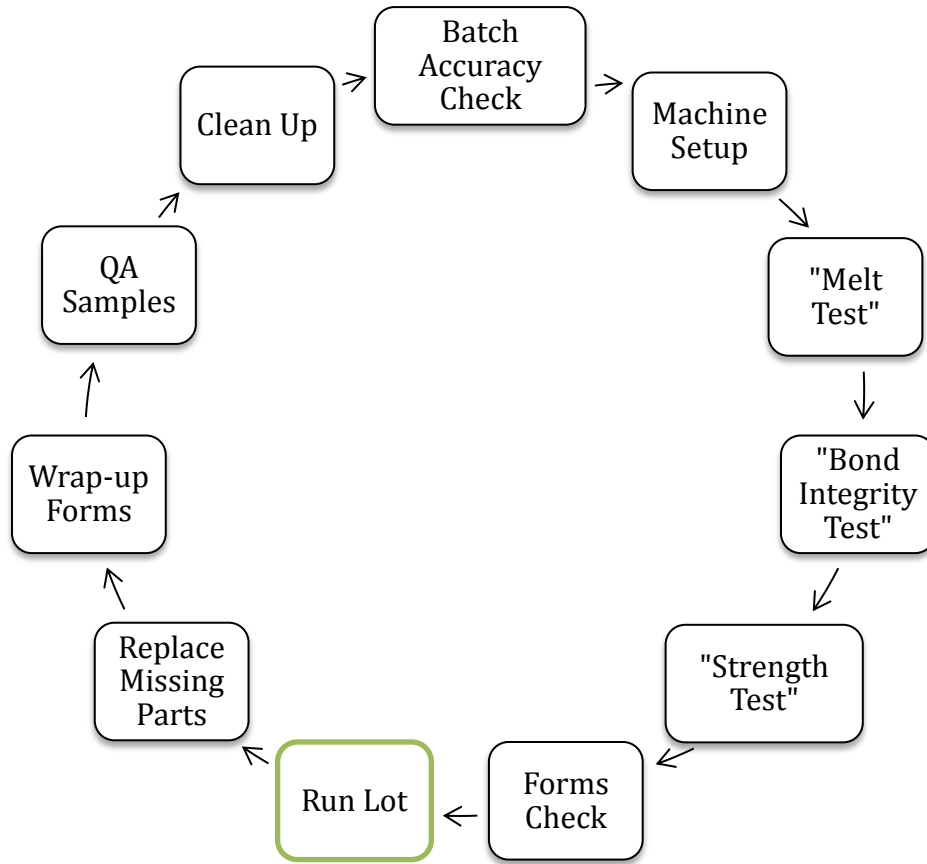
Figure 6 - Changeover Process

Before operators begin a new batch, they first have to check the accuracy of all the parts received from the kitting group. A thorough manual check of materials and paperwork is conducted in three steps. First, operators randomly select three filters and confirm that the filters' lot number matches the number on the batch record forms. Second, they count the number of filters delivered and crosscheck it with the batch record forms. Finally, they ensure that the amount of labels is correct and that they contain accurate lot details. This is done to ensure that the correct label is used for each capsule in the corresponding lot. Before starting the set-up of machinery, operators manually number, sign and date all of the batch record forms.

Machine setup is dependent on the characteristics of the previous and upcoming lot, as shown in Table 2. Procedures for machine setup can be found in Appendix B: Machine Setup Procedures. There are three tests that must be performed before

starting to process the lot, the "Melt Test", the "Cartridge Bond Test" and the "Strength Test". A detailed description of each test can be found in Appendix C: Machine Testing Procedures. Every test should be documented by filling out all required fields in designated batch record forms. All rejected capsules should be promptly entered into the system.

Table 2 - Influence of Filter Characteristics in Changeover Steps

Machine	Changeover Step	Filter Characteristics Influencing
Bonder	Upper Nest Setup	Cartridge and capsule size
	Lower Nest Setup	Cartridge and capsule size
Vibe Welder	Top Plate Setup	Capsule size
	Bottom Nest Setup	Capsule size
Housing Integrity Tester	Left and Right Seals Setup	Cap Type
	Left and Right Nests Setup	Cap Type

Once the three tests are successful, operators may start running the lot. However, while the first cartridge is in the Bonder, an operator from another line must be called to double-check that all paperwork for testing is accurate and tests were indeed within tolerance. This operator must also be present during the first run of the Vibration-Welder for this lot to check that the Clamp pressure during that run is read and documented correctly by the operator in charge.

If re-testing is necessary during the "Melt Test", additional caps might have to be used. As a result, once a lot is close to being complete there may be fewer parts available than required. If that is the case, the operator needs to collect extra parts from inventory. During the B and C shifts there are material handlers assigned to such task. However, during the A shift, individual operators need to walk over to the inventory storage location and search for the specific missing part. Wrapping up the lot involves documenting the production of the lot and producing QA samples according to the requirements specified in the batch record forms.

The changeover process in the production of Opticap XL filters is known to be a lengthy non-valued added process requiring significant time and effort from the operators for two reasons.

First, there are many combinations of filters and capsules to be produced in the encapsulation process. The set-up of machines can take a considerable amount of time depending on the characteristics (i.e.: capsule size, cap types) of the previous and upcoming lot. Therefore, if production scheduling does not take into consideration the machine changeovers required, the changeover time between lots can be longer than necessary.

Second, minimum lot size requirements do not exist and lots can range from one to six hundred capsules. Because the changeover procedure is the same for any lot size, at times an operator might even be required to implement a complete changeover for production of a single Opticap XL filter. If too many small lots are planned for a line on the same day, a large number of changeovers will have to be performed.

2.3   Current State Analysis

Bill Teeter, an Industrial Engineer at EMD Millipore, built a capacity model for the Opticap XL filter encapsulation process in early 2012. This capacity model was based on machine availability and capability; meaning human labor was not taken into consideration. The model's assumptions include that the production floor operates 24 hours a day, five days a week, and 50 weeks per year. Additionally, lot sizes are always 50 units. Results from this model indicate the bottlenecks in the production process as well as the current capacity levels.

According to the model, the bonder is the bottleneck in the encapsulation process. The housing integrity tester closely follows the bottleneck, while the vibration welder has plenty of capacity. These results align with our observations. The model indicates that the current bottleneck has an average yielded demand of 9,738 units per week, maxing out process capacity with 103%.

The capacity model indicates that EMD Millipore could accommodate current demand by either producing 9,884 units per week or by operating 5.25 days per week. However, EMD Millipore's forecasts indicate that there will be a 16% yearly growth in demand for the Opticap XL filter line. According to the model, capacity will be maxed out by 137% in 2017. As current production rates, EMD Millipore would have to add two new cells to cover demand for the next five years. Additionally, at full line utilization, the number of backorders has grown. The current backorders are valued at approximately $600,000 for the Express line and around $100,000 – 200,000 for the Durapore line, and will continue to grow if no action is taken.

A final aspect that must be considered when analyzing the current state of the encapsulation process is the variety of products, as this determines the frequency and duration of the changeover processes, which in turn impacts production levels. As mentioned in Section 2.2, EMD Millipore has over 3,000 different Opticap XL filter SKUs that customers could order. As of September 18th, 2013, the year to date built list included 494 different catalog products from the Opticap XL line.

Future Implementations

Three significant changes will be occurring in the Opticap XL filter encapsulation process.

First, by the end of March 2014, new machines called "plug bonders" will be added to manufacturing cells XL1 and XL4. Currently a robot in the finishing cell plugs the bonder to the filter before the encapsulation process, requiring time-consuming documentation before filters can be transferred from the finishing cell to the encapsulation lines. Plug bonders will be for 10" cartridges only, substituting the robot and eliminating documentation.

The second change in the Opticap XL encapsulation lines refers to their enterprise resource planning (ERP) system. EMD Millipore's current ERP system will be replaced by SAP in the summer of 2014. Consequently, production must plan to build inventory to make up for the four weeks that lines will be down during SAP

implementation. This extra production represents around 10,320 units, which signifies a Sales Volume of Production (SVOP) of $786,000, and is equivalent to producing thirteen months worth of inventory in only twelve months.

Lastly, a fourth manufacturing cell will be added to the production floor of the Opticap XL encapsulation lines between late 2014 and early 2015. This line will be physically located between XL2 and XL4 and will be referred to as XL3. EMD Millipore is looking to postpone implementation as much as possible due to the $1.5 million investment the new encapsulation line entails.

2.4   Time Studies

Time studies are used to determine the representative or standard time taken by a repetitive activity (Wilson & Corlett, 2010). In simulation studies, time studies are a commonly used tool to collect data. A simulation model is only valid if it is logical and the data used is appropriate (Law, 2008). Therefore, conducting time studies correctly is of high importance.

Time studies consist of: understanding the objective of the study, breaking down the process to be studied to the desired level of complexity, ensuring the study is being conducted during a representative time period, using good sampling procedure for reliable results, and analyzing the data appropriately (Holpp, 2010). Each of these steps is essential to the collection of valid data for a model. However, the complexity of a process composed of many sequenced sub-processes can result in difficulties when collecting data (Wilson & Corlett, 2010). To better outline the studies, activities are defined to occur between pre-determined events (Wilson & Corlett, 2010). For example, in the case of the study presented in this report, the activity "Burst Test" of the Opticap XL encapsulation process is defined to start at the event "touch the tool" and finish at the event "throw the cap out". Activities that happen out of sequence and are not usually part of the process should be noted as a "foreign element" (Wilson & Corlett, 2010).

When analyzing the data, it is important to fully understand the numbers presented, including the process that produced the data (Law, 2008). Outliers refer to occurrences in the data that are outside of the norm. However, only through in depth study of the data and underlying process can someone identify if these data points are a recording error or legitimate values that occur with very small probabilities (Law, 2008).

Law (2008) lists common difficulties that accompany time study data collection and analysis and ways to overcome them. Holpp (2010) notes that the modeler is ultimately responsible for confirming the accuracy of the data before using it in the model.

2.5 Simulation

In today's business world it is often difficult, costly, or even impossible to conduct physical studies on a facility or process (Kelton, Sadowski, & Swets, 2010). This is why simulation is such a powerful analysis tool. Simulation is the imitation of the operation of a real-world system, which allows the user to analyze the impact of business ideas before implementing them (Banks, Carson, Nelson, & Nicol, 2001).

Simulation studies a system through the use of mathematical models (Banks et al., 2001) (Figure 7). Simulation can be used for many purposes such as describing system performance, improving system design or operations, or managing its day-to-day decisions (Kelton et al., 2010). Simulation is used to design and create models of complex systems using software that imitates the system's operations over time. This modeling is done to conduct numerical experiments that help a user understand how the system would act under a given set of conditions (Kelton et al., 2010).

There are a number of ways to classify simulation models (see Kelton et al., 2010 and Harrell, Gosh, & Bowden, 2004). Examples include systems dynamics (Rowell & Wormley, 1997), agent-based simulation (Railsback & Grimm, 2011), discrete-event simulation and micro simulation (Mitton, Sutherland, & Weeks, 2000), among

others. This project will use discrete event simulation (DES). DES refers to a type of simulation in which the state of the system changes at discrete points in time (Kelton et al., 2010). In this project we selected discrete-event simulation because no change in the system is assumed to occur between consecutive events of the filter encapsulation process. This means that events happen as a sequence of steps in discrete time periods.
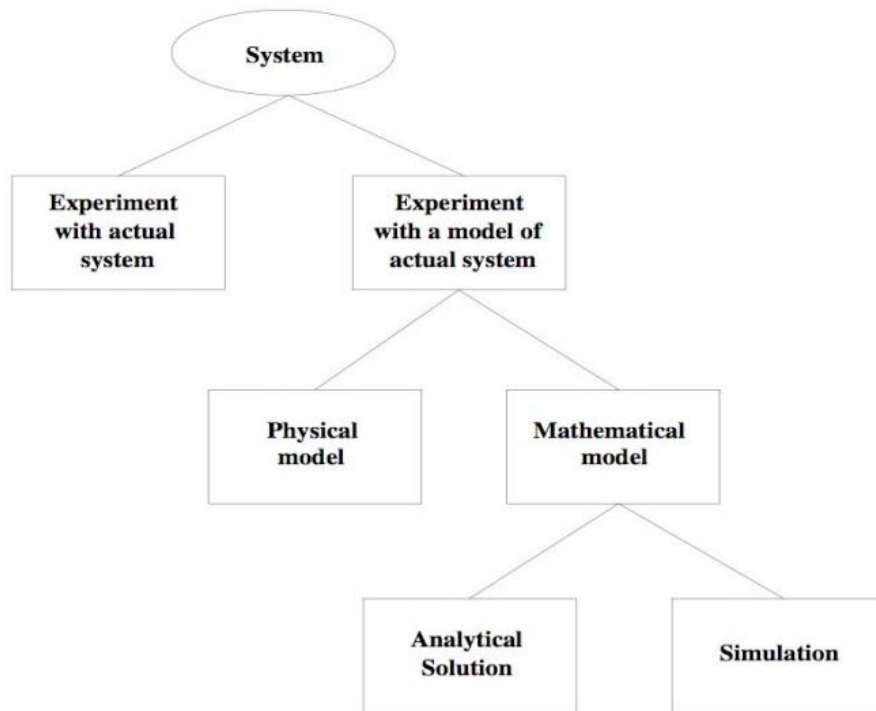
Figure 7 - Types of Models (Banks et al., 2001)

Advantages

Many studies have ranked simulation as one of the most popular tools in operations research (Kelton et al., 2010) as it provides a number of advantages to users. First, simulation is not disruptive. It can be used to determine the effects of a change in real life without actually having to implement the change itself. This could help a company save time and money (Meng, 1998). Moreover, a simulation model can be

easily replicated and used to perform a wide variety of analyses (Banks et al., 2001). Finally, in the last decade computer hardware and software have rapidly evolved, making simulation more effective and easy to use (Kelton et al., 2010).

Disadvantages

Despite its popularity, simulation has its disadvantages. For instance, sometimes it is difficult to represent complex models, causing users to make simplifying assumptions. An over-simplified model may not be a valid representation of the system and lead to inaccurate conclusions (Kelton et al., 2010). Moreover, even when a model is valid, it is sometimes difficult to interpret the simulation results, which may once again lead to the wrong course of action. Finally, it takes time and money to build complex and valid models of a system, which in cases may not be readily available (Meng, 1998).

It is important to consider both the advantages and disadvantages of simulation to determine if it is the best tool for solving the problem in hand. Moreover, there is a set of best practices that should be followed if simulation is chosen as the appropriate tool. Refer to Appendix D: Simulation Best Practices for a list of these steps (Balachandran, Rabuya, Shinde, & Takalkar, 2000) and (Kelton et al., 2010).

2.6   Rockewell Arena Discrete-Event Simulation Software

Arena is a DES software developed by Rockwell Automation (Rockwell Automation, 2013). Arena allows the user to simulate a given process and obtain metrics such as lead time, throughput and queuing time; thus providing a base for analysis of potential changes or improvements to be implemented in a process. Arena has been applied in a wide variety of industries including manufacturing, packaging, supply chain and warehousing, healthcare, military and defense, and call center processes (Rockwell Automation, 2013).

Arena is one of the most popular simulation software packages because of its simulation features, user-friendliness and graphic interface. "A flowchart-style modeling methodology, hierarchical modeling, and an extensive graphical library

are just some of the features that make Arena the world's leading simulation system" (Rockwell Automation, 2013). Arena allows the user to build a process flowchart and connect its elements, which are called modules. Entities can be created to represent the parts that are going through the process.

Various modules are used to simulate events of a process such as the work performed by operators or machines, route separation of parts according to chance or condition, batching, queuing and transportation around the facility, among others. "An *event* is something that happens at an instant of (simulated) time that might change attributes, variables, or statistical accumulators" (Kelton et al., 2010). The modules represented by a block in the simulation flowchart are called flowchart modules. These modules depict dynamic processes and are generally connected to each other (Kelton et al., 2010). The modules that are not visually represented in a simulation flowchart are called data modules. These modules set values and conditions for the entire model and are typically associated to a flowchart module and an element of the model (Kelton et al., 2010). For example, a queue is an element in the model that has a data module associated to it, the queue data module. There can be several instances of the same flowchart module in a model but there is only one instance of each data module. Different entries in a data module represent different occurrences of the corresponding element. Following the same example, there is only one queue data module but there are several entries in it representing different queues.

For a list of the most important and commonly used features in Arena, as well as the ones used for our simulation model, refer to Appendix E: Arena Modules.

2.7   Discrete-Event Simulation Case Studies

Many case studies demonstrate the impact of using discrete-event simulation to evaluate and improve manufacturing operations. Silva, Ramos and Vilarinho (2000) assessed a set of changes to a chest freezer company's current manufacturing operations to determine if an increase in throughput and overall productivity was attainable. Using a DES model bottlenecks, machine capacities, usage rates, and

work in progress (WIP) were accurately identified. As a result, a recommended set of changes was implemented causing the manufacturing system operation to be smoother, the workload to be more evenly distributed and WIP to be considerably reduced (Silva, Ramos, & Vilarinho, 2000).

Detty and Yingling (2000) analyzed the efficiency of DES in lean manufacturing implementations. They used DES in this study to analyze the current state of the process and analyze the impact of proposed modifications to the process. Having tested and collected statistics on the impact of implementing the proposed modifications, the implementation of such modifications was efficient and effective (Detty & Yingling, 2000).

Abdulmalek and Rajgopal (2007) analyzed the benefits of lean manufacturing and value stream mapping through the use of simulation. They developed a simulation model to contrast the "before" and "after" states of an integrated still mill, to illustrate to managers potential benefits without actually implementing the changes. These benefits included but were not limited to reduction in production lead-time and lower WIP inventory (Abdulmalek & Rajgopal, 2007).

Zuluaga and Ruiz (2012) used simulation to improve the efficiency of a brewery. They developed a model of the overall behavior of the brewery system by modeling its resources and inputting its control methods. Using the "digital factory of the brewery" they developed a scheduling tool that could take into consideration all the limiting factors of the physical brewery. In contrast to our project's goal of analyzing an existing process, Zuluaga and Ruiz used simulation to compliment an ongoing scheduling process. Their study highlights key advantages of using simulation, such as being able to modify their schedule to increase resource utilization considering all limitations (Zuluaga & Ruiz, 2012).

Bangsow (2012) includes a case study of optimization at a shoe manufacturing plant using DES with Arena. Voorhorst, Avai and Boër explored the impact of changing the production process sequence and the allocation of operators on daily throughput, labor utilization and process flow. The plant had 13 different shoe styles, which

resulted in 11 possible sequence combinations (Voorhorst, Avai, & Boër, 2012). Their study provided insight to the process stakeholders regarding the key factors that affect the plant's performance as well as optimization of production mixes (Voorhorst et al., 2012).

In summary a review of the literature illustrates that simulation, in particular DES is widely used to support managerial decision-making. A number of successful case studies demonstrate how DES models have improved key performance metrics in the manufacturing setting.

3 Methodology

The goal of this project is to improve the workflow and output of the Opticap XL filter encapsulation process by recommending alternative production schedules.

Figure 8 shows an overview of our goal and related objectives, as introduced in Section 1.2, and associated tasks for each objective. Each will be discussed in detail below.

Improve workflow and output of Opticap XL filter encapsulation process	Understand the encapsulation process	SOPs
		Gemba Walks
		Interviews
	Comprehend current state of production scheduling	Interview Production Lead
		Interview Planning Division
		Analysis of Sample Schedule
	Collect data on current state of changeover process	Changeover Time Studies
		Data Summary and Analysis
	Build DES model	Build Model
		Validate Model
	Determine impact of line dedication	Scenario Analyses
	Analyze results and provide recommendations	Results Evaluation
		Best Practices Guidelines

Figure 8 - Project Overview- Goal, Objectives and Associated Tasks

3.1 Gain an in depth understanding of the Opticap XL filter encapsulation process

Understanding the encapsulation lines is essential to improve output and workflow of the Opticap XL filter encapsulation process. To achieve this we reviewed standard

operating procedure (SOP) documents; conducted Gemba walks in the production floor; and informally interviewed operators, production supervisors, and production leads.

EMD Millipore provided our team with all the SOP documents for the Opticap XL encapsulation process. These SOPs detail the specifics of how operators should complete each step in the production line, including changeovers between different products. Gemba walks, which consist of observing the actual process, allowed us to gain a better understanding of the encapsulation process. Additionally, our time on the production floor allowed us to informally interview operators, supervisors, and leads regarding current state of production and best practices.

3.2 Comprehend the current state of production scheduling of the Opticap XL encapsulation lines

We met with the representatives of the groups responsible for the production scheduling process listed below:

- **Shirley Daniels** – Master Scheduler, Planning Division
- **Kristine Teto** – A-Shift Production Lead, Production Floor

The interview with Shirley Daniels provided us with a more detailed understanding of the timelines and procedures the Planning Division follows when scheduling production and how they interact with the Production Floor.

Kristine Teto is responsible for scheduling the daily production for all three shifts in all three lines of the Opticap XL encapsulation process. An informal interview with her helped us observe and understand how she performs this task, the software used, priorities considered, and potential areas for improvement.

Appendix F: Interview Questions includes a pool of questions prepared before both meetings. Further questions were added during the conversations when deemed necessary.

3.3 Collect data on the current state of the changeover process through time studies.

With an understanding of the encapsulation process, we conducted time studies to determine the length of the changeover procedure for each machine based on different product characteristics. As explained in Section 2.2.3, the three machines, bonder, vibe welder and housing integrity tester, have a specific set of changeover steps that should be performed before starting the production of a new lot. The times determined through the studies served as input data for the DES model.

Our first task consisted of flowcharting the changeover process to develop an efficient strategy for conducting time studies (Appendix G: Changeover Process Flowcharts). We then developed a data collection form to standardize the process. A data collection form for operators was also designed and introduced to the floor with the aim of complementing the information obtained through the time studies. Guidelines for data collection along with both forms can be found Appendix H: Time Study Guidelines and Appendix I: Data Collection Sheets. After data was collected, we summarized it in a spreadsheet to simplify the process of inputting it in the DES model.

3.4 Build a DES model of the current Opticap XL encapsulation process

To understand the impact of line dedication, we first had to develop a DES model of the current state of the encapsulation process. Two main tasks enabled us to accomplish this objective. First, we researched simulation literature. Second, we built the model based on our research and previous experience using Rockwell Automation's software Arena, version 13.9, licensed to Worcester Polytechnic Institute.

In depth research of DES modeling was done through the analysis of literature, included in Sections 2.5 and 2.6. We met and discussed with Prof. Renata Konrad, an expert in discrete-event simulation from Worcester Polytechnic Institute (WPI), who guided us through the development of the DES model.

Details of the model structure can be found in Appendix J: DES Model Structure. Section 4.2 includes information on input modeling. Appendix K: DES Test Matrices contains a description of how the model was validated.

3.5 Determine the impact of dedicating lines to product characteristics by conducting scenario analyses in the DES model

An important functionality of the DES model is its capacity to analyze different scenarios of line dedication. These analyses determined the impact on changeover time reduction of dedicating lines to specific product characteristics. We analyzed three scenarios that the Opticap XL encapsulation area could possibly implement:

- Dedicating lines by filter size
- Dedicating lines by capsule cap type
- Dedicating lines by material type (gamma or non-gamma)

The potential impact that line dedication may have is determined by the fact that fewer steps are required for changeovers between lots of the same characteristics. A line dedicated to a specific filter size will experience a reduction in changeover time for the bonder and the vibe welder. A line dedicated to a particular cap type will have a shorter changeover for the tester. Similarly, a line dedicated to one material type will see its bonder changeover time reduced. We are interested in quantifying the changeover time reduction that can be achieved through each scenario. It is important to note that demand for each product type is a limiting factor for line dedication. For instance, if there were not enough demand for 10" products, it would not be feasible to dedicate a line solely to that product characteristic.

From the current state of the process simulated in the model, we modified the production schedules to represent each of the three scenarios. The schedules used for our scenarios correspond to real productions schedules used on a period of ten days during the months of November and December of 2013. The times of the changeover steps are modified automatically based on the previous lot to represent the time reduction obtained by having lots of the same characteristic produced back to back. For example, the time required for a vibe welder changeover is less when

switching from a 10" filter to a 10" filter than from a 10" filter to a 4" filter. This reduced time is automatically introduced in the model without further changes required. A simulation run of the model for each scenario provided us with the desired results and a basis for comparison.

3.6 Analyze the results from the different scenarios and provide recommendations regarding line dedication

After conducting scenario analyses of the different production scheduling scenarios, we evaluated the total changeover time and cycle time results. This evaluation helped determine the feasibility and effectiveness of dedicating lines based on such product characteristics. Additionally, it provided us with the order in which specific product characteristics should be considered when assigning lots to production lines.

Finally, we provided EMD Millipore with a set of guidelines that should be used in order to make production scheduling more efficient. The guidelines were based on the results from the scenario analyses, suggestions that come from the leads' experience with daily scheduling, and other factors that may affect day-to-day production.

4 Results

This section details the results of the data collection, the assumptions made in our discrete-event simulation (DES) model, and the results of the production schedule scenario analysis.

4.1 DES Model

The Opticap XL encapsulation process model consisted of two parts, the production process and the changeover process (Figure 9). We made the distinction in the model as filters are produced in single units and changeovers occur in batches of units. Appendix J: DES Model Structure contains a more detailed explanation of the structure of the model.
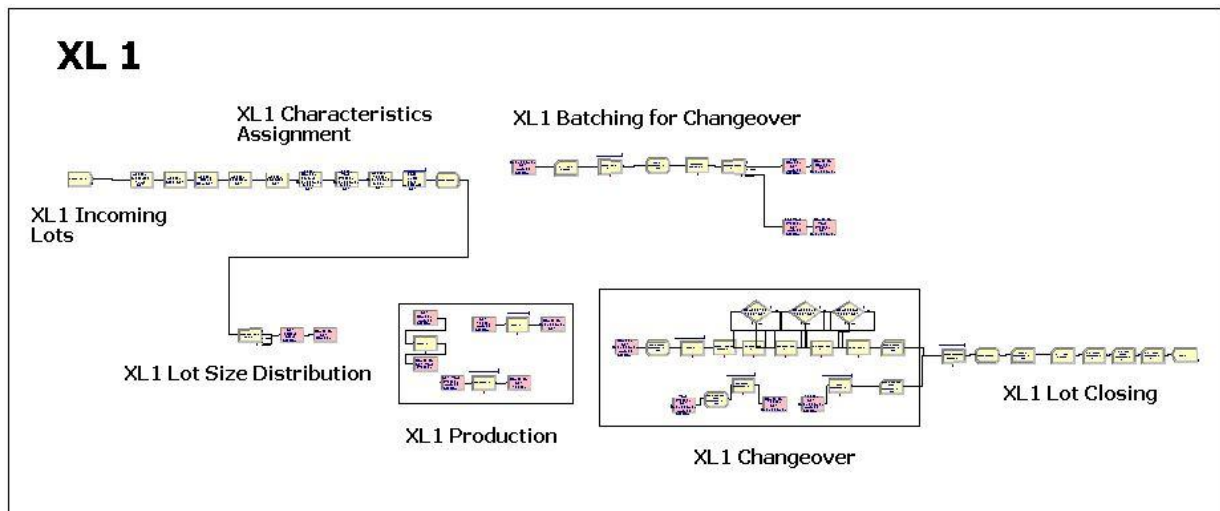
Figure 9 –Screenshot of the Opticap XL Encapsulation Process DES Arena Simulation Model

4.2 Input Data

Through data analysis and interviews we were able to collect the necessary information to build, validate, and run the discrete-event simulation (DES) model for the Opticap XL filter encapsulation process. This information includes production process times, changeover process times, and production schedules.

4.2.1 Production Process Times

As mentioned in Section 2.3, the production process times for the Opticap XL filter encapsulation process were obtained from the time study data that Industrial Engineer Bill Teeter gathered to build a capacity model in early 2012. From this data Mr. Teeter determined that for all lines bonder production times depend on the material type (gamma or non-gamma), tester production times depend on capsule size (2", 3", 4", 5" or 10") and vibe welder production times are independent of any product characteristic. Moreover, he determined that all lines have different processing times, so he had to collect data for each line separately. We used Arena's Input Analyzer to fit statistical distributions needed as parameters in the DES model. The distribution selected was based best fit (square error), or if the sample size was small (less than 6 data points) a triangular, uniform, or empirical distribution was selected.

Table 3, Table 4, and Table 5 summarize this information for each production line along with the number of data points (N) collected for each characteristic.

Table 3 - Production Process Times for XL1

XL 1				
Bonder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
Gamma	Triangular	TRIA(0.91,0.92,0.94)	0.06	4
Non-Gamma	Uniform	UNIF(1.01,1.17)	N/A	2
Vibe Welder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
N/A	Uniform	UNIF(0.28,0.35)	0.08	5
Tester Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
2"	Constant Value	0.79	N/A	1
3"	Constant Value	0.95	N/A	1
4"	Uniform	UNIF(0.88,0.88)	N/A	2
5"	Uniform	UNIF(0.99,1.00)	N/A	2
10"	Constant Value	1.15	N/A	1

Table 4 - Production Process Times for XL2

XL 2				
Bonder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
Gamma	Triangular	TRIA(1.22,1.23,1.28)	0.14	5
Non-Gamma	Uniform	UNIF(1.22,1.33)	0.05	4
Vibe Welder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
N/A	Triangular	TRIA(0.29,0.31,0.37)	0.01	9
Tester Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
2"	Uniform	UNIF(0.76,0.77)	N/A	2
3"	Uniform	UNIF(0.91,0.92)	N/A	2
4"	Uniform	UNIF(0.88,0.89)	N/A	2
5"	Constant Value	0.985	N/A	1
10"	Uniform	UNIF(1.15,1.15)	N/A	2

Table 5 - Production Process Times for XL4

XL 4				
Bonder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
Gamma	Empirical	DISC(0.33,1.00,0.66,1.01,1,1.04)		3
Non-Gamma	Triangular	TRIA(1.04,1.04,1.06)	0.09	3
Vibe Welder Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
N/A	Uniform	UNIF(0.24,0.31)	0.08	6
Tester Production Times (in minutes)				
Characteristic	**Distribution Type**	**Expression**	**Square Error**	**N**
2"	Uniform	UNIF(0.76,0.77)	N/A	2
3"	Constant Value	0.967	N/A	1
4"	Uniform	UNIF(0.92,0.93)	N/A	2
5"	Constant Value	1.078	N/A	1
10"	Uniform	UNIF(1.25,1.26)	N/A	2

4.2.2   Changeover Process Times

We used two data collection forms to complete the time studies on the changeover process.   The first form, the Operator's Data Collection Sheet (Appendix I: Data Collection Sheets), was distributed to all operators on the production floor. The purpose of this form was twofold. First it was used to gather information regarding product characteristics of the previous and upcoming lot. Second, the same form collected the frequency of the three melt tests and burst test performed during each changeover. We collected a total of 107 forms from the operators over a 5-week period. With this information we were able to determine if there was a relation between the product characteristics (capsule size, cap type, and material type – gamma or non-gamma) and the likelihood of repeating the three melt tests and burst test.

We were unable to determine if there is significant statistical relation between the number of times each of the tests had to be performed and the product characteristics of the previous and upcoming lot due to insufficient data. Nonetheless, the information gathered through these forms allowed us to determine the pass/fail probability for each of the tests (Appendix M: Results from Operator's Data Collection Sheet). These probabilities were used in the decision modules that are located after each test on the DES model and that determine if the test passed or failed. Table 6 summarizes this information.

Table 6 - Bonder Tests Repetition Probabilities

	Pass	Don't Pass
Cartridge Cap Melt Test	74.76	25.24
Housing Cap Melt Test	65.05	34.95
Cartridge Bond Sample	88.35	11.65

The second form, the Student's Data Collection Sheet (Appendix I: Data Collection Sheets), recorded the timing of the different steps of the changeover process. From the data gathered, we eliminated the outliers using statistical quartiles (Appendix N: Outlier Elimination Process) and used Arena's Input Analyzer to fit distributions for

the DES model. This information and the sample size (N) (excluding outliers) are summarized in Table 7.

Table 7 - Changeover Process Times Data Summary

Bonding Changeover Times (in minutes)				
Process	**Distribution Type**	**Expression**	**Square Error**	**N**
Bonder Fixtures	Uniform	UNIF(17.5, 38.5)	0.14	11
HMI	Triangular	TRIA(30.5, 37.5, 46.5)	0.08	7
Cartridge Cap Melt Test	Triangular	TRIA(54.5,66.7,83.5)	0.06	22
Housing Cap Melt Test	Triangular	TRIA(41,79.7,172)	0.01	30
Cartridge Bond Sample	Normal	NORM(77.8,21.7)	0.04	25
Burst Test	Triangular	TRIA(74,106,250)	0.05	20
Vibe Welder Changeover Times (in minutes)				
Process	**Distribution Type**	**Expression**	**Square Error**	**N**
One change	Triangular	TRIA(67.5,82.8,145)	0.15	4
Two changes	Triangular	TRIA(210,241,258)	0.16	5
Tester Changeover Times (in minutes)				
Process	**Distribution Type**	**Expression**	**Square Error**	**N**
One change	Triangular	TRIA(58,61.5,107)	0.03	18
Two changes	Triangular	TRIA(116,122,214)	0.042356	16

4.2.3 Production Schedules

We received ten days' worth of production schedules from Kristine Teto, A-shift Production Lead. These ten days are representative of a typical ten-day period throughout the year. These schedules included XL1, XL2, and XL4 filter encapsulation lines and go from November 22, 2013 to December 13, 2013, excluding weekends and Thanksgiving. Throughout the paper we refer to these schedules as "original schedules A, B and C" and they can be found in Appendix O: Original Schedules.

The original schedules served as a base of comparison for the different scenarios that we ran in order to determine the impact of dedicating lines to product characteristics.

4.3 DES Model Assumptions

Below is a list of the assumptions that had to be made to build the DES model.

- Characteristics of the "First Lot" are assumed to be:

  - Capsule Size: 10"
  - Cap Type: Hose Barb – Hose Barb
  - Material Type: Non Gamma

- The process of changing the fixtures in the bonder machine follows the same distribution for all changes in capsule size.

- If there is no change in capsule size, the process of changing the bonder fixtures is not performed. In reality, there is always some fixture changing due to the melt tests but the time it takes can be considered negligible.

- The times for the Production section of the simulation model were extracted from Bill Teeter's capacity model data.

- The transfer time is one second for each of the following transfers:

  - Lot creation to Production
  - Bonder to Vibe Welder
  - Vibe Welder to Tester
  - Tester to Batching for Changeover
  - Batching to Bonder Changeover
  - Batching to Vibe Welder Changeover
  - Vibe Welder Changeover to Tester Changeover

- The flow between the three machines in the Production section is continuous as we assign one resource/operator per machine. This doesn't happen in reality because there are a maximum of two operators per line. There are always machines idling or filters sitting in WIP waiting to be moved.

- The time accounted for paperwork during the changeover is assumed to be a constant value of 15 minutes. This is based on observations of the process. The reason why this value is constant rather than a statistical distribution is that we did not want this action, which is independent of lot characteristics, to create fluctuations in the total changeover time.

- The bonder changeover occurs in parallel with the vibe welder changeover and the tester changeover. Two operators are assigned to perform a changeover every time.

- The bonder changeover has a priority over the vibe welder and tester changeovers when seizing an operator because it's the longest changeover process.

- The vibe welder changeover and the tester changeover occur in sequence.

- The melt tests and burst test process times follow the same distribution for every changeover, regardless of the lots' characteristics.

- The failure or repeat rates (represented in percentage) for each of the three melt tests are constant for every changeover.

- The production schedules obtained from the A-shift Production Lead correspond to a time period of ten days. To create our versions of the schedules, we rearranged lots for that entire period of time, as if we had received the ten-day schedule all at once. In reality, the Production Lead only receives one or two day's worth of schedule at a time. Because the Production Lead has fewer possibilities to consider, he/she will be less likely to produce an optimal schedule.

4.4 Experimentation Set Up

4.4.1 Replications

Before running the model with the different scenarios it was important to determine the number of replications that would be used. Replications are the repetitions of an experimental condition so that the variability associated with the phenomenon can be estimated (Palaniswamy, 2005). This was calculated using the following formula (Kelton et al., 2010):

$$n \cong n_0 \frac{h_0^2}{h^2}$$

n_0 = initial number of replications

h_0 = half width from initial number (n_0) of replications

h = desired half width

For all lines, the number of replications (n_0) was set to 5 and the desired half width (h) was set to 0.20. Table 8 summarizes h_0 and n or each of the lines and the average number of replications. . For our DES model we used 17 replications. We decided to use the average of n because each line had a different n. Using one of this three values for n would have resulted on a higher or lower h for the other two lines; by using the average we make sure that h is as close to 0.20 as possible for all three lines. Additionally, we had to have the same number of replications for each line because all lines were in the same simulation model and the number of replications can only be set to the entire model; not to specific lines.

Table 8 - Replications

	h0	n
XL1	0.26	9
XL2	0.56	39
XL4	0.13	2
Average		17

4.5 Scenario Analysis

4.5.1 Performance Measures

Three performance metrics were used to determine how lines should be dedicated. These metrics were:

1. Average vibe welder and tester changeover time,
2. Average bonder changeover time,
3. Total average changeover time.

Appendix H: Time Study Guidelines states the beginning and ending points for each of the changeover processes. The total changeover time does not correspond to the sum of the average vibe welder, tester and bonder changeover times. This is because the vibe welder and tester changeover and the bonder changeover occur in parallel.

4.5.2 Scenario Sets

Three sets of scenarios were created, each corresponding to one analysis stage of the data analysis process. Each scenario set has three production lines, each being evaluated by the three performance metrics listed in Section 4.5.1. These sets are listed below, in chronological order of analysis. A more detailed explanation of how we built each scenario can be found in Section 4.5.3, Section 4.5.5 and Section 4.5.7 respectively.

- Ideal Scenarios Analysis Set
- Refined Ideal Scenario Analysis Set
- Improved Schedule Analysis Set

Analysis of each scenario set followed the same procedure. We first calculated the average reduction in time for the three performance metrics by comparing the results of the original schedules with the results of each scenario in each of the three production lines. Next, we looked at the scenarios with the largest sum of time reduction for each metric (each of the three lines in each scenario had one value for

reduction time). From this we developed a list with the best scenarios, which were the inputs for the subsequent set.

4.5.3   Ideal Scenarios Analysis Set

To better understand the impact of assigning production lines to specific product characteristics we classified three types of scenarios to be evaluated: dedication by capsule size (2" and 4", 3" and 5", and 10"), cap type (T, H, N, F, in several combinations), and material type (gamma and non-gamma). From the original schedules, we modified one characteristic at a time to develop what we termed an "ideal" line assignment scenario. Through the rest of this report, we will refer to these scenarios as "Ideal Scenarios". These ideal scenarios were used to study the impact of assigning lines by a specific characteristic. It allowed us to compare each of the scenarios to the original schedule on the basis of a single characteristic. These scenarios were created using the following steps. The figures demonstrate each step using a sample schedule A.

1) Triplicate original Schedule A to correspond to a schedule for each production line. Column B refers to Material Type, Column C to Size, and Columns D and E to Cap Type.

	A	B	C	D	E	F	G
1	KR25	A	10 H	H	1	5
2	KGW6	A	10 H	T	1	36
3	KGEP	A	3 T	T	3	135
4	KVGL	A	2 F	F	1	300
5						

Sample A +

Figure 10 - Sample of Original Schedule A

	A	B	C	D	E	F	G
1	KR25	A	10 H	H	1	5
2	KGW6	A	10 H	T	1	36
3	KGEP	A	3 T	T	3	135
4	KVGL	A	2 F	F	1	300
5						

Sample A   Sample A (2)   Sample A (3)   +

Figure 11 - Triplicate Sample A

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a. For the first copy, modify only capsule size to be 50% 2" and 50% 4"

	A	B	C		D	E	F	G
1	KR25	A	2	H	H		1	5
2	KGW6	A	2	H	T		1	36
3	KGEP	A	4	T	T		3	135
4	KVGL	A	4	F	F		1	300
5								

Sample A | Sample A (2) | Sample A (3) | +

Figure 12 – First ideal scenario schedule with line dedication by capsule size 2" and 4"

b. For the second copy, modify only capsule size to be 50% 3" and 50% 5"

	A	B	C		D	E	F	G
1	KR25	A	3	H	H		1	5
2	KGW6	A	3	H	T		1	36
3	KGEP	A	5	T	T		3	135
4	KVGL	A	5	F	F		1	300
5								

Sample A | Sample A (2) | Sample A (3) | +

Figure 13 - First ideal scenario schedule with line dedication by capsule size 3" and 5"

c. For the third copy, modify only capsule size to be all 10"

	A	B	C		D	E	F	G
1	KR25	A	10	H	H		1	5
2	KGW6	A	10	H	T		1	36
3	KGEP	A	10	T	T		3	135
4	KVGL	A	10	F	F		1	300
5								

Sample A | Sample A (2) | Sample A (3) | +

Figure 14 – First ideal scenario schedule with line dedication by capsule size size 10"

2) Triplicate Schedule A again (Figure 11)

a. For the first line schedule, modify only material type to be non-gamma

	A	B	C		D	E	F	G
1	KR25	A	10	H	H		1	5
2	KGW6	A	10	H	T		1	36
3	KGEP	A	3	T	T		3	135
4	KVGL	A	2	F	F		1	300
5								

Sample A | Sample A (2) | Sample A (3) | +

Figure 15 - Second ideal scenario schedule with line dedication by material non-gamma

b. For the second line schedule, modify only material type to be non-gamma

	A	B	C	D	E	F	G
1	KR25	A	10 H	H		1	5
2	KGW6	A	10 H	T		1	36
3	KGEP	A	3 T	T		3	135
4	KVGL	A	2 F	F		1	300
5							

Sample A | Sample A (2) | Sample A (3) | +

Figure 16 - Second ideal scenario schedule with line dedication by material, non-gamma

c. For the third copy, modify only material type to be gamma

	A	B	C	D	E	F	G
1	KR25	G	10 H	H		1	5
2	KGW6	G	10 H	T		1	36
3	KGEP	G	3 T	T		3	135
4	KVGL	G	2 F	F		1	300
5							

Sample A | Sample A (2) | Sample A (3) | +

Figure 17 - Second ideal scenario schedule with line dedication by material, gamma

There are two schedules for non-gamma and one for gamma because there was a significant larger amount of non-gammas in the original schedules.

3) Triplicate Schedule A again (Figure 11)

a. For the first copy, modify only capsule type to be all HH

	A	B	C	D	E	F	G
1	KR25	A	10 H	H		1	5
2	KGW6	A	10 H	H		1	36
3	KGEP	A	3 H	H		3	135
4	KVGL	A	2 H	H		1	300
5							

Sample A | Sample A (2) | Sample A (3) | +

Figure 18 - Third ideal scenario schedule with line dedication by capsule type HH

b. For the second copy, modify only capsule type to be all TT

38

	A	B	C	D	E	F	G
1	KR25	A	10 T	T		1	5
2	KGW6	A	10 T	T		1	36
3	KGEP	A	3 T	T		3	135
4	KVGL	A	2 T	T		1	300
5							

Sample A | Sample A (2) | Sample A (3) | +

Figure 19 - Third ideal scenario schedule with line dedication by capsule type TT

c. For the third copy, modify only capsule type to be 33.3% TH, 33.3% FH, and 33.3% FF

	A	B	C	D	E	F	G
1	KR25	A	10 T	H		1	5
2	KGW6	A	10 T	H		1	36
3	KGEP	A	3 F	H		3	135
4	KVGL	A	2 F	F		1	300
5							

Sample A | Sample A (2) | Sample A (3) | +

Figure 20 -Third ideal scenario schedules with line dedication by capsule type TH, FH, FF

4) Repeat steps 1-3 for original Schedules B and C for a total of 9 schedules and 15 ideal scenarios.

Additionally, we needed to analyze how the differences in machine efficiency between XL1, XL2 and XL4 impacted line assignment. To accomplish this, we tested 15 possible combinations of the ideal scenarios within the lines. Table 9 is a summary of all the ideal scenarios that were tested.

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Table 9 - Ideal Scenarios

Scenario #	Dedication type	Schedule A			Schedule B			Schedule C		
		XL1	XL2	XL4	XL1	XL2	XL4	XL1	XL2	XL4
	Original	Original XL1	Original XL1	Original XL1	Original XL2	Original XL2	Original XL2	Original XL4	Original XL4	Original XL4
1	*Size*	2,4	3,5	10	2,4	3,5	10	2,4	3,5	10
2	*Size*	3,5	2,4	10	3,5	2,4	10	3,5	2,4	10
3	*Size*	10	2,4	3,5	10	2,4	3,5	10	2,4	3,5
4	*Size*	10	3,5	2,4	10	3,5	2,4	10	3,5	2,4
5	*Size*	2,4	10	3,5	2,4	10	3,5	2,4	10	3,5
6	*Size*	3,5	10	2,4	3,5	10	2,4	3,5	10	2,4
7	*Material*	Gamma	Non-Gamma	Non-Gamma	Gamma	Non-Gamma	Non-Gamma	Gamma	Non-Gamma	Non-Gamma
8	*Material*	Non-Gamma	Gamma	Non-Gamma	Non-Gamma	Gamma	Non-Gamma	Non-Gamma	Gamma	Non-Gamma
9	*Material*	Non-Gamma	Non-Gamma	Gamma	Non-Gamma	Non-Gamma	Gamma	Non-Gamma	Non-Gamma	Gamma
10	*Cap Type*	hh	tt	ff,fh,th	hh	tt	ff,fh,th	hh	tt	ff,fh,th
11	*Cap Type*	tt	hh	ff,fh,th	tt	hh	ff,fh,th	tt	hh	ff,fh,th
12	*Cap Type*	tt	ff,fh,th	hh	tt	ff,fh,th	hh	tt	ff,fh,th	hh
13	*Cap Type*	hh	ff,fh,th	tt	hh	ff,fh,th	tt	hh	ff,fh,th	tt
14	*Cap Type*	ff,fh,th	hh	tt	ff,fh,th	hh	tt	ff,fh,th	hh	tt
15	*Cap Type*	ff,fh,th	tt	hh	ff,fh,th	tt	hh	ff,fh,th	tt	hh

4.5.4 Ideal Scenarios Results and Analysis

The analysis was performed following the procedure described in Section 4.5.1. The data summary tables used to collect and analyze the data can be found in Appendix P: Ideal and Refined Ideal Scenarios Results. Noticeably better results were obtained across all three metrics if production lines were dedicated by size and cap type compared to material type. Further comparing size and cap type dedication, production lines dedicated by size had a lower average bonder changeover time and total average changeover time. The following scenarios produced the overall best metrics and will be used for the next set of scenarios, the refined ideal scenarios.

Table 10 - Chosen Ideal Scenarios

Scenario #	Dedication type	XL1	XL2	XL4
1	*Size*	2,4	3,5	10
2	*Size*	3,5	2,4	10
3	*Size*	10	2,4	3,5
5	*Size*	2,4	10	3,5
11	*Cap Type*	tt	hh	ff,fh,th
13	*Cap Type*	hh	ff,fh,th	tt
14	*Cap Type*	ff,fh,th	hh	tt
15	*Cap Type*	ff,fh,th	tt	hh

4.5.5 Refined Ideal Scenarios Analysis Set

Once the best ideal scenarios were selected, we noted that they did not consider the possibility of reorganizing the order of the lots within the line assignments. For example, after assigning a scenario to be only 2" and 4" capsules, it is still possible to organize a schedule so as to minimize cap type changeovers. Therefore, we developed a new set of scenarios on the basis of the "ideal scenarios". For the scenarios assigned by size, we then sorted the lots by cap type and finally by material type. For the ones assigned by cap type, we further sorted by size and then material type. Figure 21 and Figure 22 are an example of the latter. In Figure 21 a changeover is required on the bonder and vibe welder machines to accommodate the change in size between lot KR25 and KGEP. This change is again required from KGEP to KGW6. By organizing production by size as shown in Figure 22, we hypothesized that the time on the tester machine would be reduced, as this step would be eliminated. Throughout the rest of this report, we call these reorganized ideal schedules "refined ideal scenarios". Table 10 is a summary of all the refined ideal scenarios that were tested.

	A	B	C	D	E	F	G
1	KR25	A	10	H	H	1	5
2	KGEP	A	3	H	H	3	135
3	KGW6	A	10	H	H	1	36
4	KVGL	A	2	H	H	1	300

Figure 21 - Before sorting by size

	A	B	C	D	E	F	G
1	KR25	A	10	H	H	1	5
2	KGW6	A	10	H	H	1	36
3	KGEP	A	3	H	H	3	135
4	KVGL	A	2	H	H	1	300

Figure 22 - After sorting by size

4.5.6 Refined Ideal Scenarios Results and Analysis

The process described in Section 4.5.1 was also followed to analyze the refined ideal scenarios. The summary tables used to collect and analyze the data can be found in Appendix P: Ideal and Refined Ideal Scenarios Results. Dedication by size was found to have lower vibe welder and tester changeovers time compared to dedication by

cap type. The bonder changeover time and total changeover time did not show a difference across the two dedication options. The following scenarios in Table 11 produced the best metrics and will be used for the next set of scenarios, the improved schedules.

Table 11 - Refined Ideal Scenarios selected for further analysis

Scenario #	Dedication type	XL1	XL2	XL4
2	*Size*	3,5	2,4	10
3	*Size*	10	2,4	3,5
14	*Cap Type*	ff,fh,th	hh	tt
15	*Cap Type*	ff,fh,th	tt	hh

4.5.7   Improved Schedules

In Section 4.5.6, we determined the scenarios that have the greatest impact on changeover time. However, it was still important to validate our results in a more realistic setting, where it's not possible to modify the lots from the original schedules. To accomplish this, we returned to the original schedules and instead of modifying product characteristics, we reorganized the existing lots. We used the following steps to achieve these new scenarios:

1) Combine original Schedules A, B and C

	A	B	C	D	E	F	G
1	KR25	A	10 H	H	1	5
2	KGW6	A	10 H	T	1	36
3	KGEP	A	3 F	H	3	135
4	KVGL	G	2 F	F	1	300
5	KVVL	A	10 H	H	1	75
6	KVGL	G	10 T	H	1	150
7	KTGR	G	5 H	H	1	5
8	KVGL	A	5 H	H	1	300
9	KPHL	A	2 F	F	3	15
10	KVVL	G	4 T	T	3	18
11	KVGB	A	4 T	T	3	600
12	KVGL	A	4 T	T	3	600

Sample All +

Figure 23 - Sample "All Originals" schedule

2) Triplicate the "all originals" spreadsheet

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	A	B	C	D	E	F	G
1	KR25	A	10 H	H		1	5
2	KGW6	A	10 H	T		1	36
3	KGEP	A	3 F	H		3	135
4	KVGL	G	2 F	F		1	300
5	KVVL	A	10 H	H		1	75
6	KVGL	G	10 T	H		1	150
7	KTGR	G	5 H	H		1	5
8	KVGL	A	5 H	H		1	300
9	KPHL	A	2 F	F		3	15
10	KVVL	G	4 T	T		3	18
11	KVGB	A	4 T	T		3	600
12	KVGL	A	4 T	T		3	600

Sample All | Sample All (2) | Sample All (3) | +

Figure 24 - Triplicate Sample All

3) Filter each of the copies so that the first copy is composed of only the chosen characteristic (i.e.: only 2" and 4", or only HH)

	A	B	C	D	E	F	G
1							
5	KVGL	G	2 F	F		1	300
10	KVVL	G	4 T	T		3	18
11	KVGB	A	4 T	T		3	600
12	KVGL	A	4 T	T		3	600
14	KPHL	A	2 F	F		3	15

Figure 25 - Example of filtering by only 2 and 4's

4) Sort each copy by the remaining characteristics (same as performed in the refined ideal scenarios)

	A	B	C	D	E	F	G
1							
5	KVGL	G	2 F	F		1	300
10	KVVL	G	4 T	T		3	18
11	KVGB	A	4 T	T		3	600
12	KVGL	A	4 T	T		3	600
14	KPHL	A	2 F	F		3	15

Figure 26 - Filtered by 2 and 4's before sorting

	A	B	C	D	E	F	G
1							
5	KVGL	G	2 F	F		1	300
10	KPHL	A	2 F	F		3	15
11	KVVL	G	4 T	T		3	18
12	KVGB	A	4 T	T		3	600
13	KVGL	A	4 T	T		3	600

Figure 27 - Filtered by 2 and 4's after sorting

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5) Balance the new scenarios so that each line would take approximately the same amount of time, minimizing the amount of changeovers as much as possible.

4.5.8 Improved Schedules Analysis

The procedure detailed in Section 4.5.1 was used for this analysis as well. We first run the scenarios without balancing lines. We knew this was not realistic because of the different demand volumes of each type of filter. However, we were still interested in evaluating the case with a level demand for all capsule sizes or all cap types, in the event this could happen in the future. The results from these scenarios showed that dedicating by size was clearly better than dedicating by cap type in all three metrics. A set of bar graphs illustrating this conclusion can be found in Figure 28 below. Detailed results can be found in Appendix Q: Improved Scenarios Results. After this first analysis, we proceeded to balance the lines so that total production time would be similar across all three lines. This time the results didn't show noticeable better results in any of the two dedication options. A different set of bar graphs portraying these results can be found in Figure 29 below. These results can be found in Table 28 in Appendix Q: Improved Scenarios Results.
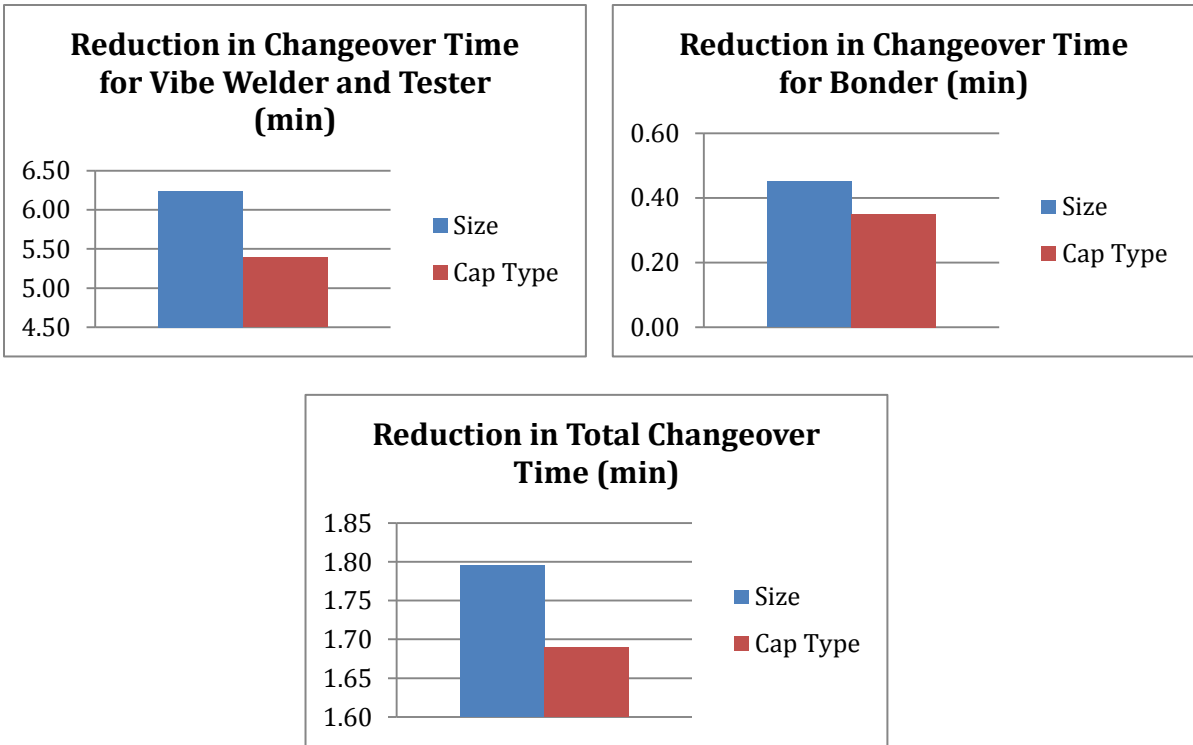
Figure 28 - Improved Schedules Results in minutes – Average across 17 replications
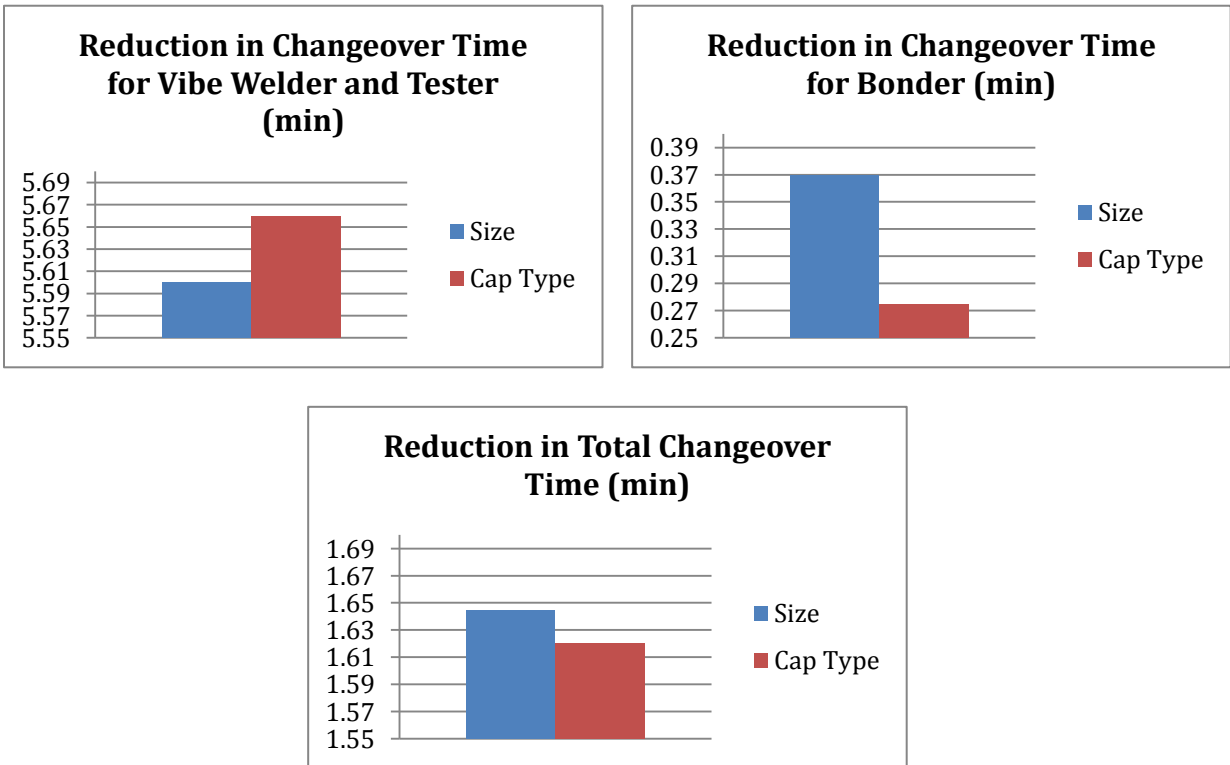
Figure 29 - Improved Balanced Schedule Results in minutes - Average across 17 replications

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4.6 Discussion

We discussed the results of our approach with Tim Allen, the Manufacturing Manager in charge of the Opticap XL encapsulation process. The scheduled implementation of new machines called "plug bonders" (as explained in Section 2.3) will soon happen in XL1 and XL2. This would make size dedication a more suitable option given that 10" filters can only be processed in these lines. We decided to try two more size dedication scenarios, Scenario # 4 and Scenario # 6, to account for the new conditions and limitations imposed by this implementation. These two scenarios were selected because they assign 10" filters to either XL1 or XL2. The results of these two scenarios were very similar to the results of the other two size dedication scenarios, especially when considering confidence intervals (Section 4.4.1). Table 12 includes a list and description of all the six scenarios we ran in this set. Table 29 in Appendix Q: Improved Scenarios Results contains the results obtained from running these scenarios.

Table 12 - Improved Schedule Scenarios

	XL1	XL2	XL4
Scenario # 2	3,5	2,4	10
Scenario # 3	10	2,4	3,5
Scenario # 4	10	3,5	2,4
Scenario # 6	3,5	10	2,4
Scenario # 14	fth	hh	tt
Scenario # 15	fth	tt	hh

Based on the analysis performed and the existing limitations in the Opticap XL encapsulation lines we determined that utilizing Scenario # 6 would provide the best results for EMD Millipore. We selected this scenario because it has the highest reduction in average vibe welder and tester changeovers time, as well as the second highest reduction in total average changeover time. Scenario # 4 has the highest reduction in total average changeover time; however, the difference in this reduction between the two scenarios is only 0.04 minutes, which is not a significant value. Figure 30 illustrates this conclusion.

Reduction in Changeover Time for Vibe Welder and Tester (min)

Reduction in Changeover Time for Bonder (min)

Reduction in Total Changeover Time (min)
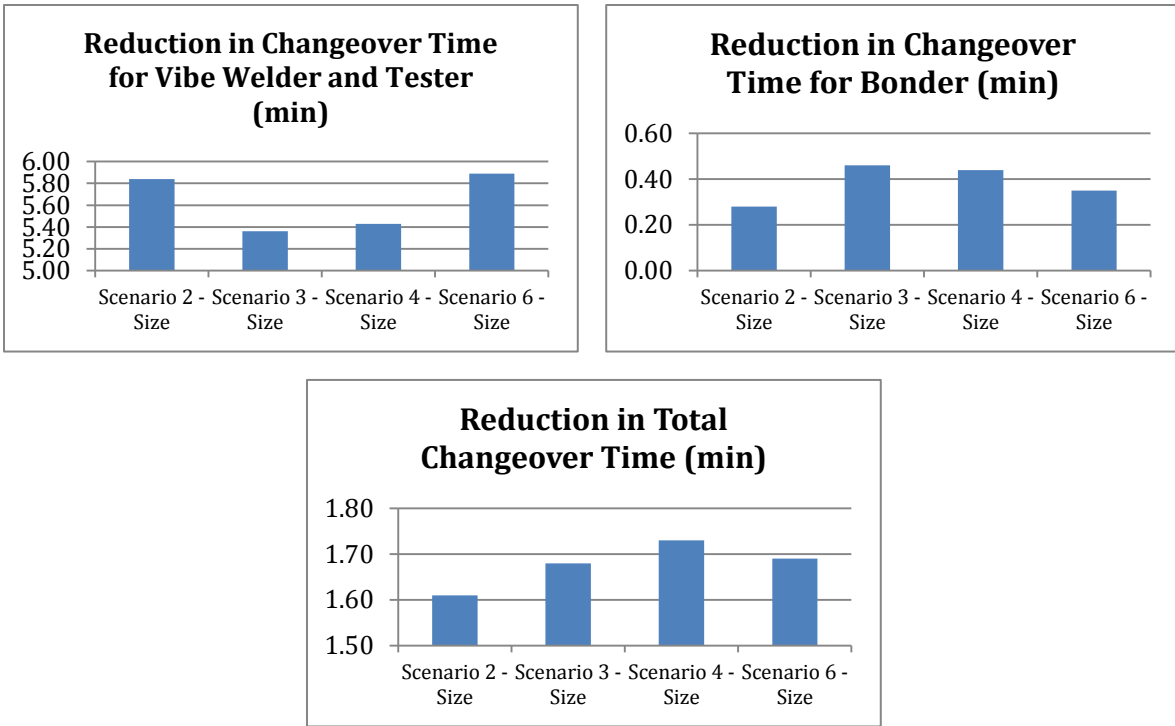
Figure 30 - Improved Schedules by Size Dedication Results in minutes - Average across 17 replications

5 Conclusion

5.1 Limitations of the study

A simulation model is a representation of the process being studied. When developing this model of the Opticap XL Encapsulation lines at EMD Millipore, we strived to make it as accurate as possible. However, we acknowledge that there are limitations to this study.

A significant limitation was that the model did not account for the likely differences in the three shifts. Because of time limitations, our data collection was biased towards Shift A. We learned from operators, production employees, and engineers at the Opticap XL Encapsulation lines that each shift has its own rhythm and, therefore, particular production standards. However, we were only able to observe A shift and occasionally B shift during this study. As a result even though this model is simulates 24-hour production, it only uses data from the shifts we were able to observe.

The biggest limitation we faced was insufficient data for the model. Throughout the study we collected as much data as possible by conducting time studies of changeovers and distributing data collection sheets to the operators at the Opticap XL Encapsulation lines. However, due to the low frequency and nature of changeovers in this process, we were unable to collect the appropriate amount of data for adequate statistical analysis for some parts of the model. While we believe that we were still able to achieve the desired results, collection of additional data in the future by other teams at EMD Millipore could result in a more accurate model. Given that our conclusions and recommendations were a direct product of the outputs of the model, we can only assure that these are as accurate as the model itself. The insufficiency of data points imposed an additional limitation. Having few data points may have resulted in the distributions used for process times not being an accurate representation of the real process times. As a result of this, some results for time reduction were very close to each other. Considering that the confidence interval for these results ranged between 0.10 and 0.17 minutes, some of these

results may not have been statistically significantly better than others. This posed a challenge for the analysis and comparison of different scenarios. For future uses of the model, we recommend obtaining tighter confidence intervals, which can be achieved by having more data points and increasing the number of replications in the model.

5.2 Recommendations

Based on our study of the changeovers of the Opticap XL encapsulation process we were able to develop a set of recommendations regarding future use of our model and the best practice guidelines.

DES Model

The final version of the DES model of the Opticap XL encapsulation lines corresponds to the process of production and changeover during the time of our study. This model was tested and verified to be an accurate representation of the actual system. Therefore, we recommend that EMD Millipore use this model for further studies of the Opticap XL encapsulation lines. We provided EMD Millipore with a set of guidelines on how to run the current version of the model (Appendix L: How to run the DES Model). We also provided a guide to how the model works, so that they can make modifications as deem necessary (Appendix J: DES Model Structure).

There are two specific recommendations that we suggest EMD Millipore should focus for future uses of the model. First, as mentioned in Section 5.1, we were unable to collect enough data to guarantee accuracy of the model. Further collection of data on both production and changeover processes could significantly improve the outputs of the model and its resulting recommendations. Second, as operational changes in the Opticap XL encapsulation lines occur, the model needs to be updated. For example, as mentioned in Section 2.3, when the Plug Bonders are added to the lines they should be also included in the model. This might involve not only

collecting new data on the performance of the plug bonders, but also measuring if and how the performance of the other machines in those lines is affected.

Best Practice Guidelines

We believe that we were able to gain a significant amount of knowledge of the Opticap XL encapsulation lines throughout the duration of the study. We used this knowledge combined with the output from the DES model to develop a set of best practice guidelines that could potentially be of use to production leads. With these guidelines, any production lead should be able to organize the daily production schedule. In doing so the creation of production schedules moves towards a standardized process. By having a guideline for production schedule creation, which can be used by multiple individuals, EMD reduces the risk of inefficient scheduling should the production lead by absent. In the future, we suggest that the production leads responsible for scheduling keep these guidelines updated according to changes in production. They can also make suggestions for future production leads, and changes according to their own experiences.

6 Project Reflection

6.1 Engineering Design Process

The engineering design process is the set of steps that must be taken to go from identifying a problem to creating and developing a solution. These steps include recognizing the problem, identifying constraints, creating the solution, testing and then evaluating the results. This section contains a reflection on how our team used the engineering design process to find a way to improve the output and workflow of the Opticap XL filter encapsulation process at EMD Millipore.

During the first phase of the project, the team closely observed the filter encapsulation process to identify opportunities for improvement. After several Gemba walks and interviews with key stakeholders we narrowed our problem statement to reducing the number and length of the changeover process to improve output and capacity at the Opticap XL filter encapsulation process.

In the process of developing a solution, we evaluated several approaches such as optimization with linear programing and discrete simulation modeling. We decided to build a discrete event simulation model because of the ease and cost efficiency of analyzing several production scheduling approaches without performing changes on the floor. More specifically, we conducted scenario analysis to determine the impact of dedicating production lines by product characteristics. To build such a model we had to continue to observe the process, conduct time studies of the various changeover steps, and define the logic of the model. Then we proceeded to validate and verify the model. This helped us ensure that the model was working as expected and that it matched EMD Millipore's filter encapsulation process operations.

The final step in our project and the design process was to run the model with a variety of production schedule scenarios to determine the best option for line dedication. Considering the constraints of the process mentioned in Section 2.3, we

recommended dedicating lines according to capsule size. Specifically we recommended assigning 3" and 5" filters to XL1, 10" filters to XL2, and 2" and 4" filters to XL4.

6.2 Overall Project Experience

The team spent a total of 21 weeks working toward the successful completion of this report. However, our learning experience goes far beyond the contents of this paper. During this period, while working towards a solution to the problem presented, we had the opportunity to closely observe and measure the manufacturing process, interact with line operators, and discuss with key stakeholders. All of this was possible thanks to the support from our sponsor, EMD Millipore.

One of the main takeaways obtained from this project was the interaction we had with the various levels of management in the organization. We learned that different communication approaches should be taken with the various stakeholders in order to be effective. We had the opportunity to spend a considerable amount of time with operators on the production floor, understanding how they complete the process and listening to their concerns. Here, we learned it was important to listen to them and gain their confidence. We also had the chance to ask many questions to the production lead, allowing us to understand how the schedules were set up. We quickly understood that they are very busy and have very limited time so we worked on being direct with our questions and requests. Finally, we held meetings with the manufacturing manager in which the primary focus was the discussion of our progress and the planning of the results implementation phase. Here, it was important to clearly communicate our goals while we realize that the manager was less concerned about the details of how we were planning on reaching the goal.

Another important takeaway was the understanding that projects and the implementation of results usually do not go as planned, especially in a manufacturing environment where elements are constantly varying and issues tend to arise at any time. We came across various constraints that had to be considered when proposing a solution. These did not appear all at once, but were rather

discovered as we increased our familiarity with the process. Eventually, we reached a point when we had to reconsider our strategy and revise our goals. Ultimately, the discussion of ideas and solutions to the changes in our project plan were extremely valuable to our learning.

Overall we had a well-rounded project experience. Throughout the duration of our project we had the opportunity to conduct background research, visit the production floor, conduct time studies, build a simulation model and examine different solutions to the problem presented. These experiences were extremely valuable and complement the "theory and practice" learning experience we have had at WPI.

References

Abdulmalek, F. A., & Rajgopal, J. (2007). Analyzing the benefits of lean manufacturing and value stream mapping via simulation: a process sector case study. *International Journal of production economics, 107*(1), 223-236.

Balachandran, A., Rabuya, L., Shinde, S., & Takalkar, A. (2000). Basic Steps and Decisions for Simulation - Simulation and Modeling Team.   Retrieved 12/01/13, from http://www.uh.edu/~lcr3600/simulation/steps.html

Banks, J., Carson, J., Nelson, B., & Nicol, D. (2001). *Discrete-Event System Simulation*. Englewood Cliffs, NJ: Prentice Hall.

Detty, R. B., & Yingling, J. C. (2000). Quantifying benefits of conversion to lean manufacturing with discrete event simulation: a case study. *International Journal of Production Research, 38*(2), 429-445.

EMD Millipore. Opticap XL Disposable Capsule Filters with 0.22 μm Hydrophobic Durapore Membrane.   Retrieved 02/09/2014, from http://www.millipore.com/catalogue/module/c527

EMD Millipore. (2013a). EMD Millipore, Jaffrey: Our Facility.   Retrieved 10/06/2013, from http://www.emdmillipore.com/our-facility/c_O8msHfETudYAAAE1rFs6Pc3n?back=true

EMD Millipore. (2013b). EMD Millipore: Divisional Profile.   Retrieved 09/24/13, from http://www.emdmillipore.com/divisional-profile/c_MAKsHfETiycAAAE1nqU2Vc2d

EMD Millipore. (2013c). EMD Millipore: Our History.   Retrieved 10/10/13

EMD Millipore. (2013d). Locations.   Retrieved 10/06/2013, from http://www.emdmillipore.com/locations/c_xxmsHfET4OYAAAE1I5YsFu9z

EMD Millipore. (2013e). We are now EMD Millipore.   Retrieved 09/24/13, from http://www.emdmillipore.com/all-products/c_haisHfETjoAAAAE1gaU2Vc2d

Gifford, J. (2013). Jaffrey Site Overview: EMD Millipore.

Harrell, C., Ghosh, B., & Bowden, R. (2004). *Simulation Using ProModel* (2nd ed.): McGraw-Hill.

Holpp, L. (2010). Preparing to Measure Process Work with a Time Study. from http://www.isixsigma.com/methodology/business-process-management-bpm/preparing-measure-process-work-time-study/

International Organization for Standardization. (2014). About ISO - ISO.   Retrieved 03-02-2014, from http://www.iso.org/iso/home/about.htm

Kelton, D., Sadowski, R., & Swets, N. (2010). *Simulation with Arena* (5th ed.). New York: McGraw-Hill.

Kimmel, P. (2007). Financial Accounting: Tools for Business Decision Making 4E with Peachtree Workbook CD and Wiley Plu s Set Tools for Business Decision Making WITH Peachtree Workbook CD-ROM.

Koch Membrane Systems. (2014). About Ultrafiltration Membranes - Koch Membrane Systems. from http://www.kochmembrane.com/Learning-Center/Technologies/What-is-Ultrafiltration.aspx

Law, A. M. (2008). *How to build valid and credible simulation models.* Paper presented at the Proceedings of the 40th Conference on Winter Simulation.

Meng, X. (1998). Simulation CSCI 6337 - Advantages and Disadvantages.   Retrieved 12-01-13, from http://www.eg.bucknell.edu/~xmeng/Course/CS6337/Note/master/node3.html

Mileham, A., Culley, S., Owen, G., & McIntosh, R. (1999). Rapid changeover–a pre-requisite for responsive manufacture. *International Journal of Operations & Production Management, 19*(8), 785-796.

Mitton, L., Sutherland, H., & Weeks, M. (2000). *Microsimulation modelling for policy analysis: challenges and innovations*: Cambridge University Press.

Palaniswamy, U. (2005). *Handbook of statistics for teaching and research in plant and crop science*: CRC Press.

Railsback, S. F., & Grimm, V. (2011). *Agent-based and individual-based modeling: a practical introduction*: Princeton University Press.

Rockwell Automation. (2013). Arena Simulation Software - Solutions.   Retrieved 12/03/2013, from http://www.arenasimulation.com/Solutions_Solutions.aspx

Rowell, D., & Wormley, D. N. (1997). *System dynamics: an introduction*: Prentice Hall Upper Saddle River, NJ.

Silva, L., Ramos, A. L., & Vilarinho, P. M. (2000). *Using simulation for manufacturing process reengineering-a practical case study.* Paper presented at the Simulation Conference, 2000. Proceedings. Winter.

Singh, B. J., & Khanduja, D. (2009). SMED: for quick changeovers in foundry SMEs. *International Journal of Productivity and Performance Management, 59*(1), 98-116.

U.S. Food and Drug Administration. (2014). FDA Basics - FDA Fundamentals. Retrieved 03-02-2014, from http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm

United States Environmental Protection Agency. (2014). Guidance for Preparing Standard Operating Procedures.   Retrieved 03-02-2014, from http://www.epa.gov/QUALITY/qs-docs/g6-final.pdf

Voorhorst, F., Avai, A., & Boër, C. (2012). Optimizing a Highly Flexible Shoe Production Plant using Simulation. In S. Bangsow (Ed.), *Use Cases of Discrete Event Simulation* (pp. 131-145): Springer-Verlag Berlin Heidelberg.

Wilson, J. R., & Corlett, N. (2010). *Evaluation of human work*: CRC Press.

Zuluaga, D., & Ruiz, C. (2012). Production Planning and Resource Scheduling of a Brewery with Plant Simulation. In S. Bangsow (Ed.), *Use Cases of Discrete Event Simulation* (pp. 321-330): Springer-Verlag Berlin Heidelberg.

Appendices

Appendix A: List of Acronyms

- **DES**: *discrete-event simulation*. Refers to a type of simulation in which the state of the system changes at discrete points in time (Kelton et al., 2010).

- **FDA**: *Food and Drug Administration*. It is an agency within the U.S. Department of Health and Human Services that is mainly responsible for "protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices" (U.S. Food and Drug Administration, 2014).

- **ISO**: *International Organization for Standardization*. ISO is the world's largest developer of voluntary International Standards, which give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective (International Organization for Standardization, 2014).

- **NFF filters**: *normal-flow filtration filters*. Refers to a type of filter that retains the unwanted particles and let the fluid pass (Gifford, 2013).

- **TFF filters**: *tangential-flow filtration filters*. Refers to a type of filter that retains the desired fluid, letting the contaminating particles pass (Gifford, 2013).

- **UF**: Ultrafiltration. UF is "a pressure-driven process that removes emulsified oils, metal hydroxides, colloids, emulsions, dispersed material, suspended solids, and other large molecular weight materials from water and other solutions" (Koch Membrane Systems, 2014).

- **SOP**: standard operating procedure. Refers to "a set of written instructions that document a routine or repetitive activity followed by an organization" (United States Environmental Protection Agency, 2014).

- **WIP**: *work in progress/process.* Refers to "the portion of manufactured inventory that has begun the production process but is not yet complete" (Kimmel, 2007).

- **T**: *tri-clover*. Refers to a cap type for Opticap XL filter capsules.

- **H**: *hose barb*. Refers to a cap type for Opticap XL filter capsules.

- **N**: *NPT*. Refers to a cap type for Opticap XL filter capsules.
- **F**: *fractional*. Refers to a cap type for Opticap XL filter capsules.
- **HMI**: *human machine interface.*

Appendix B: Machine Setup Procedures

Machine: Bonder and Cooler

1. Upper Nest Setup
    a. 3", 5", 10" – No inserts used. Remove inserts if installed for previous lot using thumbscrew and HMI controls.
    b. 2", 4" – Install right and left inserts using thumbscrew and HMI controls.
2. Lower Nest Setup
    a. Install spacers according to cartridge size.
3. Program Setup (HMI)
    a. Select the "Product Recipe" (Gamma or Non-Gamma and size of

Machine: Vibration Welder

1. Select proper fixtures (top plate and bottom nest) according to capsule size
2. If necessary, remove existing fixtures
3. Set/Check torque wrench is at 60 in/lbs.
4. Install bottom nest with hex head torque tool. If fixtures do not need to be changed, tighten existing fixtures using the tool
5. Install top plate using same tool as bottom nest

Machine: Housing Integrity Tester

1. Select proper program on machine according to capsule and cartridge size
2. Outfit leak tester with fastest seals and nests according to inlet and outlet type
    a. Verify the inlet and outlet type on unit
    b. Disconnect quick disconnects mounted on back wall of test cabinet
    c. If necessary to change fastest fittings, unscrew thumbscrews of fastest desired size
    d. Attach color-coded quick disconnects
    e. If necessary to change nests, remove and replace nests with desired size

Test: "Melt Test"

Description: The temperature required by the Bonding Machine changes depending on the lot's characteristics. This test is to adjust the temperature to be within tolerance for the upcoming batch.

1. Cartridge Cap Melt Sample:
   a. Load the melt depth gauge into the top fixture
   b. Place a sample cap (available with each incoming batch) into the cap holder fixture in the lower machine fixture
   c. Run the machine
   d. Check melt depth of run on HMI against tolerance found on the set up sheet of the batch record
   e. Adjust temperature if necessary and retest until melt depth is within tolerance
   f. Record melt depth on the set up sheet of the batch record
2. Housing End Melt Cap Sample:
   a. Load melt depth gauge into the lower fixture
   b. Place housing endcap into the upper fixture
   c. Run the machine
   d. Check melt depth of run on HMI against tolerance found on the set up sheet of the batch record
   e. Adjust temperature if necessary and retest until melt depth is within tolerance
   f. Record melt depth on the set up sheet of the batch record
3. Construct bond sample for Cartridge Bond Integrity test:
   a. Place an open end cartridge cap into the cap holder fixture
   b. Place the cap holder fixture in the lower nest
   c. Place a housing endcap from the current lot in the upper nest
   d. Run test
   e. If bond is considered a "good bond" (will be displayed in HMI) and is within tolerance, perform next test
4. If bond is not considered a "good bond", re-test steps 1 and 2

Test: "Cartridge Bond Test"

Description: This test ensures that the bond of the cartridge and the endcap is a "good bond". This is performed by testing for bubbles coming from he bond in a water tank.

2. Connect the endcap fitting of the bond sample (sample from Step 3 of "Melt Test") to the air supply
3. Submerge the sample in the bubble tank and turn the air on
4. Once pressure reaches 30 psig, check for bubbles

Test: "Strength Test"

Description: There is a minimum requirement of 350 psi a capsule should be able to withstand. This test measures the maximum pressure that can be applied to the capsule before it bursts.

1. Place bond sample in burst tester
2. Run test
3. Compare maximum pressure achieved with minimum required in batch record sheet

Appendix D: Simulation Best Practices

In simulation each model has specific requirements. Regardless, in order for a simulation study to be successful there is a set of basic steps that should be completed. Below is a combined list of these steps from Kelton et al. and Balachandran-Rabuya-Shinde-Takalkar (Balachandran et al., 2000).

> *Understanding the system:* the first and most important thing is to have a clear understanding of the process to be modeled. This will most likely involve visiting the site, observing the process, and talking to the people who work closely with the system (Kelton et al., 2010).
>
> *Setting clear goals:* before modeling one must realistically define the problem to be solved and the goal of the study. One good question to ask at this point is if simulation is the right tool for the problem in hand (Balachandran et al., 2000).
>
> *Formulating the model:* at this stage it is important to determine the basic requirements, appropriate level of detail and modeling assumptions for the different components of the system (Kelton et al., 2010) (Balachandran et al., 2000).
>
> *Translating the model*: depending on the model, this stage might involve translating into general-purpose language such as Fortran or simulation software such as Arena (Balachandran et al., 2000).
>
> *Verifying and validating the model*: before running experiments, it is necessary to walk through the system, verify that the model behaves as intended and validate that the model reflects reality. Animation and statistical analysis are great resources at this stage (Kelton et al., 2010).
>
> *Designing and running the experiments:* this involves planning what you want to know and how the simulation experiments will help you get those answers

(Harrell, Ghosh, & Bowden, 2004). You then develop the alternative models and execute the simulation runs (Balachandran et al., 2000).

Analyzing the results: the alternative model(s) must be compared with the real system and among them to identify the best solution (Balachandran et al., 2000). Statistical analyses are fundamental for making accurate and precise statements (Kelton et al., 2010).

Implementing & documenting: the different stakeholders must discuss the results from the study and determine the best course of action. Moreover, the model and experiments must be properly documented so that other can understand it and use it in the future (Kelton et al., 2010) (Balachandran et al., 2000).

Below is a full list of the most important and commonly used features in Arena, as well as the ones used for our simulation model. Table 13 details the flowchart modules along with their respective data modules and elements.

Table 13 - Arena Modules

Flowchart Modules	Data Modules/Elements
Create	Entity
Dispose	
Process	Resource
	Queue
	Schedule
Assign	Attribute
	Variable
Decide	
Record	Statistic
Batch	
Separate	
Hold	
Read/Write	
Station	
Route	Sequence
	Expression

Create Module

This module creates entities according to a specified interarrival time that can be defined by the user. It simulates the arrival of entities to the process. The interarrival time can be constant or follow a distribution or schedule. The number of entities per arrival and the maximum number of arrivals are also parameters that can be modified (Kelton et al., 2010).

Entities and Entity Module

Entities refer to the dynamic objects in a simulation model. They are created, move around the system, and are usually disposed (Kelton et al., 2010). In our simulation

model, the entities are Opticap XL filters and lots. The entities are listed and managed in the entity data module.

Dispose Module

Entities exit the system through this module once the process is complete. It provides an output number and offers a way to eliminate entities after they have gone through the process (Kelton et al., 2010).

Process Module

This module represents a given step of the process in the simulation model. It allows the user to do one of the following: delay an entity for some time; seize a resource, delay the entity and then release the resource; or simply delay the entity and release the resource (Kelton et al., 2010). This provides flexibility to simulate various types of processes where a resource may or may not be utilized. The user can specify the length of the delay to follow a particular distribution, be constant, or be equal to another value (Kelton et al., 2010). The delay represents the length of a process step in the actual process.

Resources and Resource Module

A resource represents the elements that perform an action on different steps of the process. They "represent things like personnel, equipment, or space in a storage area of limited size" (Kelton et al., 2010). The resources in EMD Millipore's encapsulation process are the operators in the case of the changeover and the machines in the case of the production process. The resources are listed and managed through the resource data module. The user can specify a fixed capacity or capacity based on a schedule for each resource (Kelton et al., 2010).

Queues and Queue Module

Queues represent a place to wait for an entity that can't move on through the system. This occurs because the entity must seize a resource that is not available at that time (Kelton et al., 2010). Queues can also simulate wait time due to inventory between steps of the process. Queues are listed and managed through the queue

data module where a queue type can be specified – FIFO, LIFO, or by characteristic (Kelton et al., 2010).

Schedule Module

Schedules are managed through this data module. A schedule can be assigned to a resource or to the interarrival rate of entities (Kelton et al., 2010).

Assign Module

This module is used to assign different characteristics to an entity or to the entire model. The module can assign attributes, entity types and entity pictures to a specific entity or variables to the entire model (Kelton et al., 2010).

Attributes and Attribute Module

Attributes are common properties of all entities, but with specific values that can differ from one entity to the next. Examples of attributes assigned to entities can be size, weight or color (Kelton et al., 2010). The EMD filters and lots have four attributes: housing size, right side cap type, left side cap type, and material type. Lots have an additional attribute, which is lot size. The attributes are listed and managed through the attribute data module.

Variables and Variable Module

Variables represent information that is characteristic of the entire system modeled, not just of a specific entity. Variables can be modified at any time by an entity or by a module in the model (Kelton et al., 2010). "If you think of attributes as tags attached to the entities currently floating around in the room, then think of variables as (rewriteable) writing on the wall" (Kelton et al., 2010). The variables are listed and managed through the variable data module.

Decide Module

This module is used to represent decision points in the system where entities can be split into different paths. Decision can be based on chance (percentage true or false) or on a specific condition that generally looks at entity types, attributes or variables

(Kelton et al., 2010). For example, a decision module can be used to direct parts of type A to process 1 and parts of type B to process 2.

Record Module

This module is used to record specific statistics or metrics such as time intervals or number out given a specific condition (Kelton et al., 2010). For instance, a record module can be used to count the number of type A parts that have successfully gone through the system. It can also be used to record the time between two specific points of the entire process.

Batch Module and Separate Module

The batch module is utilized to batch entities according to a specific batch size. The type of entity to be batched can also be specified (Kelton et al., 2010). On the other hand, the separate module splits an existing batch or creates a certain number of duplicates of an entity (Kelton et al., 2010). These modules are used in our model to simulate the existence of lots and single filters throughout the system.

Hold Module

This module retains entities in a queue until a specific condition is met or a signal is emitted (Kelton et al., 2010). In our model, entities are held before the beginning of the process and can only enter it once the previous entity has left the process. This goes in accordance to how the process occurs in reality.

Read/Write Module

This module allows the system to read information from an external database (typically Excel or Access files) and then assign attributes or variables based on that information (Kelton et al., 2010). We use this module in the model to simulate the accurate order of the production schedule of Opticap XL filters.

Station Module, Route Module and Sequence Module

These modules work together to simulate the transfer of entities between steps of the process. A station is placed before the module to which the entity needs to be directed and can serve as both a destination point and a departure point. A station

module is always located before a route module. The route module is then used to create the transfer path by specifying the destination of entities and sending them to the next station. A route time can be included to simulate the transfer time between steps of the process. The transfer path of a particular entity can also follow a pre-determined sequence that is defined in the Sequence data module (Kelton et al., 2010).

Expressions and Expression Module

Expressions are used to refer to values associated to attributes, entities, processes, queues, resources or variables. An expression can be built with the Expression Builder tool so that complex formulas can be defined, similar to the ones found in Microsoft Excel. Expressions can be used throughout the model to refer to these values (Kelton et al., 2010). For example, the delay time for a process may be equal to an expression that refers to a variable defined for the system. Expressions can also be created in the Expression data module and several values can be entered in different rows of that data module. These values can then be used to refer to indexes that correspond to a particular row (Kelton et al., 2010). For example, a delay time in a process may refer to index 2, which corresponds to the value in the second row of the expression that defines the delay times for that process. This is particularly useful when different entities have different cycle times for the same process.

Statistical Accumulators

These are statistics or metrics that correspond to a particular point in time (usually the end) of each run of a simulation model. They inform the user about the performance of the system. Some metrics that can be obtained are: number of entities that went through the system, average wait time for entities, total process time, average time for each queue and utilization of each resource. Most of the statistical accumulators are created by default in the report after each simulation run; however, the user can define additional accumulators according to the simulation needs (Kelton et al., 2010).

Planning Division:

Could you please explain the logistics behind the process of determining the following?
- What to produce
- When to produce it
- The lot sizes

Are there any reasons that would prevent you from putting together two lots of the same product as a single lot?

What role does forecasting play in determining what needs to be produced?

What is the capsule ordering and supply procedure?

What is the timeline between receiving an order and sending it to production?

How does production-scheduling work for the different steps of the filter production process? How does one step affect the other?

In which ways do you communicate with other groups – e.g. production?

Production Floor:

What criteria do you use in order to determine what when and where to produce?

How were these criteria determined?

Do you take into account any difference in between the lines or do you treat them as equal – e.g. production speed?

How much time does it take you to put together the schedule?

Would you consider the current method to be efficient and/or effective?

What are the biggest challenges you currently face with the current method?

Do you have any suggestions for improvement that you might just not have the time or tools to implement?

Appendix G: Changeover Process Flowcharts

Receive lot at production line → Count filters → Do paperwork and cross-check forms → Change fixtures in Vibe Welder (if needed) → Change fixtures in Tester (if needed) → Set up Bonder via HMI

Melt Test → Pass? → [Pass] Bond Integrity Test → Pass? → [Pass] Strength Test → Pass? → [Pass] RUN LOT

[Fail loops back to Melt Test, Bond Integrity Test, and Strength Test respectively]

AFTER PRODUCTION

RUN LOT → Obtain Additional Parts (if needed) → Prepare samples for QA → Wrap up Paperwork → Count number of labels left → Clean up machines and work stations → Receive next lot

Appendix H: Time Study Guidelines

The following guidelines will be used for data collection at the Opticap XL filter encapsulation lines.

Previous Lot Assembly Number
The lot assembly number should be recorded as it appears in the lot documentation (e.g. K002A05FF1)

Current Lot Assembly Number
The lot assembly number should be recorded as it appears in the lot documentation (e.g. K002A05FF1)

Changeover Start Time:
This refers to the time when the operator starts doing the paperwork for the lot. The time should be recorded in the following format: HH:MM AM or PM

Changeover End Time:
This refers to the time when the first cartridge is placed in the Bonder. The time should be recorded in the following format: HH:MM AM or PM

Total Changeover Time:
This field will be calculated once the data is transferred to Excel and will be in the following format: MM Min.

Vibe Welder Fixture Changing Time (sec)
Changing fixtures for the vibe welder entails changing the top nest and bottom nest.
The start time will be when the operator grabs the hex head torque tool.
The end time will be when the operator puts back the hex head torque tool.
Time should be recorded in seconds.

Tester Fixture Changing Time (sec)
Changing fixtures for the tester entails changing the nests and pressure cables.
The start time will be when the operator opens the door of the Tester.
The end time will be when the operator closes the door of the Tester.
Time should be recorded in seconds.

Bonder Human Machine Interface (HMI) Time (sec)
Interacting with the Bonder HMI entails entering the correct information of the lot in the system.
The start time will be when the operator first touches the HMI.
The end time will be when the operator leaves the HMI to start setting up the fixtures for the first melt test.
Time should be recorded in seconds.

Bonder Fixture Changing Time (sec)
Changing fixtures for the bonder entails changing the upper and lower nests.
The start time will be when the operator's hand crosses the window of the Bonder
The end time will be when the operator's hand crosses the window after the last fixture is set up.
Time should be recorded in seconds.

Bonder 1st, 2nd and 3rd Melt Tests Time (sec)
Performing the three melt tests entails setting up the sample cap, cap holder fixture, housing end cap and open end cartridge cap in the bonder for each test, as well as running the bonder.
The start time for each test will be when the operator starts setting up the respective pieces.
The end time for each test will be when the operator grabs the piece from the bonder.
Time should be recorded in seconds.

Burst Test (sec)
Performing the burst test entails ensuring that the bond sample is able to resist a certain level of pressure applied to it.
The start time will be when the operator gets to the burst test station and touches the burst test tools.
The end time will be when the operator leaves the burst test station.
Time should be recorded in seconds.

Change in Size Family for Vibe Welder
Product families are the following:

XL1, XL2 and XL4 lines – Lower Nest
Family A: 2" and 4"
Family B: 3", 5" and 10"

XL1 and XL2 lines – Upper Nest
Family A: 2" and 4"
Family B: 3" and 5"
Family C: 10"

XL4 line – Upper Nest
Family A: 2" and 4"
Family B: 3", 5" and 10"

This field should be recorded as 'Y' if there is a change in family or 'N' if there is no change.

0,1 or 2 Fixtures Changed for Tester?
0: when no fixtures are changed in the Tester
1: when only 1 fixture is changed in the Tester
2: when both fixtures are changed in the Tester

Notes:
Any unusual happenings should be recorded in this section. The changeover number should be recorded first, and then the related comments (e.g. break during changeover, machine down, missing pieces, etc.)

Last Updated: *December 9th, 2013*

Appendix I: Data Collection Sheets

Table 14 - Operator's Data Collection Sheet

Opticap XL - Data Collection

Date: _____

Cell: ☐ XL 1   ☐ XL2   ☐ XL4   **Shift:** ☐ A   ☐ B   ☐ C

Changeover Start Time: _____
Time when the last filter from the previous lot is packed in the box

Lot Information:

Previous Assembly Number: _____   **Lot Size:** _____

Material Type: ☐ Gamma   ☐ Non-gamma   ☐ Other

                                    If other, please specify: _____

Current Assembly Number: _____   **Lot Size:** _____

Material Type   ☐ Gamma   ☐ Non-gamma   ☐ Other

                                    If other, please specify: _____

Bonding and Cooling Tests Information:

Test Name	# of Times Performed
Cartridge Cap Melt Test	_____
Housing Cap Melt Check	_____
Cartridge Bond Sample	_____
Burst Test	_____

Changeover End Time: _____
** Time when the first cartridge is placed in the bonding and cooling machine**

Notes: _____

_____

** Please note any unusual happening that might have affected the total changeover time**
i.e. break during changeover, machine down, missing pieces, etc.

Table 15 - Student's Data Collection Sheet

	Date	Shift	Cell	Previous Catalog Number	Current Catalog Number	Changeover Start Time	Changeover End Time	Vibe Welder Fixture Changing Time	Tester Fixture Changing Time
1									
2									
3									
4									
5									
6									

	HMI	Bonder Fixture	1st Test	R	2nd Test	R	3rd Test	R	Bonder Fixture	Burst Test	R	Total Time
1												
2												
3												
4												
5												
6												

NOTES:	
Changeover Number	Comments

The EMD Optical XL Encapsulation Process simulation model is composed of the three production lines, XL1, XL2 and XL4, which are identical in structure. Each line is divided in seven sections that are connected with each other. This division was done for the purpose of simplicity when explaining the model's structure to the key stakeholders of the project. The seven sections are listed and explained below, in order of flow through the model.

1. **Incoming Lots**

In this section the entities are created as lots at a certain rate, with a maximum number of entities created corresponding to the number of lots in the schedule on hand.
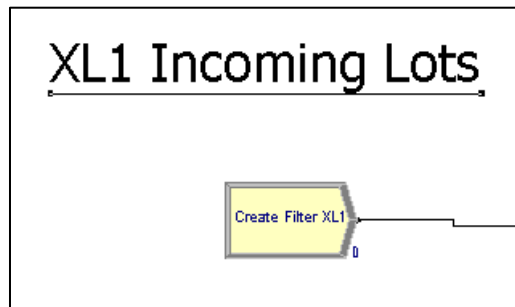
2. **Characteristics Assignment**

After each lot is created, it is assigned all the corresponding characteristics according to the type of filter it contains and the lot description. These characteristics are: material type, capsule size, right cap type, left cap type, and lot size. Additionally, indexes are assigned for each changeover (bonder, vibe welder and tester) based on what the previous lot was and what the current lot is. These indexes will then be used to determine the appropriate changeover time for each machine in the changeover process.

It's important to note that a lot can only proceed to the next section, Lot Size Distribution, once the previous lot has exited the system.
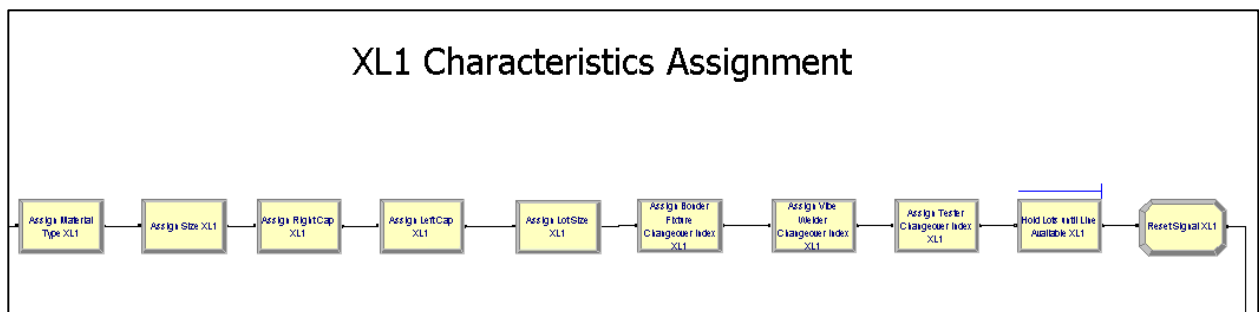
3. Lot Size Distribution

Once characteristics are assigned, the lot is separated into its corresponding number of filters. For example, a lot with a lot size of 100 will get separated into 100 filters.

XL1 Lot Size Distribution
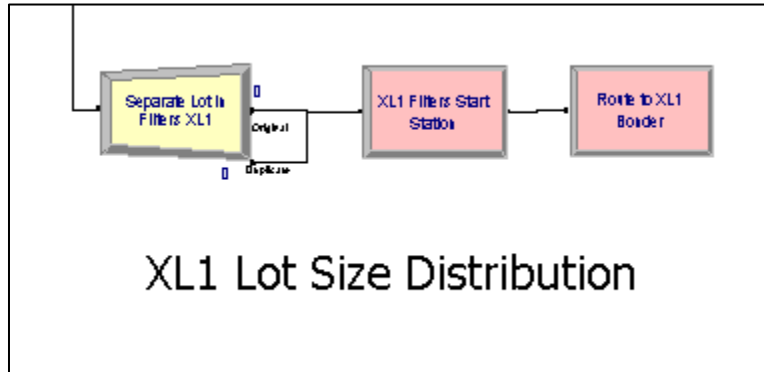
4. Production Process

After the separation takes place, individual filters are directed to the production process. In this section they go through the bonder, vibe welder and tester, with processing times assigned based on the characteristics of each filter.
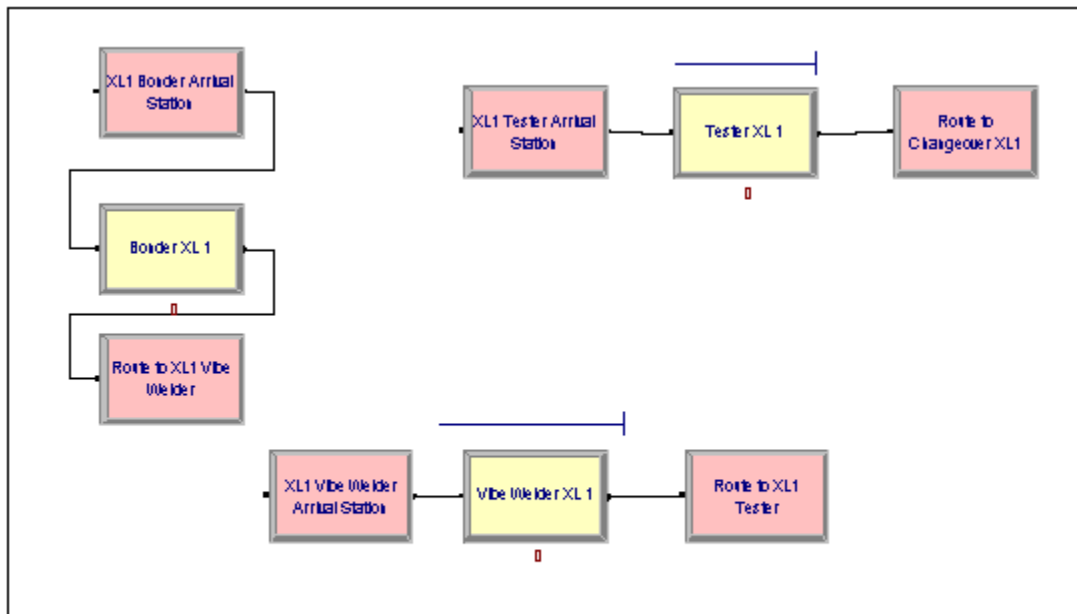
XL1 Production

5. Batching for Changeover

After production is simulated, filters proceed to being batched again into a single lot so they can move to the changeover process. The lot is then virtually duplicated so one

duplicated copy can go to the bonder changeover process and the other to the vibe welder changeover.

XL1 Batching for Changeover
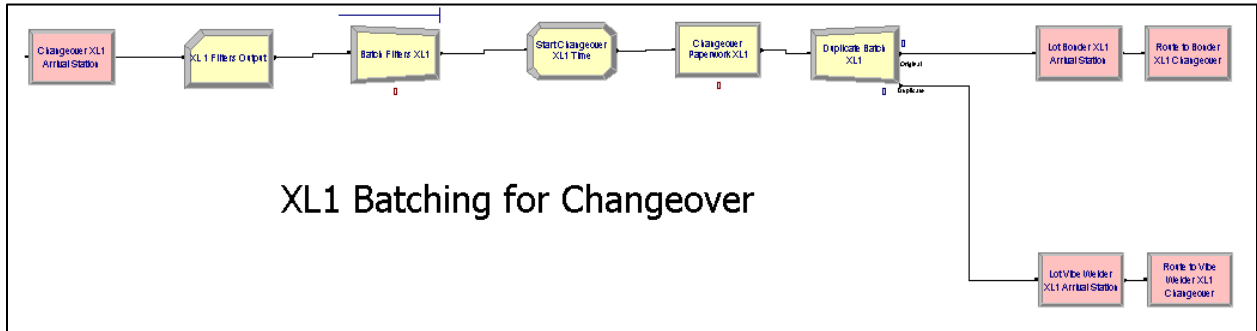
6. Changeover Process

This process is divided into two sub processes: bonder changeover and vibe welder + tester changeovers. The duplicated copies go through the sub processes at the same time to simulate what occurs in the real process. The changeover processing times are determined based on the indexes assigned in the second section. Two metrics are recorded in this section: Bonder Changeover Time and Vibe Welder + Tester Changeovers Time.
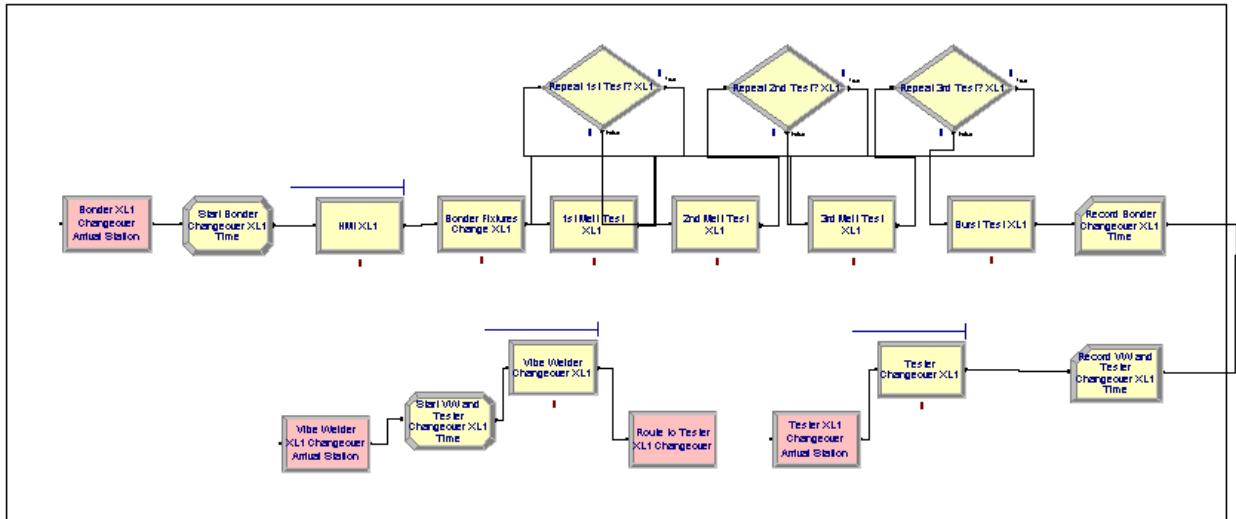
XL1 Changeover

7. Lot Closing

In the final section, the duplicated copies are put together again as a single lot. As the lot exits the system, a signal is sent to the second section so that the next lot is allowed to enter the system. Five metrics are recorded in this section: Total Changeover Time,

Output in Number of Lots, Number of Bonder Changeovers performed, Number of Vibe Welder Changeovers performed and Number of Tester Changeovers performed.

XL1 Lot Closing
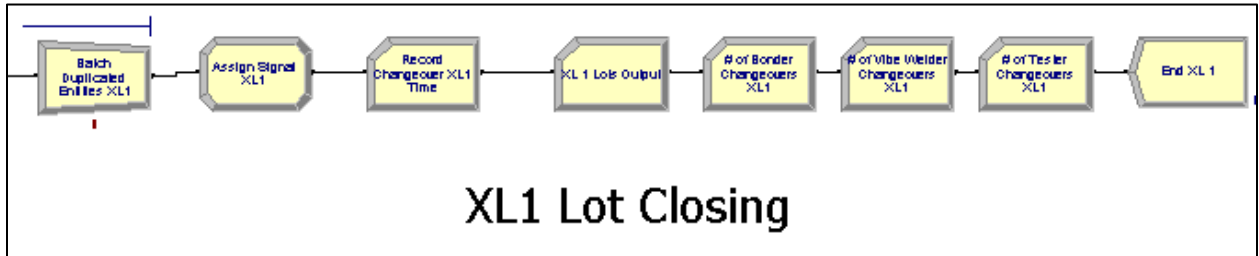
Appendix K: DES Test Matrices

Allowable Conditions:

Conditions	How it will be identified	Run 1	Run 2	Run 3
Follows Correct Order (Creation [Incoming Lots, Characteristic Assignment and Lot Size Distribution] --> Production)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Correct Order (Production --> Batching for Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Correct Order (Batching for Changeover --> Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Correct Order (Changeover --> Lot Closing)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Correct Order (Production)	Evaluate order and logic of modules before running simulation model. Run simulation model and track animation of production to ensure correct order is being followed. Additionally use "Highlight Active Module" run control.	Pass	Pass	Pass

Follows Correct Order (Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track animation of changeover to ensure correct order is being followed. Additionally use "Highlight Active Module" run control.	Pass	Pass	Pass
Assign Correct Attributes in the Scheduled Order	Created a test model of the entity creation part of model that uses decision modules to ensure correct assignment of attributes. These attributes were assigned using an excel file and read/write modules.	Pass	Pass	Pass
Hold entities until flagged (previous entity leaves the system) before entering the production	Run model and observe animation of hold module to ensure entity is only released after previous entity has left the system.	Pass	Pass	Pass
Entity splits into assigned amount when entering production	Use a temporary record module to count passing entities created by the split module.	Pass	Pass	Pass
Entity re-batches the assigned amount when leaving the production (before entering changeover)	Run model and observe animation of entities during batching.	Pass	Pass	Pass

Non-allowable Conditions:

Conditions	How it will be identified	Run 1	Run 2	Run 3
Follows Incorrect Order (NOT: Creation [Incoming Lots, Characteristic Assignment and Lot Size Distribution] --> Production)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Incorrect Order (NOT: Production --> Batching for Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Incorrect Order (NOT: Batching for Changeover --> Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Incorrect Order (NOT: Changeover --> Lot Closing)	Evaluate order and logic of modules before running simulation model. Run simulation model and track "Highlight Active Module" run control.	Pass	Pass	Pass
Follows Incorrect Order (production)	Evaluate order and logic of modules before running simulation model. Run simulation model and track animation of production to ensure correct order is being followed. Additionally use "Highlight Active Module" run control.	Pass	Pass	Pass

Follows Incorrect Order (Changeover)	Evaluate order and logic of modules before running simulation model. Run simulation model and track animation of changeover to ensure correct order is being followed. Additionally use "Highlight Active Module" run control.	Pass	Pass	Pass
Assign Incorrect Attributes (error in read/write modules)	Created a test model of the entity creation part of model that uses decision modules to ensure correct assignment of attributes. These attributes were assigned using an excel file and read/write modules.	Pass	Pass	Pass
Assigns lots in incorrect order (i.e.: Schedule shows A -> B, model assigns attributes for B first, and then A)	Created a test model of the entity creation part of model that uses decision modules to ensure correct assignment of attributes. These attributes were assigned using an excel file and read/write modules.	Pass	Pass	Pass
Hold module releases entities before previous entity leaves the system	Run model and observe animation of hold module to ensure entity is only released after previous entity has left the system.	Pass	Pass	Pass
When entering production entity splits into an amount different than the assigned amount.	Use a temporary record module to count passing entities created by the split module.	Pass	Pass	Pass
When leaving the production (before entering changeover) entity re-batches an amount different than the assigned amount.	Run model and observe animation of entities during batching.	Pass	Pass	Pass

During the changeover process, there is more than one operator in the bonder (HMI, Melt Tests, Burst Test) at one time.	Check resource list under process module. Confirm correct amount of resources seized by observing animations.	Pass	Pass	Pass
During the changeover production, there is more than one operator in the VW at one time.	Check resource list under process module. Confirm correct amount of resources seized by observing animations.	Pass	Pass	Pass
During the changeover production, there is more than one operator in the Tester at one time.	Check resource list under process module. Confirm correct amount of resources seized by observing animations.	Pass	Pass	Pass
During the changeover production, there is one operator in the VW and one operator in the Tester at the same time.	Check resource list under process module. Confirm correct amount of resources seized by observing animations.	Pass	Pass	Pass
More entities leave the system than the number of entities created	Check number of entities that left system is less or equal to the number of entities created.	Pass	Pass	Pass

Appendix L: How to run the DES Model

Setting up the schedule

1. Open a new Excel File

2. Copy and paste the Assembly Numbers of the XL1 schedule to column A

3. Copy and paste the Lot Sizes of the XL1 schedule to column G

	A	B	C	D	E	F	G	H
1	KW06A04NN3						15	
2	KTGRA02FF3						600	
3	KWLSA02FF3						3	
4	KPHLA02FF3						15	
5	KGW3A02FF3						30	
6	KGW3A04FF3						24	
7	KGW3A04FF3						60	
8	KVGLS04FF3						150	
9	KWSSA05FF1						2	
10	KVGLA05FF1						100	
11	KVGLA05FF1						100	
12	KVGLA05FF1						100	
13	KR01A05FF1						2	
14	KW19A05FF1						2	
15	KR10A05FF1						30	

4. If you already have the "Developer" tab in Excel go to step # 7, if not go to the next step.

5. Click "File" → "Options" → "Customized Ribbons"

6. Select "Developer"
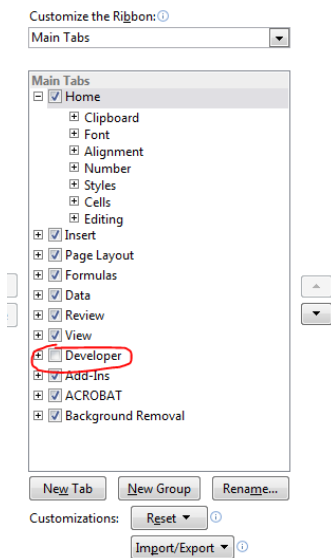
7. Go to "Developer" → "Visual Basic"
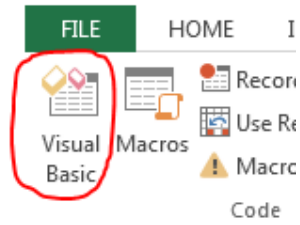
8. On the left, click the sheet you are working on (Sheet1)
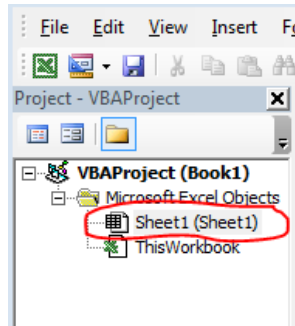
9. File→ Import File
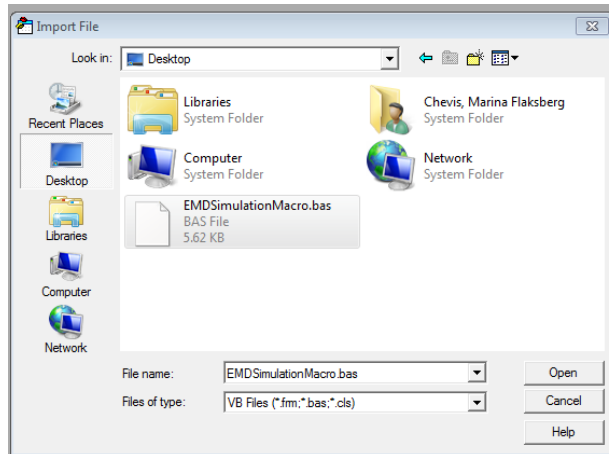
10. Browse the Macro file "EMD Simulation Macro", select it and click "OK"

11. On the left, click "Modules" → "Module 1"
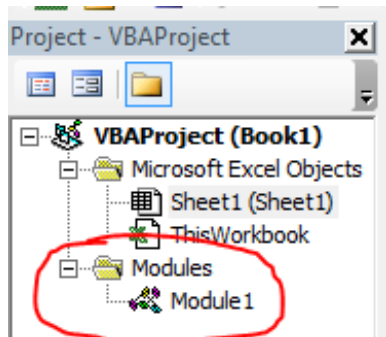
- Find "100" and replace with the number of lots in your schedule (lines in the Excel file)
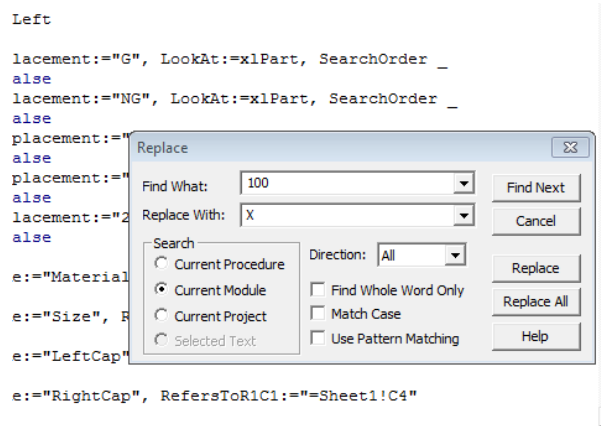
12. Click "Save"

- Save the file as "XL1 Schedule" with format: Excel 97-2004 Workbook (.xls)

13. Close the VBA window

14. Go to "Developer" → "Macros"

15. Click "Run"

- Find "100" and replace with the number of lots in your schedule (lines in the Excel file)

12. Click "Save"

- Save the file as "XL1 Schedule" with format: Excel 97-2004 Workbook (.xls)
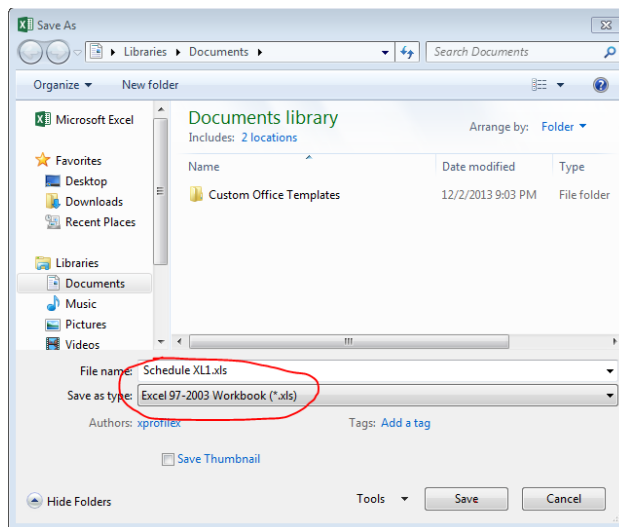
13. Close the VBA window

14. Go to "Developer" → "Macros"

15. Click "Run"
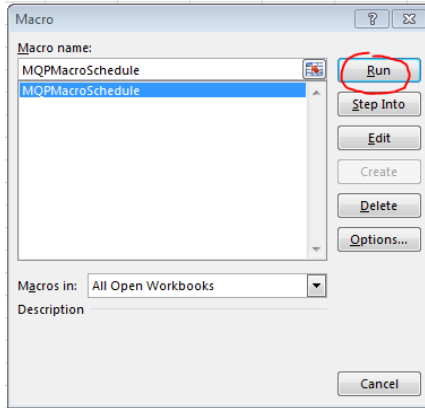
16. Repeat steps 1-15 using the schedule for XL2 and save the file as "XL2 Schedule" with format: Excel 97-2004 Workbook (.xls)

17. Repeat steps 1-15 using the schedule for XL4 and save the file as "XL4 Schedule" with format: Excel 97-2004 Workbook (.xls)

Running the Model

1. Open the Arena file "EMD MQP Simulation Model"

2. Go to "Basic Process" → "Create"
   - Change the "Max Arrivals" of the "Create Filter XL1" module to the number of lots in the XL1 Excel File.
   - Repeat for the "Create Filter XL2" and "Create Filter XL4" modules\

3. Go to "Advanced Process" → "File"
   - Under " Operating System File Name" for the "Data File" Advanced Process module, click ...

   - Browse the file you named "XL1 Schedule"

- Select that file and click "OK"

- Repeat for the "Data File XL2" Advanced Process module using the file you named "XL2 Schedule"

- Repeat for the "Data File XL4" Advanced Process module using the file you named "XL4 Schedule"

4. Go to "Run" → "Setup…" → "Replication Parameters"
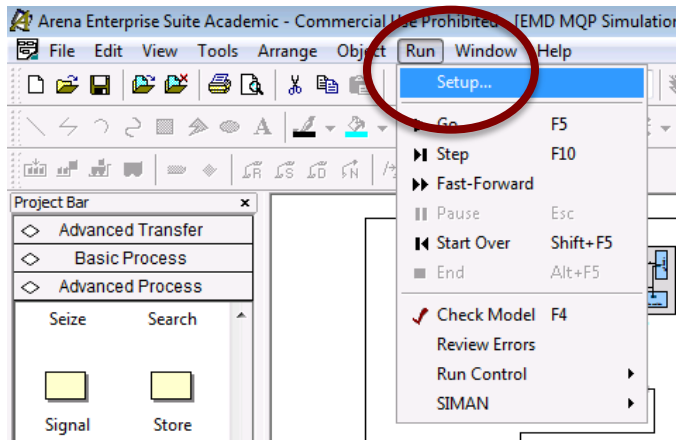
- Make sure the following are correct:
    - "Number of Replications" is set to be 17
    - "Warm-up Period" is 0.0
    - "Time Units" for the replication length is "Days"
    - "Hours per Day" is set to be 24
    - "Base Time Units" is minutes
    - "Terminating Condition" is blank

- Set "Replication Length" to the number of days of production that you have in your schedule. Check if all lots are processed within this timeframe. If possible, try with fewer days until you reach the least amount of days in which all lots are processed.

5. Click to run the model

6. When the following message appears, click "YES".
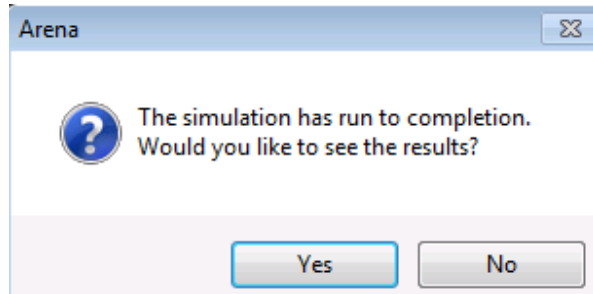
This will open the report for your simulation run.

- Page 19 of the report shows the times for the changeover in each machine for each of the lines

- Page 20 of the report shows the filters and lots output for each line and the number of changeovers for each machine for each line

Appendix M: Results from Operator's Data Collection Sheet

Table 16 is a summary of the information gathered through the "Operator's Data Collection Sheets". For each of the melt tests we indicate the total of changeovers in which this test was repeated. Additionally, from this total we specify the number of changeovers that corresponded to a change in size and the number of changeovers that corresponded to a change in material. The last column indicates the percentages that were used to determine the pass/fail probability for each of the tests in the model. It was calculated using the following formula: "total changeovers repeated/total changeovers".

Table 16 - Operator's Data Collection Sheet Results Summary

Repeated Melt Tests	Total Changeovers Repeated	Change Size	No Change Size	Change Material	No Change Material	Percentage for Model (Total Changeovers Repeated / Total Changeovers)
1st Melt Test	26	16	10	10	16	25.24%
2nd Melt Test	36	24	12	10	26	34.95%
3rd Melt Test	12	10	2	5	7	11.65%
Total Changeovers	**103**					

Appendix N: Outlier Elimination Process

Table 17 - Outlier Elimination Process' Procedure

PROCEDURE	
Median	
Q1	25%
Q3	75%
Interquartile	(Q3-Q1)*3
Out	MEDIAN -/+ INTERQ

Table 18 - Outlier Elimination Process' Calculations

	HMI	Bonder Fixture	1st MT	2nd MT	3rd MT	Burst Test	VW 1 Change	VW 2 Changes	Tester 1 Change	Tester 2 Changes
N	16	7	27	30	25	20	4	7	18	16
MED	38	27	70	92	80	133	90.5	240	72	139.5
Q1	35.5	21.5	65	81.25	60	103	84.5	219	62.375	121.75
Q3	43	32	77.5	111	89	161	104.25	248.5	76.125	150.75
INTERQ	22.5	31.5	37.5	89.25	87	174	59.25	88.5	41.25	87
LOW	**15.5**	**-4.5**	**32.5**	**2.75**	**-7**	**-41**	**31.25**	**151.5**	**30.75**	**52.5**
HIGH	**60.5**	**58.5**	**107.5**	**181.25**	**167**	**307**	**149.75**	**328.5**	**113.25**	**226.5**

Table 19 - Outlier Elimination Process' Data

HMI	Bonder Fixture	1st MT	2nd MT	3rd MT	Burst Test	VW 1 Change	VW 2 Changes	Tester 1 Change	Tester 2 Changes
8	18	48	41	39	74	68	149	58	116
22	20	55	54	53	80	90	210	58.5	117
31	23	56	64	55	89	91	228	58.5	117
34	27	56	67	56	99	144	240	60.5	121

36	27	60	69	56	100	240	61	122
36	37	64	73	57	104	257	66.5	133
38	38	65	76	60	109	447	69	138
38		65	81	63	121		69.5	139
38		65	82	65	122		70	140
40		65	82	66	130		74	148
41		66	82	72	136		75	150
42		67	84	75	150		75	150
46		67	89	80	150		75	153
63		70	92	80	155		76.5	165
65		70	92	83	156		82.5	172
84		71	92	86	176		86	213
		73	95	87	191		93	
		73	95	88	226		106.5	
		75	100	89	246			
		75	101	92	250			
		80	101	94				
		80	108	97				
		83	112	98				
		112	113	114				
		118	127	140				
		131	135					
		134	141					
			148					
			159					
			172					

Appendix O: Original Schedules

Table 20 - Original Schedules

A		B		C	
Catalog Number	Lot Size	Catalog Number	Lot Size	Catalog Number	Lot Size
KR25A10HH1	5	KTGRA10HH1	4	KR10A51HH1	30
KGW6A10HH1	36	KVHLA10HH1	60	KN12A10HH1	5
KVGLA10HH1	600	KW19A10HH1	28	KWLSA02FF3	3
K010A10HH1	10	KWLCA10HH1	35	KWSSA04HH3	150
KGW9A10HH1	600	KVVLA10HH1	75	KPHLA02FF3	15
KGEPA03TT3	135	KVGLA10TH1	150	KVVLG04TT3	18
KVGLA05HH1	300	KTGRA05HH1	5	KVGBA04TT3	600
KN06A05TT1	14	KVGLA05HH1	300	KVGLA04TT3	600
KN12A05TT1	14	KVGLA05TH1	60	KVGLG04TH3	300
KR05A10TT1	5	KWSSA05HH1	4	KVGLA10TT1	300
KP20A10HH1	15	KVGLA05HH1	300	KGW9A10HH1	300
KR03A10HH1	20	KHVEG05HH1	1	KVGLA04HH3	600
KW03A10HH1	4	KHGEG03TT3	18	KN03A10HH1	2
KW19A10HH1	40	KVPVA10HH1	5	KHGLA10TH1	2
KVGLS10HH1	200	KVGLA10HH1	600	KWL9A10TT1	10
KVGLG10HH1	600	KWSSA10FF1	8	KWSSA05TT1	2
KHVEG10TH1	180	KR10A51HH1	5	KVGLA05FF1	100
KVGLA10TH1	250	KR50A51HH1	3	KVGLA05HH1	300
KGEPG03HH3	333	KVVLA05HH1	34	KGW9A10HH1	200
KVGLA05HH1	300	KWSSA05FF1	2	KR10A05HH1	30
KHGES03TT3	75	KVGLA05TT1	200	KR05A51HH1	40
KVGLG10HH1	500	KVGLA05FF1	100	K002A51FF1	2
KWSCA10HH1	75	KZZZA02TH3	3	KR01A05FF1	2
KR05A10HH1	5	KVGLG10HH1	600	KHGEG03TH3	24
K030A10HH1	20	KHVEG03HH3	120	KW19A04HH3	30
KVGLG10HH1	500	KVVLG04TH3	225	KVGLA04HH3	600
KVPVA10TT1	75	KGW6A02HH3	30	KVGLA04HH3	600
KHGES05HH1	75	KVGLA04HH3	300	KGW3A02HH3	9
KHVES03HH3	39	KVGLA04TT3	300	KP20A05TT1	15
KHGES05TH1	3	KGW3A04TT3	9	KGW6A05TT1	15
KHGES03HH3	30	KGW3A04FF3	24	KP20A05HH1	36
KVGLG10HH1	300	KVGLA04HH3	600	KGEPG05TH1	10
KVGLA04HH3	600	KVVLA04HH3	45	KGEPG10TH1	10
KTGRA02TT3	600	KGW2A04TT3	12	KGEPG10TH1	40

KGW3A02HH3	30	KWL9A04TT3	2	KHGES10TT1	110
KGW3A05TT1	3	KPHLA02TT3	312	KGEPS10TT1	315
KHGEG05HH1	35	KVVLA02TT3	33	KHGEG05TH1	36
KHGES03HH3	93	KW03A04TT3	45	KN25A10TT1	15
KHGEG03HH3	45	KTGRA02FF3	600	KN50A10TT1	30
KHGEG03TH3	15	KGW3A04FF3	60	KVVLG04HH3	15
KP20A05HH1	50	KWSSA04TT3	45	KVGLG04HH3	600
KHGES10TH1	3	KW03A04HH3	12	KPHLA02HH3	57
KVGLA10TT1	600	KWSCA02HH3	15	KWLCA02HH3	18
KVGLA10TT1	600	KWSCA10TT1	30	KGW6A02TT3	15
KHVEA10HH1	60	KVHLA10TT1	525	KPHLA05TT1	40
KGEPA10TT1	10	KHGES10HH1	6	KVGBA05TT1	30
KPHLA10TT1	300	KVGLS10TT1	290	KVGLA05TT1	200
KVGLG10TT1	200	KVGLA10TT1	600	KW06A05TT1	5
KVGLG10TH1	300	KVGLS10HH1	100	KV06A10TT1	4
KVVLG10TH1	100	KVGLA05TT1	200	KGW3A02FF3	30
KVVLG10FH1	260	KHGES05TT1	20	KPHLA02HH3	75
KVVLG10HH1	50	KHGES03TH3	3	KVVLG04HH3	90
KWLSA10HH1	33	KGEPG03TH3	42	KW03A04TT3	15
KP20A10TT1	45	KW06A04NN3	15	KTGRA02TT3	600
KW19A05TT1	10	KVGLS04FF3	150	KVVLG04FH3	150
KP20A05HH1	100	KTGRA05TT1	50	KVVLG04TH3	300
KPHLA10HH1	100	KVGLA05HH1	600	KW19A05FF1	2
KVGLA10TH1	300	KVGLA05HH1	300	KR10A05FF1	30
KVGLS04TT3	300	KVGLA05FF1	100	KVGLA10FF1	100
		KVGLG04TH3	300	KP15A10TT1	20
				KTGRA02TT3	600

Appendix P: Ideal and Refined Ideal Scenarios Results

Table 21 - Ideal Scenarios XL1 – Results in minutes – Average across 17 replications

IDEAL SCENARIOS XL1

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	3.96	3.37	3.07		8.68	8.64	8.62		24.10	24.04	23.85	
Schedule 1 - Size	2.82	2.86	2.95	1.77	8.53	8.49	8.55	0.37	23.73	23.74	23.74	0.78
Schedule 2 - Size	3.50	2.80	2.93	1.17	8.50	8.52	8.58	0.34	23.78	23.75	23.79	0.67
Schedule 3 - Size	3.65	2.75	3.03	0.97	8.49	8.46	8.48	0.51	23.66	23.69	23.66	0.98
Schedule 4 - Size	3.65	2.99	3.27	0.49	8.53	8.68	8.53	0.20	23.70	23.94	23.71	0.64
Schedule 5 - Size	2.71	2.97	3.04	1.68	8.46	8.52	8.44	0.52	23.62	23.76	23.62	0.99
Schedule 6 - Size	3.61	2.88	3.34	0.57	8.62	8.49	8.56	0.27	23.92	23.73	23.75	0.59
Schedule 7 - Material	3.67	3.08	3.40	0.25	8.56	8.63	8.68	0.07	24.04	23.90	23.94	0.11
Schedule 8 - Material	3.77	3.40	3.39	-0.16	8.59	8.65	8.76	-0.06	24.04	23.84	24.00	0.11
Schedule 9 - Material	3.82	3.00	3.04	0.54	8.72	8.69	8.72	-0.19	24.16	23.96	23.95	-0.08
Schedule 10 - Cap	2.99	2.81	2.30	2.30	8.60	8.66	8.59	0.09	23.81	23.96	23.66	0.56
Schedule 11 - Cap	3.35	2.36	2.24	2.45	8.70	8.64	8.67	-0.07	24.05	23.79	23.74	0.41
Schedule 12 - Cap	3.43	2.47	2.14	2.36	8.67	8.77	8.70	-0.20	24.00	23.95	23.72	0.32
Schedule 13 - Cap	2.96	2.46	2.51	2.47	8.66	8.67	8.68	-0.07	23.86	23.85	23.74	0.54
Schedule 14 - Cap	3.05	2.33	2.50	2.52	8.65	8.64	8.56	0.09	23.86	23.79	23.64	0.70
Schedule 15 - Cap	3.13	2.87	2.04	2.36	8.50	8.75	8.68	0.01	23.81	24.05	23.71	0.42

Table 22 - Ideal Scenarios XL2 – Results in minutes – Average across 17 replications

IDEAL SCENARIOS XL2

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	4.07	4.40	3.86		8.66	8.72	8.73		24.14	24.32	24.26	
Schedule 1 - Size	3.51	3.47	2.69	2.66	8.49	8.56	8.48	0.58	23.81	23.91	23.70	1.30
Schedule 2 - Size	3.33	3.32	2.71	2.97	8.47	8.49	8.38	0.77	23.73	23.81	23.62	1.56
Schedule 3 - Size	3.40	2.95	3.14	2.84	8.41	8.41	8.55	0.74	23.75	23.68	23.84	1.45
Schedule 4 - Size	3.35	3.42	2.87	2.69	8.50	8.55	8.51	0.55	23.83	23.90	23.72	1.27
Schedule 5 - Size	3.45	3.88	3.08	1.92	8.54	8.49	8.51	0.57	23.85	23.91	23.80	1.16
Schedule 6 - Size	3.32	3.49	2.88	2.64	8.45	8.45	8.53	0.68	23.71	23.82	23.75	1.44
Schedule 7 - Material	3.81	4.77	3.75	0.00	8.75	8.67	8.67	0.02	24.15	24.25	24.18	0.14
Schedule 8 - Material	4.06	3.75	3.71	0.81	8.60	8.67	8.59	0.25	24.12	24.11	24.11	0.38
Schedule 9 - Material	4.16	4.83	4.13	-0.79	8.64	8.72	8.64	0.11	24.16	24.31	24.03	0.22
Schedule 10 - Cap	2.80	3.77	2.93	2.83	8.75	8.72	8.64	0.00	23.84	24.16	23.82	0.90
Schedule 11 - Cap	3.26	3.10	2.96	3.01	8.69	8.77	8.52	0.13	23.99	24.02	23.69	1.02
Schedule 12 - Cap	3.25	3.28	2.86	2.94	8.69	8.75	8.65	0.02	23.98	24.08	23.76	0.90
Schedule 13 - Cap	2.73	3.29	3.36	2.95	8.64	8.75	8.60	0.12	23.78	24.07	23.86	1.01
Schedule 14 - Cap	2.88	3.21	3.31	2.93	8.80	8.75	8.69	-0.13	23.96	24.05	23.94	0.77
Schedule 15 - Cap	2.84	3.64	2.88	2.97	8.66	8.75	8.64	0.06	23.78	24.20	23.73	1.01

Table 23 - Ideal Scenarios XL4 – Results in minutes – Average across 17 replications

IDEAL SCENARIOS XL4

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	4.52	3.94	3.84		8.77	8.78	8.80		24.33	24.05	24.26	
Schedule 1 - Size	3.42	3.30	2.72	2.86	8.50	8.55	8.51	0.79	23.81	23.86	23.75	1.22
Schedule 2 - Size	3.04	2.97	3.39	2.90	8.43	8.52	8.49	0.91	23.62	23.60	23.77	1.65
Schedule 3 - Size	3.22	2.98	3.61	2.49	8.58	8.43	8.65	0.69	23.89	23.52	24.04	1.19
Schedule 4 - Size	3.26	2.97	3.72	2.35	8.53	8.55	8.52	0.75	23.85	23.62	23.83	1.34
Schedule 5 - Size	2.95	2.90	3.66	2.79	8.58	8.47	8.57	0.73	23.75	23.57	23.99	1.33
Schedule 6 - Size	3.15	2.88	3.74	2.53	8.54	8.44	8.55	0.82	23.74	23.53	23.86	1.51
Schedule 7 - Material	4.33	4.24	4.40	-0.67	8.59	8.84	8.84	0.08	24.31	24.27	24.50	-0.44
Schedule 8 - Material	4.75	4.71	4.55	-1.71	8.73	8.72	8.81	0.09	24.33	24.55	24.50	-0.74
Schedule 9 - Material	4.73	4.20	4.21	-0.84	8.89	8.68	8.67	0.11	24.47	24.12	24.37	-0.32
Schedule 10 - Cap	3.42	3.68	3.01	2.19	8.68	8.73	8.74	0.20	24.04	23.97	24.00	0.63
Schedule 11 - Cap	4.26	2.90	2.94	2.20	8.73	8.67	8.69	0.26	24.29	23.77	23.96	0.62
Schedule 12 - Cap	4.23	3.10	2.83	2.14	8.73	8.65	8.64	0.33	24.31	23.76	23.89	0.68
Schedule 13 - Cap	3.42	3.05	3.56	2.27	8.79	8.69	8.87	0.00	24.13	23.81	24.43	0.27
Schedule 14 - Cap	3.56	2.84	3.55	2.35	8.80	8.70	8.84	0.01	24.18	23.81	24.37	0.28
Schedule 15 - Cap	3.60	3.66	2.88	2.16	8.78	8.77	8.84	-0.04	24.17	24.00	24.08	0.39

Table 24 - Refined Ideal Scenarios XL1 – Results in minutes – Average across 17 replications

REVISED IDEAL XL1

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	3.96	3.37	3.07		8.68	8.64	8.62		24.10	24.04	23.85	
Schedule 1 - Size	2.02	2.59	1.98	3.81	8.62	8.61	8.57	0.14	23.67	23.71	23.62	0.99
Schedule 2 - Size	2.27	1.68	2.11	4.34	8.68	8.52	8.69	0.05	23.76	23.54	23.75	0.94
Schedule 3 - Size	1.06	1.82	2.30	5.22	8.49	8.63	8.60	0.22	23.51	23.65	23.69	1.14
Schedule 5 - Size	2.10	2.46	2.26	3.58	8.63	8.66	8.56	0.09	23.69	23.72	23.64	0.94
Schedule 11 - Cap	2.51	2.88	1.75	3.26	8.61	8.57	8.61	0.15	23.70	23.59	23.64	1.06
Schedule 13 - Cap	2.3	2.85	2.7	2.55	8.51	8.56	8.67	0.20	23.56	23.63	23.72	1.08
Schedule 14 - Cap	2.06	2.85	2.67	2.82	8.59	8.66	8.52	0.17	23.67	23.68	23.59	1.05
Schedule 15 - Cap	2.07	2.94	2.46	2.93	8.63	8.48	8.45	0.38	23.71	23.50	23.47	1.31

Table 25 - Refined Ideal Scenarios XL2 – Results in minutes – Average across 17 replications

REVISED IDEAL XL2

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	4.07	4.40	3.86		8.66	8.72	8.73		24.14	24.32	24.26	
Schedule 1 - Size	2.33	2.35	2.51	5.14	8.62	8.64	8.58	0.27	23.66	23.73	23.66	1.67
Schedule 2 - Size	1.75	2.62	2.23	5.73	8.64	8.54	8.47	0.46	23.67	23.63	23.55	1.87
Schedule 3 - Size	1.88	2.55	1.47	6.43	8.42	8.51	8.56	0.62	23.44	23.60	23.58	2.10
Schedule 5 - Size	2.36	2.19	1.48	6.30	8.58	8.45	8.64	0.44	23.62	23.54	23.65	1.91
Schedule 11 - Cap	2.53	2.16	2.23	5.41	8.55	8.41	8.69	0.46	23.59	23.47	23.71	1.95
Schedule 13 - Cap	2.43	2.32	2.45	5.13	8.52	8.62	8.61	0.36	23.54	23.72	23.64	1.82
Schedule 14 - Cap	2.40	2.38	2.38	5.17	8.51	8.57	8.47	0.56	23.57	23.66	23.51	1.98
Schedule 15 - Cap	2.49	2.35	2.25	5.24	8.54	8.55	8.51	0.51	23.60	23.71	23.53	1.88

Table 26 - Refined Ideal Scenarios XL4 – Results in minutes – Average across 17 replications

REVISED IDEAL XL4

Scenario	Average VW & Tester			Sum ofAvg Reduction	Average Bonder			Sum ofAvg Reduction	Total Avg Changeover Time			Sum ofAvg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	4.52	3.94	3.84		8.77	8.78	8.80		24.33	24.05	24.26	
Schedule 1 - Size	1.95	2.09	2.15	6.11	8.60	8.68	8.57	0.50	23.64	23.70	23.59	1.71
Schedule 2 - Size	1.79	2.06	1.96	6.49	8.48	8.63	8.47	0.77	23.52	23.65	23.49	1.98
Schedule 3 - Size	1.83	1.79	2.01	6.67	8.60	8.56	8.54	0.65	23.64	23.60	23.59	1.81
Schedule 5 - Size	2.19	2.08	2.00	6.03	8.48	8.59	8.59	0.69	23.52	23.61	23.64	1.87
Schedule 11 - Cap	2.32	2.31	2.38	5.29	8.50	8.59	8.72	0.54	23.52	23.62	23.74	1.76
Schedule 13 - Cap	2.21	2.56	2.53	5.00	8.65	8.55	8.60	0.55	23.67	23.84	23.73	1.40
Schedule 14 - Cap	2.73	2.30	2.63	4.64	8.66	8.66	8.53	0.50	23.75	23.68	23.65	1.56
Schedule 15 - Cap	2.70	2.31	2.53	4.76	8.62	8.62	8.56	0.55	23.72	23.64	23.64	1.64

Appendix Q: Improved Scenarios Results

Table 27 - Improved Scenarios Unbalanced – Results in minutes – Average across 17 replications

IMPROVED UNBALANCED

Scenario	Average VW & Tester			Sum of Avg Reduction	Average Bonder			Sum of Avg Reduction	Total Avg Changeover Time			Sum of Avg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	3.77	4.30	3.85		8.72	8.59	8.74		24.11	24.21	24.20	
Schedule 2 - Size	1.68	2.14	1.71	**6.39**	8.53	8.43	8.53	**0.56**	23.56	23.49	23.56	**1.91**
Schedule 3 - Size	2.09	2.05	1.68	6.10	8.49	8.60	8.62	0.34	23.54	23.66	23.64	1.68
Schedule 14 - Cap	2.33	2.13	1.92	5.54	8.57	8.58	8.56	0.34	23.61	23.61	23.60	1.70
Schedule 15 - Cap	2.34	2.01	2.33	5.24	8.58	8.59	8.52	0.36	23.63	23.67	23.54	1.68

Table 28 - Improved Scenarios – Results in minutes – Average across 17 replications

IMPROVED SCENARIOS

Scenario	Average VW & Tester			Sum of Avg Reduction	Average Bonder			Sum of Avg Reduction	Total Avg Changeover Time			Sum of Avg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	3.77	4.30	3.85		8.72	8.59	8.74		24.11	24.21	24.20	
Schedule 2 - Size	2.22	1.98	1.88	5.84	8.70	8.57	8.50	0.28	23.73	23.64	23.54	1.61
Schedule 3 - Size	2.28	2.04	2.24	5.36	8.50	8.43	8.66	**0.46**	23.56	23.50	23.78	**1.68**
Schedule 14 - Cap	2.01	2.08	2.53	5.30	8.67	8.59	8.52	0.27	23.71	23.66	23.54	1.61
Schedule 15 - Cap	1.96	1.84	2.10	**6.02**	8.60	8.59	8.58	0.28	23.64	23.65	23.60	1.63

Table 29 - Improved Scenarios by Size Dedication – Results in minutes – Average across 17 replications

Scenario	Average VW & Tester			Sum of Avg Reduction	Average Bonder			Sum of Avg Reduction	Total Avg Changeover Time			Sum of Avg Reduction
	XL1	XL2	XL4		XL1	XL2	XL4		XL1	XL2	XL4	
Original	3.77	4.30	3.85		8.72	8.59	8.74		24.11	24.21	24.20	
Schedule 2 - Size	2.22	1.98	1.88	5.84	8.70	8.57	8.50	0.28	23.73	23.64	23.54	1.61
Schedule 3 - Size	2.28	2.04	2.24	5.36	8.50	8.43	8.66	**0.46**	23.56	23.50	23.78	1.68
Schedule 4 - Size	2.11	2.31	2.07	5.43	8.39	8.63	8.59	0.44	23.45	23.69	23.65	**1.73**
Schedule 6 - Size	1.57	2.35	2.11	**5.89**	8.59	8.56	8.55	0.35	23.62	23.60	23.61	1.69

IMPROVED SCENARIOS - SIZE DEDICATION

Appendix R: Best Practice Guidelines

Step Number	Step
1	Receive schedule from Planning Division
2	Group lots by capsule size family: • 2" & 4" filters • 3" & 5" filters • 10" filters
3	Sort lots by cap type to reduce the number of tester changeovers.
4	Assign each group to a production line: • XL1 → 3,5 • XL2 → 10 • XL4 → 2,4
5	Move any lots that can't be produced in its assigned line to a suitable line. If possible, keep 3", 5", and 10" filters together and 2" and 4" filters together.
6	Balance the amount of filters assigned to each line. This may require moving lots between lines, even though this may result in a size change. When moving lots, always give priority to capsule size but try to take into consideration cap type, and lastly material type.

Considerations after "Plug-Bonder" Implementation:

- 10" filters can only be assigned to XL1 and XL2
- If possible, assign 3" and 5" filters to either XL1 or XL2 as well. This would give you flexibility when balancing the lines as to minimize the number of vibe welder changeovers.