Leveraging Flexible Manufacturing to Streamline New Product Launch Processes

By

Taylor K. Robinson

B.S. Mechanical Engineering, Columbia University, 2014

Submitted to the Sloan School of Management and the Department of Mechanical Engineering
in partial fulfillment of the requirements for the degrees of

Master of Business Administration
and
Master of Science in Mechanical Engineering

in conjunction with the Leaders for Global Operations Program at the

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
May 2020

Signature of Author: _____
MIT Sloan School of Management, MIT Department of Mechanical Engineering
May 8, 2020

Certified by:_____
Dr. Brian Anthony, Thesis Supervisor
Principal Research Scientist, MIT Department of Mechanical Engineering

Certified by: _____
Dr. Sean Willems, Thesis Supervisor
Visiting Professor of Operations Management, MIT Sloan School of Management

Certified by: _____
Maura Herson
Assistant Dean, MBA Program, MIT Sloan School of Management

Certified by: _____
Nicolas Hadjiconstantinou
Chairman of the Committee on Graduate Students, Department of Mechanical Engineering

This page is intentionally left blank.

Leveraging Flexible Manufacturing to Streamline New Product Introduction Processes

By

Taylor K. Robinson
B.S., Mechanical Engineering, Columbia University, 2014

Submitted to the Sloan School of Management and the Department of Mechanical Engineering on May 8, 2020, in partial fulfillment of the requirements for the degrees of

Master of Business Administration
and
Master of Science in Mechanical Engineering

Abstract

Johnson & Johnson Vision (JJV), manufacturer of the ACUVUE® Brand Contact Lenses, is committed to launching new contact lens products every year to maintain competitive edge and long-term relevancy. However, manufacturing lines currently operate at high utilization rates to satisfy steadily growing demand, limiting opportunity to beta test new products or validate manufacturing lines. Beta testing provides feedback on product design and manufacturability while validation qualifies a line to make a particular product at commercial scale – contributing to the more than 5 billion contact lenses produced by JJV yearly. To build manufacturing capacity and introduce flexibility into the system, JJV built the Flexible Manufacturing Platform (FMP). FMP is a modular manufacturing line capable of producing any contact lens in the JJV portfolio. This thesis explores how to strategically leverage FMP to enable quicker transitions from pilot-line production to commercial-scale production.

A case study was performed on the FMP heat seal manufacturing process step, providing insight into both the technical capability and organizational processes of FMP. The heat seal was chosen due to its critical importance in maintaining product quality and patient safety. Prior to the start of this project, the heat seal process step lacked consistency and reliability. Statistical process control techniques were employed to generate a heat seal capability model that measured the effect of changing the contact time, contact temperature, and contact pressure. This revealed contact time and contact temperature to have the most influence on heat seal integrity. The capability model ultimately improved decision quality and reduced product failures by 80%. Successful execution of the case study also required observation of upstream and downstream process steps to the heat seal, yielding a thorough understanding of the entire FMP line. This FMP current state analysis shows the remaining work needed to efficiently scale between pilot-line production and commercial-scale production. As such, there is a need for continuous knowledge transfer between the R&D and Operations teams as they develop new governance processes to merge into a single domain. In doing so, FMP can become an efficient structure to continuously launch new products.

Acknowledgments

This internship was made possible by the dedicated guidance and encouragement from Scott Fyfe who ensured that I not only was being challenged in my internship, but that I was also enjoying the overall experience. Secondly, special thanks goes to Amy Gobel for her reliable mentorship and friendship along the way. She was instrumental in helping me settle into both the company and Jacksonville at large. I would also like to acknowledge the Heat Seal Characterization core team members for their dedicated efforts throughout the three-month study. These members include Brian Aitken, Mike Larsen, Pete Pylipow, and Geoff Tizard. Other people at the company who substantially contributed to my positive experience include Jim Conroy, Ann Pittman, Steve Vincent, Kim Boulware, Carrie Davis, Venkatesh Ketty, Jeff Caltrider, and Jason Hill. A sincere thank you to each of you.

At MIT, I want to thank my advisors Dr. Sean Willems and Dr. Brian Anthony for their contributions to my research. To my LGO and Sloan family, I am undoubtedly grateful to be a part of this community. Thank you for welcoming me and for always cheering me on.

As always, a massive thank you to my parents and brother for their continued love and support throughout all of my life adventures.

This page is intentionally left blank.

Table of Contents

1. Introduction

Johnson & Johnson Vision is comprised of three companies: Johnson & Johnson Vision Care (e.g. contact lens products), Surgical Products (e.g. cataract surgery and LASIK), and Consumer Eye Health Products (e.g. contact lens solution). The scope of this thesis takes place at Johnson & Johnson Vision Care (JJVC). Headquartered in Jacksonville FL, Vision Care employs more than 4,100 workers globally, including 1,800 at its Jacksonville facilities. The company manufactures 5 billion ACUVUE® Brand Contact Lenses per year and generated more than $3.3 billion in worldwide revenue in 2018. Product innovation is important to Vision Care's long-term success, but this is challenging to achieve in a capacity-constrained environment. The introduction of the Flexible Manufacturing Platform (FMP) provides a promising solution.

1.1 Problem Discussion

Johnson & Johnson Vision Care faces an enviable challenge: customer demand is continuously outpacing their supply capacity. More specifically, demand for daily disposable contact lenses is growing rapidly. Johnson & Johnson introduced the first daily disposable soft contact lens in 1987. In 2002, the category only represented 5.3% of all soft contact lenses prescribed in the US, but by 2014, this same category comprised 27.1% of all soft lens prescriptions (Efron, et al). According to Grand View Research, the daily disposable market is expected to undergo a CAGR of 6.6% from years 2019 – 2025 and remain the dominant lens replacement choice during this time. "The preference for daily disposable lenses has been rising, because a new set provides greater comfort to the user…These are considered as the healthiest contact lenses by most users. Eye care professionals are also prescribing daily disposable lenses as they avoid problems associated with longer lens replacements" (Contact Lenses Market Size, Share | Global Industry Report, 2019-2025 n.d.). Due to the increased comfort levels and increased prescriptions from eye care professionals, JJVC is witnessing a steady demand increase for daily disposable lenses.

However, unlike software or service companies in which expanding capacity can be achieved relatively quickly, Vision Care is a manufacturing company. It requires significant investments in physical equipment and continuous operational improvements to satisfy its growing customer base. The company is currently facing severe capacity constraints as it works to invest in manufacturing capability, which has a lead time on the time scale of years. Yet still, continuous

product innovation is vital to JJVC maintaining its dominant market share at 42.2% (Curran 2018). While the market is highly regulated and has high barriers to entry, it still remains competitive. Small scale players gain traction by offering unique solutions to a niche market. For example, Warby Parker announced in November 2019 that it will be launching its own line of daily contact lenses called Scout Lenses. It intends to compete on pricing, packaging, and convenience by tripling its number of in-house optometrists to 80, adding 40 more eye exam suites to new and existing Warby Parker stores, and redesigning the package itself (Carr and Roache 2019).

To not only gain new wearers, but also retain existing wearers in this competitive market requires that contact lens manufacturers continuously improve quality and reliability of their products. This means increasing the number SKUs offered and potentially introducing variable demand into the system. Launching new contact lens products at Vision Care while capacity constrained is costly because existing manufacturing lines will need to temporarily halt production to undergo new product development and validation processes. As such, launching new product at Vision Care has a high opportunity cost since it impacts existing revenue streams. However, the introduction of the Flexible Manufacturing Platform could potentially alleviate this burden.

1.2 Thesis Contributions

FMP is a modular manufacturing line that incorporates new manufacturing technologies to improve both operational efficiencies and final product quality. With this new line, comes the opportunity to re-structure the new product design and development process to ultimately bring new contact lens products to market faster. The value proposition to invest in FMP is understood; yet still, the technology remains untested and current support systems will need to be restructured to serve FMP effectively long-term.

FMP offers the ability to move more efficiently between pilot-line research projects and commercial scale-up for product launch. FMP can also perform flexible change-overs between different contact lens products and FMP can propagate products to other existing manufacturing lines. This thesis will explore how Vision Care can leverage FMP to quickly bring new products to market in a capacity constrained environment. This is accomplished by performing a case

study on the heat seal characterization process. Characterization is the process of determining the control settings required to consistently produce viable product. It means defining the values of the critical parameters to the process (e.g. heat settings, cooling settings, exposure time, etc.).

Heat seal characterization is achieved by intentionally varying the contact time, contact pressure, and contact temperature that the heat seal die applies to the foil to create a seal protecting the contact lens inside of the package by maintaining a sterile barrier (Figure 1.1). A series of experiments were conducted to create a capability model predicting when a seal will maintain its integrity, but yet still not be so strong as to create an unpleasant package opening experience for the patient. Additionally, during this time, the FMP line current state operations were thoroughly observed and documented, noting areas for improvement.

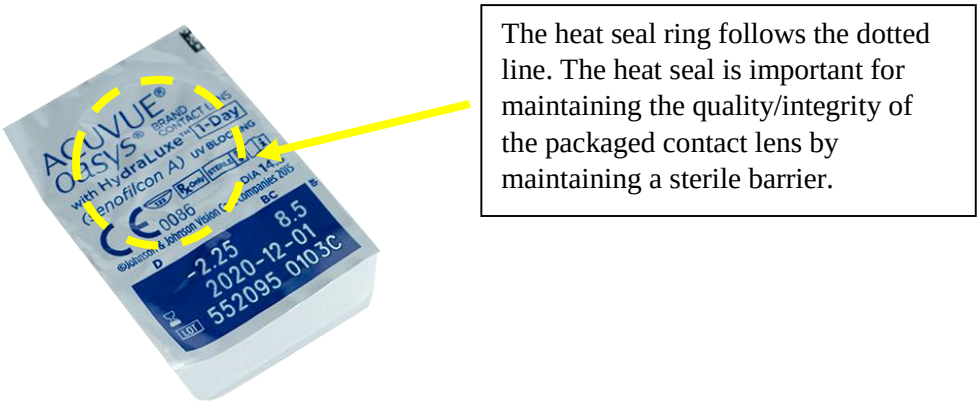

Figure 1-1: Seal Location

1.3 Thesis Overview

Johnson & Johnson Vision Care (JJVC) is an established player navigating a competitive market that is quickly growing with smaller, niche players. Moreover, the contact lens manufacturing industry is regulated by the U.S. Food and Drug Administration (FDA), providing unique challenges. **Chapter 2** provides the relevant company history, company strategy, competitive landscape, and current business challenges. Following this overview of the company's overall standing, **Chapter 3** dives deeper into how JJVC launches new contact lenses into the market. The new product introduction process will be evaluated from a team organization perspective and also from a process perspective. Doing so will provide a thorough understanding of how the cross-functional core teams work together to navigate the stage gate design process and validate

manufacturing lines. Chapter 3 will conclude by outlining the challenges encountered in the current new product introduction process.

Many of today's challenges that JJVC faces in launching new products can be partially or wholly resolved through the Flexible Manufacturing Platform (FMP). **Chapter 4** will describe FMP in detail as well as outline its value proposition. There are various benefits that arise with FMP such as increased flexibility, more robust process scale-up, and faster product launches. This chapter will conclude by highlighting potential risks in introducing this new technology. Having introduced these risks, **Chapter 5** seeks to better understand the Flexible Manufacturing Platform and its current capabilities by executing a Heat Seal Characterization case study. The heat seal is critical in maintaining product quality and ultimately patient safety. Therefore, it is important that the heat seal be strong and resistant to accidental breakage; however, the seal cannot be so strong that the patient has an unpleasant experience opening the package. This case study consists of altering the contact time (sec), contact temperature (°C), and contact pressure (lbF) through a series of controlled experiments. Doing so created a heat seal process capability model so that the engineering team could evaluate the expected heat seal quality for any given combination of inputs. Additionally, performing the case study required close observation of the entire Flexible Manufacturing Platform, yielding unique insights into the day-to-day operations.

Chapter 6 gathers these insights into FMP's day-to-day operations and builds a current state analysis of FMP. A three-lens analysis will look at the strategic, political, and cultural make-up of FMP. Communication methods and task management methods will also be evaluated. **Chapter 7** will outline the ideal future state of the Flexible Manufacturing Platform. Recommendations will be made to measure and sustain progress over time. Lastly, **Chapter 8** concludes the thesis by consolidating all observations and recommendations.

2. Company Background

In 1981, Johnson & Johnson Vision (JJV) acquired Frontier Contact Lens Company in Jacksonville, FL and renamed Frontier to Vistakon. Subsequently, contact lens manufacturing operations were centralized in Jacksonville, FL and Vistakon began to overhaul the largely

manual manufacturing process. In 1987, JJV became a world leader in the eye care industry when the company introduced the first disposable soft contact lens under the ACUVUE® brand name. This was the start of a steady launch of new contact lens products such as daily disposable lenses, UV protection, multifocal lenses for presbyopia, toric lenses for astigmatism, beauty contact lenses, and most recently, contact lenses with light-filtering capability. Today, the company produces more than 5 billion contact lenses annually serving more than 50 million consumers globally. Annual sales in 2018 were $3.3 billion and the ACUVUE® portfolio has fifteen product lines and 38,000 SKUs. This chapter will further elaborate on JJV competitive strategy and current challenges.

2.1 Johnson & Johnson Vision Care Business Model

Johnson & Johnson Vision Care operates two manufacturing plants. One is located in company headquarters in Jacksonville, FL and the other is in Limerick, Ireland. Jacksonville not only houses manufacturing capacity, but is also home to the Finance, Human Resources, Legal, Sales, Marketing, Manufacturing, R&D, and the Executive Leadership Teams. The co-location of many different business functions into one site is both a strategic and intentional choice. This not only enables quick communication but also facilitates in-person meetings, which are shown to aid in decision-making and relationship building (Swaab et al. n.d.).

From a market perspective, contact lenses in the US are predominantly comprised of single vision/spherical lenses (Figure 2-1). Toric lenses for patients with astigmatism are the second largest product segmenta. Under the ACUVUE® brand, there are a total of fifteen products available: nine for hyperopia/myopia, four for astigmatism, and two for presbyopia. Brand names include ACUVUE® OASYS, ACUVUE® MOIST, ACUVUE® VITA, ACUVUE® TruEye®, ACUVUE® 2, and ACUVUE® DEFINE®.

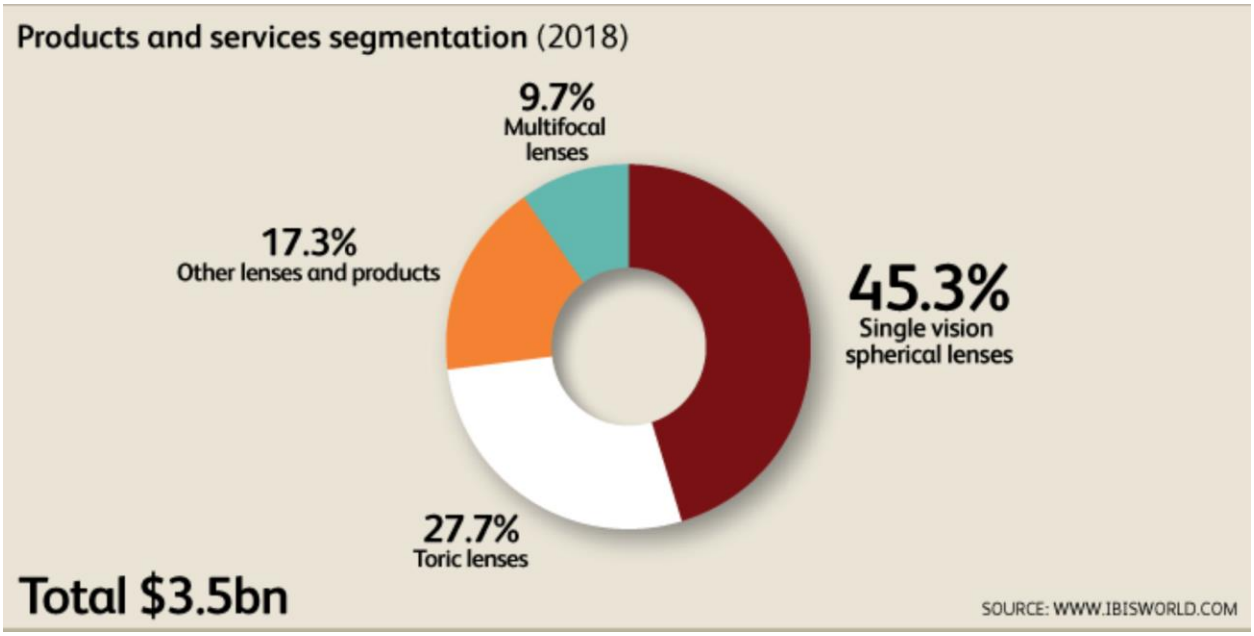

Figure 2-1: Product segments contributing to the US industry revenue total of $3.5 bn

Given that Johnson & Johnson Vision supplies equipment for LASIK eye surgery (long-lasting vision correction using laser technology), there is a risk of thus reducing demand for contact lenses and other industry products. However, there has been little impact from laser correction surgery thus far and such surgery is very costly and not suitable for all patients. More importantly, offering both LASIK and contact lens correction helps JJV realize its vision where preventable vision loss and blindness are no longer issues.

The U.S. Food and Drug Administration (FDA) categorizes contact lenses as medical devices in the same tier as hearing aids and pregnancy kits. Due to these regulations, contact lenses in the US cannot be sold directly to the patient without a written prescription from an Eye Care Professional (ECP). Vision Care, similar to other US contact lens manufacturers, therefore primarily markets to medical professionals and retailers (Figure 2-2). Over recent years, there has been a demand shift from re-useable contact lenses to daily disposable lenses partially influenced by higher ECP prescriptions due to the cleanliness of daily contact lenses. While daily disposables are more profitable for JJVC than are re-useable contact lenses, dailies require more capital investment. These challenges will be further discussed in Section 2.4

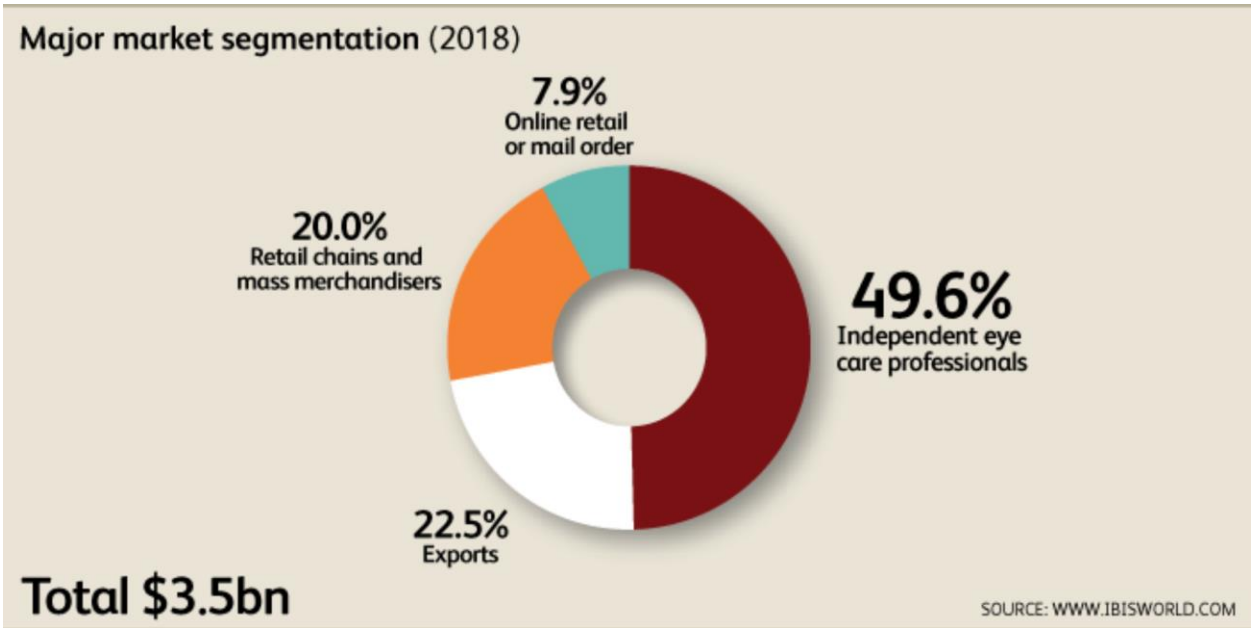

Figure 2-2: Market segments contributing to the US industry revenue total of $3.5 bn

2.2 Competitive Landscape

In the US, the contact lens manufacturing market is dominated by four top players as of year end 2018: Johnson & Johnson (42.2%), Novartis International AG (17.2%), The Cooper Companies (9.8%), and Bausch Health Companies (8.4%). Figure 2-3 visually depicts the market share and the major players. According to Curran in IBIS World, a major player is a company that generates more than 5% of industry revenue when only including the revenue earned by the company in this industry. "Major players that enjoy a large market share often benefit from cost advantages that provide a competitive edge. Where industries have a high level of market concentration, the dominance of a select few companies acts as a potential barrier to entry for new competitors in the industry. Smaller manufacturers often will specialize in niche products or novel lenses for specific eye disorders" (Curran 2018). Furthermore, these large companies often acquire smaller competitors when their products are successfully brought to market. This effectively maintains major players' industry dominance.

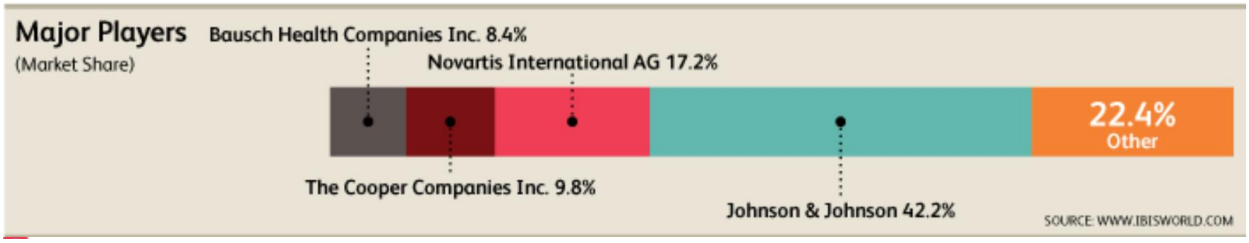

Figure 2-3:Major Players in Contact Lens Manufacturing

The health of this industry will depend upon the number of adults aged 20-64, the number of people with private health insurance, the per capita disposable income, and the trade-weighted index. Adults aged 20-64 are more likely than other ages to both afford contact lenses and care about their own physical appearance enough to purchase. While glasses could be considered a necessity for those with poor vision, contact lenses are more of a desire. As such, people who have vision insurance as well as any disposable income to make up the difference will be able to afford contact lenses. Lastly, as the American dollar becomes stronger, it will be more difficult for US manufacturers to export their products since buying US products will be more expensive than would buying from other countries (Curran 2018).

From a competitive standpoint, major players must continually invest in the best available technologies and production processes. Product differentiation based upon quality and consistency are vital to a company's success. Continued innovation that is protected by intellectual property rights and driven by a highly-skilled workforce will be essential for long-term growth.

2.3 Continued Innovation

It will be vital for top industry players to invest in new product development to stay ahead of the industry and smaller competitors. Increased contact lens comfort and quality resulting from continued innovation will not only re-attract consumers who originally found the products uncomfortable, but also allow younger consumers (<13 years) to participate in wearing contact lenses. As such, in 2018, Vision Care announced that it was committed to bringing one to two new products to market annually through 2020 (History of ACUVUE® Brand, 2018).

Throughout its history, Vision Care has not only invested heavily in product development, but also in manufacturing capability. The company has undergone five generations of technological improvements, in which each generation of manufacturing technology has an improvement in speed, efficiency, and reliability when compared to its predecessor. Now, the next technology showing great promise is the Flexible Manufacturing Platform, ultimately helping to address the capacity challenges that the company faces today.

2.4 Capacity Challenges

Vision Care currently operates three generations of manufacturing lines. Each line operates at a high utilization rate to satisfy steadily growing demand due to product innovation and a growing demand for daily disposable lenses. Operating at high utilization rates removes the slack from the system that is necessary to perform preventative maintenance, beta test new products, or validate existing manufacturing lines. To clarify, beta testing allows engineers to collect feedback on the product design and manufacturability of a potential, new contact lens at a commercial scale as opposed to a pilot-line scale. The difference being that a commercial scale manufacturing line is capable of producing at least 5x more product per hour than could a pilot line. Additionally, commercial lines are fully automated and are optimized for efficiency and speed. Whereas pilot lines have manual process steps and are optimized for flexibility and control.

Line validation qualifies a manufacturing line to make a particular lens product (e.g. 1-DAY ACUVUE® MOIST). This is because FDA regulations require that a line's ability to produce a consistent, high-quality lens must be proven and well-documented before it can be sold to the patient. Given that Vision Care has publicly promised to launch new contact lens products annually through 2020, the high utilization rates of existing lines pose a severe risk. Furthermore, the company must continue to increase build rates merely to satisfy current demand. To build manufacturing capacity and introduce flexibility into the system, Vision Care built the Flexible Manufacturing Platform (FMP). FMP is a modular manufacturing line capable of quickly and efficiently producing any contact lens in the JJV portfolio.

2.5 Chapter Summary

Chapter 2 captured the current landscape of the contact lens manufacturing industry and how Johnson & Johnson Vision Care fits into this market. According to Curran in IBIS World, as disposable income increases, more consumers will be able to afford premium products such as corrective lenses for astigmatism, hydrogel lenses and daily disposable lenses. Additionally, product innovation will continue to stimulate interest and generate new revenue streams. This is promising for manufacturers in that new, if not larger, revenue streams will develop moving forward. However, Johnson & Johnson Vision Care must build flexibility into its manufacturing abilities in order to capitalize on these opportunities. The Flexible Manufacturing Platform will

not only enable the company to beta test new corrective lenses at scale, but also expedite the new product development process.

3. New Product Introduction Process

Chapter 3 describes the overall New Product Introduction (NPI) Process at Vision Care. NPI is a framework consisting of multiple tiers and gates to ensure that projects meet all validation requirements as outlined by both the FDA's and Vision Care's internal quality metrics. Projects do not advance until their project readiness is assessed and deemed sufficient to continue development. While this process has been proven effective, it does not adequately account for the benefits provided by the Flexible Manufacturing Platform.

3.1 Cross-Functional Core Teams

Cross-functional core teams are accountable for planning and moving a new corrective lens project idea from start to finish. They are empowered to make decisions, drive alignment, and ensure project focus so that each stage gate's requirements are met and the project can continue forward. At minimum, the core team consists of one person from each of the following departments:

- Project Management Organization (Project Leader)
- R&D Product Engineering
- R&D Process Engineering
- Quality Assurance
- Finance
- Marketing
- Regulatory Affairs
- Value Stream Lead (Supply Chain)

The Project Leader is appointed from within the Project Management Organization by a strategic board. The Project Leader plays a large role in filling out the core team and subsequently leading the team through product development to product launch. R&D Product oversees the initial discovery and product design while R&D Process ensures that the manufacturing steps are correctly set to achieve the desired end product. Quality Assurance documents results and

ensures both Vision Care quality metrics and FDA quality metrics are met. Finance oversees the budget, Marketing manages branding efforts and market analysis, and Regulatory Affairs manages legal requirements, patents, intellectual property, etc. Lastly, the Value Stream Lead develops supply chain strategies and aligns product launch to the business goals. The Value Stream Lead also works across several project ideas to ensure supply chain readiness on a larger scale.

Core team members can also gather sub-teams within their respective functions for additional support. Members of these sub-teams are called Extended Team Members (Figure 3-1).

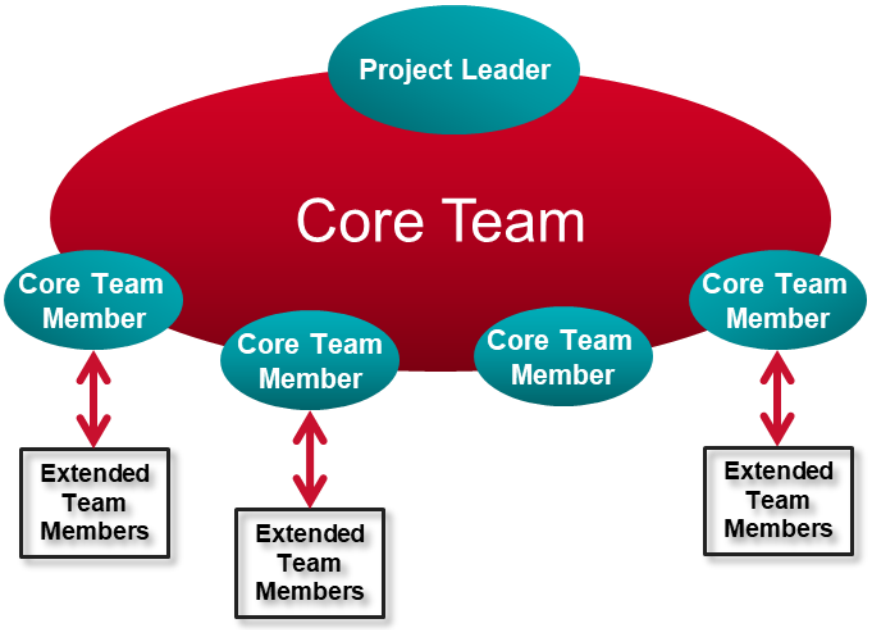

Figure 3-1: Core Team Organization

3.2 New Product Introduction Process

The Vision Care NPI process is an internally developed framework that guides the new product design and development process. It consists of five Stage Gates (Table 3-2). In order for a project idea to advance to the next stage, a series of metrics must be met proving its readiness and viability. Table 3-1 shows a subset of questions which must be answered before a project idea can successfully close out a stage gate.

		Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
		Opportunity Analysis	**Product Feasibility**	**Development and Transfer**	**Product Launch**	**Post-Launch Assessment**
		-Is this idea worth pursuing based upon market opportunity?	-Is the idea technically feasible and financially viable?	-Are manufacturing and marketing plans created and aligned?	-Is the product ready to enter the market?	-What are the lessons learned?
Level of Effort	R&D	High	High	Medium	Low	Low
	Operations	Low	Medium	High	High	Medium

Table 3-1: New Product Development Stage Gate Process

What is important to note about this framework is the relationship between Research & Development and Manufacturing Operations. Traditionally, R&D develops the concept, assesses feasibility and viability, and then "transfers" the product to the manufacturing floor in Stage 3 when it is ready to be produced at large scale. R&D assists in characterizing the line and ensuring quality is met; however, after this point, they have less involvement through the remaining stages. They monitor the process and support as needed while manufacturing and supply chain gain momentum in preparing for launch.

3.3 Validation Process

To validate a manufacturing line means to prove its ability to reliably produce a particular contact lens at a high quality. The quality metrics are influenced by both federal regulations from the FDA and Johnson & Johnson's internal standards. Line validation is a lengthy process and often requires that the line be down to allow for experimentation, equipment changes, measurements, etc. Whenever a line is down, it is not producing sellable product that brings in revenue for the company. Thus, there is an incentive to minimize line validation time to not only bring new products to market faster, but also to minimize the impact on existing revenue streams.

Line validation is a four phase process that fits within the third stage gate (Table 3-2). It also offers the greatest opportunity to improve the NPI process by incorporating the Flexible Manufacturing Platform. This is because having a flexible line dedicated to new product design

and development will ultimately allow for dedicated experimentation, faster feedback on product manufacturability, and shorter uptimes.

Phase 1	Phase 2	Phase 3	Phase 4
Site Acceptance Testing	**Installation Qualification**	**Operational Qualification**	**Production Qualification**
-Does newly installed equipment work?	-Is the equipment safe and is product tracking in place?	-Is the line capable and stable?	-Does the final product pass all quality metrics?

Table 3-2: Manufacturing Equipment Validation Process

3.4 New Product Launch Challenges

Some of the challenges that remain with the current method of new product launches include:

- Manufacturing fleet disruption
- Relocating production from the pilot line to the manufacturing floor
- Product propagations

A manufacturing fleet is a collection of manufacturing lines, often physically situated next to one another so that someone could easily walk from one line to another. Fleets are distinguished from one another by their technological capabilities. For example, the oldest manufacturing lines, which all use similar processes and equipment, comprise the same fleet. Whereas the newest manufacturing lines, which incorporate more efficient automation, comprise another manufacturing fleet. Disrupting manufacturing fleets in any form in a capacity-constrained environment is a severe setback. Whereas normally there is enough buffer stock to continue fulfilling orders, under capacity constraints there is very little slack on the manufacturing floor. Lines are highly-utilized to maintain pace with demand. Under these constrains, when a line stops for any reason, this lack of production directly impacts revenue.

Physically re-locating production from the pilot line inside the R&D building to commercial lines inside the Manufacturing building also poses a challenge to new product development. This is because the environments are not equal. Vast measures are taken to help the transfer go as smoothly as possible. However, the pilot line is optimized for flexibility and control while the manufacturing floor is optimized for speed and efficiency. Naturally, these two environments will have slight differences and this becomes apparent when trying to move a new contact lens from the pilot line to a commercial line for the first time.

Lastly, product propagation occurs when a corrective lens product is passed from one manufacturing line to another. This can be done to free-up a line for other types of production. If the two manufacturing lines are similar in equipment and design, then the receiving line will not have to undergo the full process characterization work that the passing line underwent. Therefore, the receiving line will have a shortened validation process.

3.5 Chapter Summary

Launching new products requires a dedicated team, dedicated resources, and a clear structure that is both standardized yet continuously improved. The cross-functional core team ensures that each function is involved in the product development process starting from the planning phase. This helps prevent downstream issues that would be missed if downstream functions (e.g. Manufacturing and Distribution) were not included from the beginning. The Stage Gate design process provides a system of checks and balances that minimize the risk of overlooking critical details during the development phase. Additionally, line validation verifies manufacturability at scale. However, these current processes do not come without challenges and opportunities for improvement. Such challenges can be directly addressed through the Flexible Manufacturing Platform.

4 Flexible Manufacturing Value Proposition

Chapter 4 discusses the value and strategic benefits from leveraging the Flexible Manufacturing Platform as a dedicated new product launch platform. These include cost savings through a reduction in number of shifts, time savings through shorter development cycles, and increased manufacturing capacity due to the line's flexibility. Yet, while FMP is a promising business decision, there are still several risks to mitigate and challenges to overcome. This chapter will elaborate on these concepts.

4.1 Platform Description

Flexible manufacturing is beneficial to companies that have high-volume, high-mix product lines. FMP is comprised of multiple, consecutive modules that are relatively one-meter-wide by three-meters-tall in size (Figure 4-1).

Figure 4-1: Example replica of modular manufacturing

Each module performs a singular manufacturing process step. For example, one module will place the base curve onto the front curve, shaping the monomer into a contact lens. The subsequent module will sort trays of monomer into one of several separate cure tunnels. The following module will initiate the curing process. This set-up of having multiple modules effectively means that manufacturing steps can be inserted into and removed from the line as-needed depending on the product requirements. An example of changing product requirements is the color ink needed for beauty contact lenses (Figure 4-2). Modules with printers installed could be inserted into FMP to manufacture beauty contact lenses (lenses that have color schemes to alter or enhance the color of the wearer's iris). Moreover, FMP will have dedicated resources including a team of technicians, operators, and management, ensuring that the line is continuously improving.

Figure 4-2: ACUVUE® Define Accent Style Line

4.2 Strategic Benefits

In the capacity-constrained environment of Vision Care, flexible manufacturing is needed to not only relieve existing manufacturing lines, which are fully-utilized, but also to accelerate the new

product launch process. Flexible manufacturing offers increased modularity, scalability, and efficiency. The "plug-and-play" nature of FMP allows for a variety of corrective lenses to be manufactured either in small-scale pilot lots or full-scale commercial lots all the while leveraging dedicated resources. The strategic benefits resulting from these improvements are as follows:

Enabling Large Scale Clinical Builds

Clinical trials must take place during Stage Gate 3 to prove patient safety and patient satisfaction while using the product. Given that FMP is capable of commercial-scale manufacturing, it has the ability to produce far more contact lenses than could an R&D pilot line for clinical trials. Vision Care would be able to use FMP to support larger clinical trials, creating the opportunity to receive more feedback from patients and assess the manufacturability of the lens at scale.

Supporting In-Market Assessments and Small Market Launches

FMP production rates can be scaled-down or ramped-up on an as-needed basis. Unlike existing lines, FMP is meant to meet any level of demand. Therefore, Vision Care now has the ability to test the market by offering a small-market launch (a soft launch). The benefit to this is two-fold. Firstly, it provides the ability to observe the manufacturability of a new contact lens product at a commercial-scale (vs. at pilot scale) earlier in the development process. This will reveal any unexpected abnormalities or uncover issues that only occur when manufacturing high volumes of product for long periods of time. Secondly, small market launches allow Vision Care to quickly obtain patient feedback regarding quality, comfort, and effectiveness. If needed, Vision Care can adjust the product accordingly to improve patient experience before executing a much wider product launch.

Improved Launch Cadence

Given that the same team of technicians will be running this line, changeovers between equipment and materials will ultimately become quicker due to a decreased learning curve.

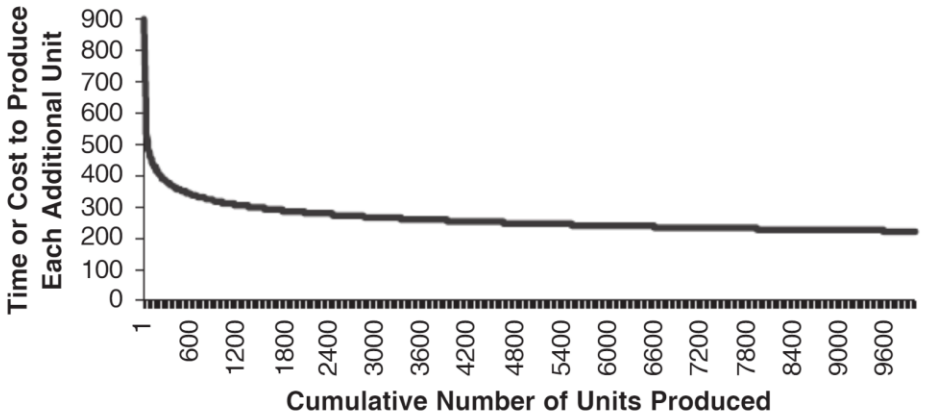

Figure 4-3: Illustration of a typical learning curve. Source: Linton and Walsh

Arguably, the learning curve for FMP will not exactly replicate Figure 4-3 given that this is a new technology and steps must first be taken to understand the equipment. However, according to Linton and Walsh, new technologies are still worth the investment despite complicated learning curves as long as the rate of learning is understood, physical constraints for learning are identified, and these physical constraints can be removed over time. Lessons learned will carry forward with the team and will be applied when executing new projects. As a result, line characterization will ultimately move more quickly than if it were to take place on an existing generational technology.

Decreased Manufacturing Fleet Disruption

Traditionally, manufacturing lines run 24/7 to continuously produce contact lenses to be sold around the world. However, when a new contact lens product is being introduced into the market, it must first be tested and proven viable on an existing manufacturing line. This means that the line would need to stop production so that it can undergo product characterization and line validation for the new lens. This interruption can take place multiple times during the product development cycle as testing is iterative. Due to the capacity constraints and low amounts of buffer stock, when a manufacturing line is stopped for any reason there will be a direct impact on the bottom line. Effectively, the effort required to prepare to launch a new product directly translates to less revenue in a capacity constrained environment. Early estimates of leveraging FMP for product development predict a decrease in existing manufacturing fleet disruption between 10-30%.

Improvements in Product and Process Scale-Up Robustness

Previously, new products were developed on the pilot lines that were physically located in the R&D building (Figure 4-4).

Figure 4-4: Jacksonville Site Overview

Upon entering Stage Gate 3, the process was transferred to the manufacturing floor in the Manufacturing building (Figure 4-4). Attempting to replicate results found using the small-scale pilot line on the large-scale manufacturing line proved difficult and frequently slowed down the launch process. However, by using FMP as both the pilot line and commercial production platform simultaneously, the transfer from the experimentation phase to the production phase is more predictable and efficient. This will allow the product development team to focus on optimization opportunities rather than trying to adequately mimic fundamental features between the two lines.

4.3 Potential Risks and Challenges

The benefits outlined above give reason to invest in FMP as a technology platform moving forward. However, the line has still yet to be proven functional. Software bugs are continuously addressed and hardware inconsistencies are uncovered as the line operates over time. Additionally, enabling FMP's success long-term will require process reconfigurations from

supporting functions such as research and development, manufacturing operations, supply chain, and distribution.

4.4 Chapter Summary

FMP ultimately enables greater innovation by employing new technologies. The modularity of FMP creates the ability to manufacture any contact lens in the Vision Care portfolio. Additional benefits include large-scale clinical builds, small market launches, shorter product development cycles, decreased impact on producing lenses for sale, and improved technical knowledge transfer. This thesis explores the technical feasibility of FMP in the following chapter.

5 Flexible Manufacturing Technical Feasibility

Now that the value of flexible manufacturing technology has been shown, Chapter 5 will explore its realization by analyzing the technical capability of the Flexible Manufacturing Platform during the initial implementation phase. This is accomplished by performing a case study on the heat seal characterization process. To reiterate, characterizing a process means to determine the process controls required to produce a viable product. The critical parameters to the heat seal were identified, defined, and studied to ultimately create a process capability model using JMP Statistical Software. Conducting the heat seal case study also provided valuable insight into the technical capability of the line as a whole since the day-to-day operations were closely observed.

5.1 Heat Seal Characterization Case Study

The heat seal was chosen as a case study due to its critical importance in the contact lens manufacturing process. The heat seal ring is the circular shape encompassing the plastic package bowl – the plastic package bowl houses the lens (Figure 5-1).

Figure 5-1: Heat Seal Location

Moreover, the heat seal ring is the point of contact where the heat seal die applies heat and pressure to the foil, effectively sealing the foil onto the plastic. If this seal were to be compromised at any point before the lens reaches the eye of the patient, then a health risk is introduced. As such, it is vitally important to have a strong heat seal that protects the contact lens from the outside environment by maintaining a sterile barrier. However, the heat seal cannot be so strong a seal that peeling the foil off of the plastic package becomes an unpleasant experience for the patient (Figure 5-2).

Figure 5-2: Breaking the seal to open a contact lens package

A 5-person cross-functional core team was created to further investigate the parameters needed to delicately balance a strong seal protecting the lens with a pleasant package opening experience for the patient. The heat seal characterization core team included the Project Leader, the FMP Software Engineer, the NPI Process Engineer, the Validation Quality Engineer, and the Design of Experiments Subject Matter Expert. To characterize the FMP heat seal, the following input variables were evaluated:

- Contact Time (sec)
- Contact Temp (°C)
- Contact Pressure (lbF)
- Reduced Headspace Heat Seal (on vs. off)
- Foil Press (on vs. off)

Note that contact time, contact temperature, and contact pressure are programmable settings into the heat seal whereas Reduced Headspace Heat Seal (RHSS) and foil press are physical configurations of the heat seal. To clarify further, RHSS is a method used to help prevent the lens from sticking to the inside of the foil package. A lens sticking to the inside of the foil is undesirable because the lens could potentially lose contact with the liquid saline. In this case, the lens will dry out and become unusable until it is re-saturated. After the foil has been sealed into place (either with or without using RHSS), foil press is implemented. Foil press is a method used

to help prevent the lens from folding in on itself (Figure 5-3). A folded lens runs the risk of resting in a deformed state and subsequently complicating the patient experience of placing the lens onto the eye.

Figure 5-3: Example of a contact lens folded in on itself (sample was collected in a controlled experiment)

Finding the balance of settings at which the heat seal does not degrade prematurely but yet does not worsen the patient experience requires careful experimentation. To begin, a baseline assessment was performed using heat seal settings from existing manufacturing line technology. Next, Two-Factor and Three-Factor Design of Experiments were executed followed by Lens-Package Interaction and Worst Case Scenario testing. The following subsections will elaborate each experiment further.

5.2 Heat Seal Characterization Approach and Results

To provide an analogy, the act of sealing the foil onto the plastic package can be compared to ironing a design onto a standard T-shirt (Figure 5-4). Firstly, transfer paper holding the design is laid directly on-top of the T-shirt. Next, the flat, uniform surface of the iron is heated to a high temperature. By placing the hot surface of the iron directly onto the paper design, applying pressure, and maintaining contact for a specific amount of time, the design adheres to the shirt.

Figure 5-4: Sealing using an Iron

In the case of the FMP heat seal, the heat seal die is of uniform temperature, presses down onto the foil, and maintains pressure thereby sealing the foil onto the plastic package. (Figure 5-5)

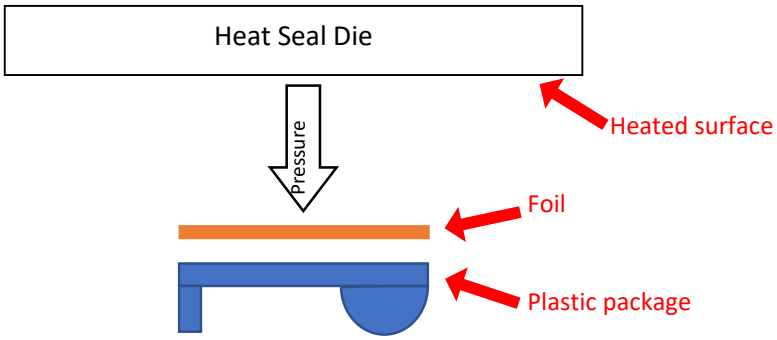

Figure 5-5: Heat Seal Illustration

There were two methods used to evaluate heat seal integrity from samples collected during the characterization study. The first method was Package Integrity Testing (PIT) and the second was peel-strength testing. PIT took place in the Quality Conformance (QC) Lab and consisted of placing a contact lens package into a small tank of liquid that had been dyed green. The tank was then pressurized and this pressure was maintained for a specific amount of time. After this time expired, the package was then removed and assessed closely. If green liquid were observed inside of the package bowl, then this was evidence of a compromised heat seal (Figure 5-6). Common causes for weak heat seals included pockets of air, commonly referred to as

"channels", along the seal (Figure 5-7) or misaligned foil. A sample successfully passed PIT if no green dye was observed inside of the package.

Figure 5-5: Heat seal failure example from a controlled experiment

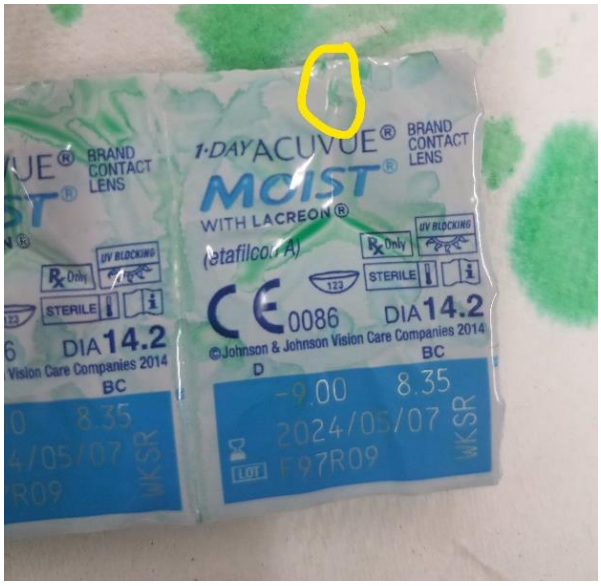

Figure 5-6: Heat seal failure example from a controlled experiment

The nature of these pass/fail results make PIT a binary test method. Given that FMP is undergoing validation, stringent statistical metrics must be achieved to prove reliability. Table 5-1 is used for binary testing methods to prove with 99% confidence that a sample will pass a test at least 99% of the time.

99% confident that the probability that a sample from the process passes the requirement is at least 99%		
sample size	maximum number of failures	minimum number of successes
459	0	459
662	1	661
838	2	836
1001	3	998
1157	4	1153
1307	5	1302

Table 5-1: Sample size Table for Binary (Pass/Fail or Attribute) Data

The second method used to evaluate heat seal integrity was peel-strength testing. This was achieved by using clinical equipment to measure the average peel strength required to open a package (Figure 5-8). A contact lens package was clamped into the base of the machine while the foil was gripped by the "claws" of the machine. Next, the foil was slowly peeled off in a controlled manner. The equipment leveraged a load a cell to continuously capture the force required to separate the foil from the plastic package.

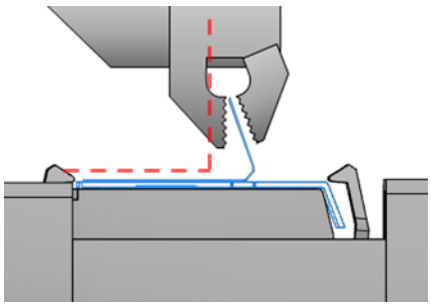

Figure 5-7: Diagram of peel-strength testing

Patient feedback data gathered from clinical trials was used to determine the peel-strength metrics of success. There must be a 99% confidence that at least 80% of the packages have an average load peel force value less than or equal to *MAX* lbf (actual values will be disguised for the remainder of this thesis to protect JJV intellectual property and data privacy). More specifically, clinical trials reveal that 100% of patients prefer an average peel strength force of *AVG* lbF, while only 72.2% of patients found an average peel strength force of *~2*AVG* lbF to be acceptable (Note: *MAX* lbf = *2.5*AVG* lbf). As such, a maximum value of *~2*AVG* lbF average peel strength was set throughout the heat seal characterization case study. Patient feedback data also revealed that an average peel strength around *~0.9*AVG* lbF risks too weak a seal and may potentially fail Package Integrity Testing. Therefore, the target range was between

*~0.9*AVG* lbF and *~2*AVG* lbF. Further alterations to this target range would depend upon the seal integrity results from Package Integrity Testing.

5.2.1 Baseline Assessment

The heat seal settings include contact time (sec), contact temperature (°C), and contact pressure (lbF). To start, a baseline run was executed to gain an understanding of the current heat seal performance. The values for time, temperature, and pressure were leveraged from existing generational technology – the design for the FMP heat seal was based upon this technology while incorporating additional improvements.

Over the span of three hours, a total of 2400 sealed packages were collected with 2000 submitted to the QC Lab for Package Integrity Testing and 160 submitted for peel-strength testing. It is important to note that these packages did *not* contain any contact lenses. This is because evaluating heat seal integrity at this stage did not require a lens in the package. Any package sample that was not submitted to PIT or peel-strength testing was reserved as a spare to be evaluated as needed.

Below is an abbreviated table of the run plan and results:

Baseline Assessment							
Run #	**Start Date**	**Start Time**	**Sample Size**	**PIT Sample Size**	**PIT Failures**	**Peel-Strength Sample Size**	**Avg. Peel Force (lbF)**
1	6/5/19	11:10 am	600	500	1	40	~1.5*AVG
2	6/5/19	12:10 pm	600	500	0	40	~1.5*AVG
3	6/5/19	1:10 pm	600	500	4	40	~1.5*AVG
4	6/5/19	2:10 pm	600	500	0	40	~1.5*AVG

Table 5-2: Baseline Assessment Run Plan and Results

As noted above, 500 samples were submitted for PIT and 40 to peel-strength testing. Of the 2,000 samples that underwent PIT, only five failures were observed. This suggests that the existing heat seal process parameters may be sufficient for FMP as it meets the acceptance criteria outlined Section 5.2. Additionally, average peel strength values hovered around *~1.5*AVG*, which also meets the acceptance criteria. The plot below (Figure 5-9) illustrates the average peel strength values in detail.

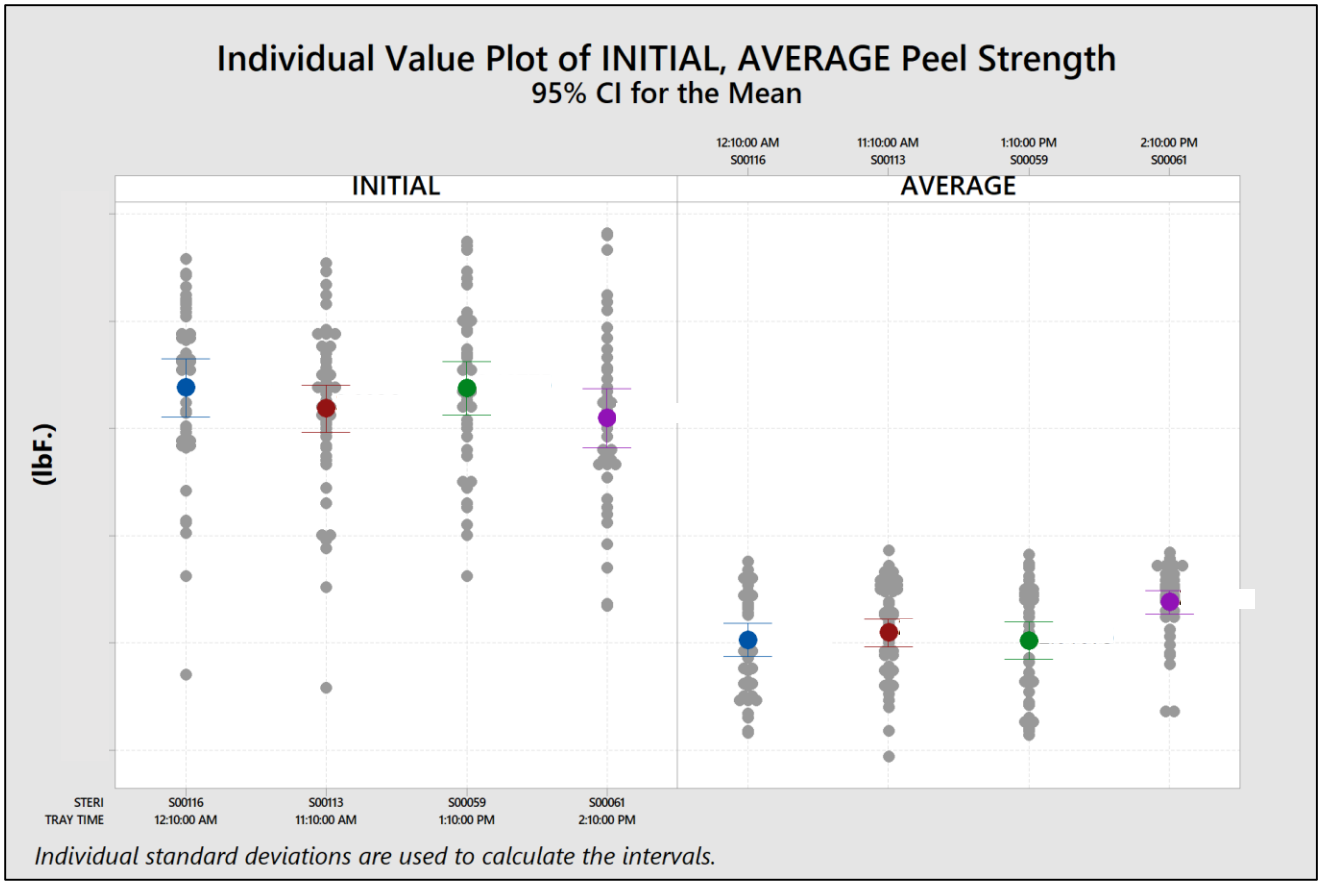

Figure 5-8: Baseline Assessment Peel Strength Results

5.2.2 Three-Factor Design of Experiments

Considering that the goal for the heat seal characterization study was to create a process capability model, ranges of temperature, pressure, and time needed to be studied. Therefore, a Three-Factor Design of Experiment (DOE) was executed in effort to determine cause-and-effect relationships. The results from the baseline assessment suggested reliability, so these were set as the control points. The extreme low and high points were set to test as wide a range as possible without compromising the equipment or the product. For example, setting any lower of a pressure point required disassembling the heat seal into its component parts and replacing the compression spring. While technically feasible, this has risks damage to the springs, increases the change-over time, and financial repercussions. Therefore, lower pressure points were not explored. Similarly, exceeding *MAX*°C risked melting the foil onto the plastic, effectively fusing the two together.

The desire was to not only observe the interactions between temperature, pressure, and time, but also to determine which were statistically significant and subsequently quantify the affect.

The full ranges were categorized as follows:

	Three-Factor DOE Variable Range				
	Extreme Low*	Low	Control Point	High	Extreme High
Temp (°C)	EXT_LOW	LOW	CONT	HIGH	EXT_HIGH
Press (lbF)	EXT_LOW	LOW	CONT	HIGH	EXT_HIGH
Time (sec)	EXT_LOW	LOW	CONT	HIGH	EXT_HIGH

Table 5-3: Three-Factor DOE Variable Range

*Note: The Extreme Low points were not captured

Over the course of three days, a total of 12,000 sealed packages were collected with 10,000 submitted to the QC Lab for Package Integrity Testing and 1,200 submitted for peel-strength testing. It is important to note that these packages did *not* contain any contact lenses. This is because evaluating heat seal integrity at this stage did not require a lens in the package. Any package sample that was not submitted to PIT or peel-strength testing was reserved as a spare to be evaluated as needed. Below is an abbreviated table of the run plan and results:

Three-Factor DOE								
Run #	Temp Target (°C)	Press Target (lbF)	Time Target (sec)	Start Date	PIT Sample Size	PIT Failures	Peel-Strength Sample Size	Avg. Peel Force (lbF)
1	CONT	CONT	CONT	6/12/19	500	4	60	~1.4*AVG
2	HIGH	HIGH	LOW	6/12/19	500	30	60	AVG
3	HIGH	LOW	LOW	6/12/19	500	28	60	AVG
4	HIGH	LOW	HIGH	6/12/19	500	0	60	~1.8*AVG
5	CONT	CONT	CONT	6/13/19	500	13	60	~1.3*AVG
6	LOW	LOW	LOW	6/13/19	500	57	60	AVG
7	LOW	LOW	HIGH	6/13/19	500	1	60	~1.6*AVG
8	LOW	HIGH	HIGH	6/13/19	500	1	60	~1.6*AVG
9	CONT	CONT	CONT	6/13/19	500	6	60	~1.5*AVG
10	HIGH	HIGH	HIGH	6/13/19	500	1	60	~2*AVG
11	LOW	HIGH	LOW	6/13/19	500	49	60	~0.7*AVG
12	CONT	CONT	CONT	6/13/19	500	4	60	~1.5*AVG
13	CONT	CONT	CONT	6/14/19	500	4	60	~1.5*AVG
14	CONT	CONT	EXT_HIGH	6/14/19	500	0	60	~1.8*AVG
15	CONT	EXT_HIGH	CONT	6/14/19	500	1	60	~1.4*AVG
16	EXT_HIGH	CONT	CONT	6/14/19	500	0	60	~1.7*AVG
17	CONT	CONT	EXT_HIGH	6/14/19	500	0	60	~1.9*AVG
18	EXT_HIGH	CONT	CONT	6/14/19	500	0	60	~1.7*AVG
19	CONT	EXT_HIGH	CONT	6/14/19	500	6	60	~1.5*AVG
20	CONT	CONT	CONT	6/14/19	500	4	60	~1.5*AVG

Table 5-4: Three-Factor DOE Run Plan and Results

Notably, there are significantly more failures observed under this experiment when compared to the baseline assessment, including at several of the control points. There are many potential explanations such as an error in executing the experiment, an error in testing the samples, or an error in the baseline assessment experimental plan. Given the tight quality controls on the manufacturing line and in the QC Lab, it is unlike to be a result of testing methods. Moreover, the test plan itself was created using JMP Statistical Software. Therefore, these failures are more likely to be a result of the variability in the system while executing the experiment. This variability was introduced by the efforts to improve line reliability (e.g. software debug and hardware change-outs).

Yet still, the data could be salvaged and was uploaded into JMP Statistical Software to perform ANOVA testing. Figures 5-10 and 5-11 show the ANOVA results for PIT and peel-strength respectively. Contact pressure as an input variable is deemed statistically insignificant in both analyses. Additionally, contact pressure induces the smallest effect out of the three input variables (time, temp, and pressure). These results provide enough quantitative evidence to setting the contact pressure at the *CONTROL* lbF value and making no further adjustments. However, additional qualitative evidence includes the inconvenience of changing the pressure. To change the contact pressure means to alter the compression of the spring inside of the heat seal. Constantly changing this compression could lead to premature part degradation over time. Therefore, given the statistical insignificance and risk to the physical components, contact pressure will remain at the calibrated *CONTROL* lbF value moving forward.

Least Squares Fit

Response Prob[ARO Failures]

Whole Model

Analysis of Variance

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|
Intercept	0.1760091	0.002911	60.47	<.0001*
Contact Temp (degC)	-0.000669	1.228e-5	-54.46	<.0001*
Contact Press. (lbf)	-1.168e-6	6.142e-7	-1.90	0.0599
Contact Time (s)	-0.034874	0.000205	-170.1	<.0001*
(Contact Temp (degC)-220.841)*(Contact Temp (degC)-220.841)	0.0001074	2.545e-6	42.19	<.0001*
(Contact Temp (degC)-220.841)*(Contact Press. (lbf)-1516.82)	5.128e-21	1.421e-7	0.00	1.0000
(Contact Press. (lbf)-1516.82)*(Contact Press. (lbf)-1516.82)	3.4813e-8	6.364e-9	5.47	<.0001*
(Contact Temp (degC)-220.841)*(Contact Time (s)-0.75)	0.0030986	4.738e-5	65.41	<.0001*
(Contact Press. (lbf)-1516.82)*(Contact Time (s)-0.75)	2.947e-19	2.369e-6	0.00	1.0000
(Contact Time (s)-0.75)*(Contact Time (s)-0.75)	0.081544	0.000715	114.02	<.0001*

Figure 5-9: ANOVA Results for Probability of a PIT failure

Analysis of Variance

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|
Intercept	-7.444866	0.537868	-13.84	<.0001*
Contact Temp (degC)	0.0375727	0.00227	16.55	<.0001*
Contact Press. (lbf)	-8.885e-5	0.000114	-0.78	0.4354
Contact Time (s)	1.7793735	0.037883	46.97	<.0001*
(Contact Temp (degC)-220.841)*(Contact Temp (degC)-220.841)	0.0010028	0.00047	2.13	0.0352*
(Contact Temp (degC)-220.841)*(Contact Press. (lbf)-1516.82)	0.0001219	2.627e-5	4.64	<.0001*
(Contact Press. (lbf)-1516.82)*(Contact Press. (lbf)-1516.82)	-2.474e-7	1.176e-6	-0.21	0.8338
(Contact Temp (degC)-220.841)*(Contact Time (s)-0.75)	0.0539628	0.008755	6.16	<.0001*
(Contact Press. (lbf)-1516.82)*(Contact Time (s)-0.75)	0.0023435	0.000438	5.35	<.0001*
(Contact Time (s)-0.75)*(Contact Time (s)-0.75)	-0.9857	0.13216	-7.46	<.0001*

Figure 5-10: ANOVA Results for Average Peel Strength

In the contour profile map below (Figure 5-12), contact pressure has been removed and only the relationship between contact temperature and contact time is studied. The blue rectangle is the range of process conditions that were tested as previously outlined in Table 5-3. Everything outside of the blue rectangle is an extrapolation based upon the DOE results. This map suggests to look at lower temperatures and longer contact times. The red shaded area represents the points at which the average peel strength will be higher than *2.5*AVG* lbF (the upper red region) and lower than *0.9*AVG* lbF (the lower red region). The green shaded region represents the points at which a package will fail PIT. Therefore, the white area is the region that meets desirable peel strength values while likely passing package integrity testing. Based upon this information,

another DOE spanning a lower temperature range and spanning a longer time range would be needed to further evaluate this process space.

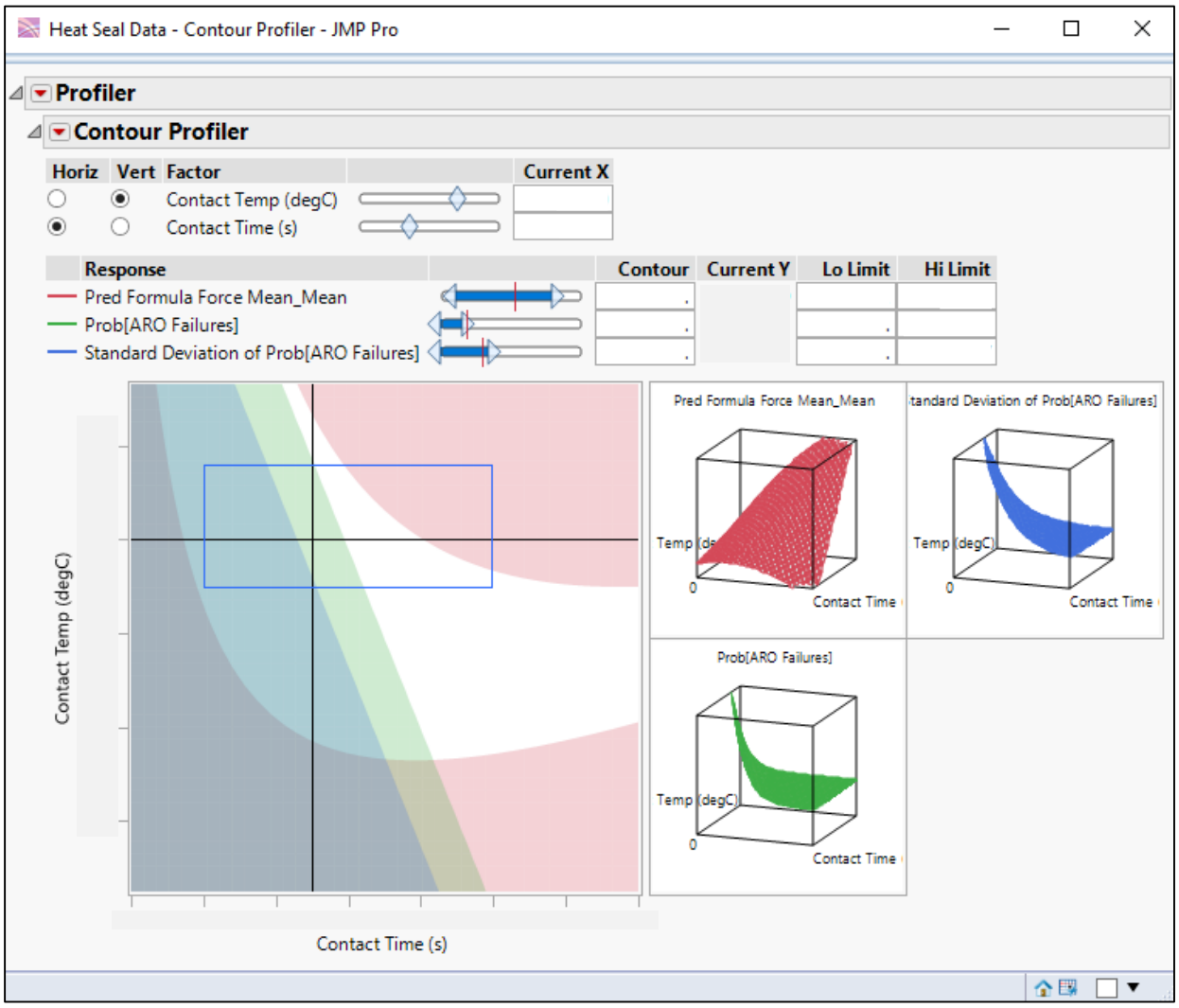

Figure 5-11: Three-Factor Contour Profile Map

However, first a root cause investigation into the large amount of PIT failures was needed. A dedicated task force of technicians, operators, and engineers studied the line to ultimately determine that the likely culprit was damaged equipment in the De-Ionized (DI) Water Removal process step. DI Water Removal was three steps upstreaming of heat sealing; yet, it was greatly influencing the seal integrity because it was leaving water droplets around the ring (Figure 5-13). These water droplets were preventing the foil from making clean contact with the plastic package and thus causing channels in the foil. To test this hypothesis, samples were collected before and after replacing the damaged hardware to measure the effect.

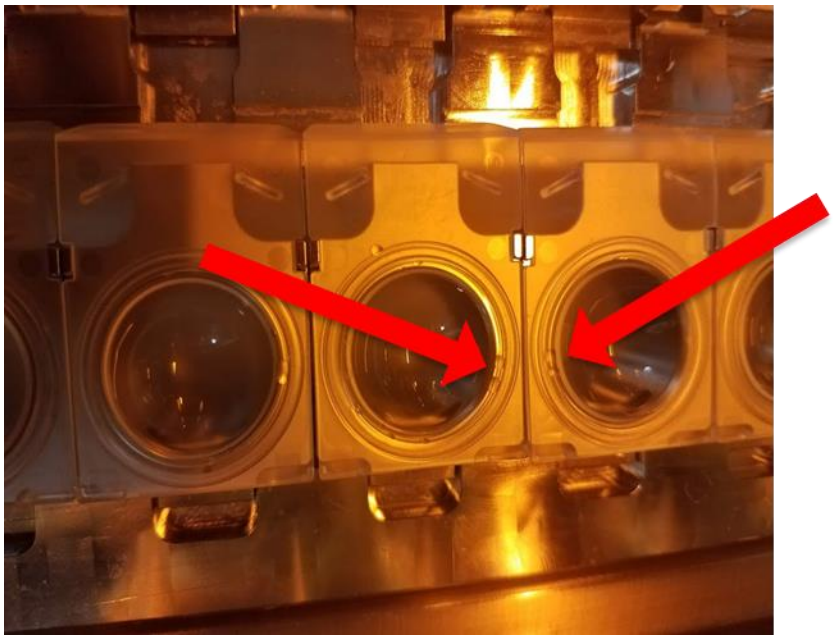

Figure 5-13: Water droplets resting on the package ring

5.2.3 DI Water Removal Nozzle Replacement Investigation

Observing the DI Water Removal module revealed that water droplets were left on the package after the DI removal process step. These water droplets had the potential to subsequently cause a channel in the heat seal ring, resulting in PIT failures. Five of the sixteen DI removal nozzles were categorized as damaged and were scheduled to be replaced. To test this hypothesis, a total of 3,600 samples were collected and submitted to the QC Lab prior to the nozzle replacement. Another 3,600 samples were collected and tested post-nozzle replacement. Furthermore, the position along the 15-package array was also captured in effort to evaluate how the heat seal performed across all fifteen packages. In other words, did the heat seal perform better/worse on the left side, center, or on its right side? Therefore, arrays 1, 2, and 3 were separately bagged and tagged. The results are as follows:

DI Water Removal Nozzle Replacement Investigation									
Run #	**Tray #**	**Date**	**Sample Size**	**Contact Temp (°C)**	**Contact Time (sec)**	**Array 1-5**	**Array 6-10**	**Array 11-15**	**Total ARO Failures**
1	1	6/27/19	600	CONT	CONT	0	0	1	**1**
1	2	6/27/19	600	CONT	CONT	0	2	2	**4**
1	3	6/27/19	600	CONT	CONT	0	0	2	**2**
2	1	6/27/19	600	CONT	1.1*CONT	1	0	0	**1**
2	2	6/27/19	600	CONT	1.1*CONT	3	0	0	**3**
2	3	6/27/19	600	CONT	1.1*CONT	0	0	2	**2**
Replaced nozzles on 7/15/19									
3	1	7/16/19	600	CONT	CONT	0	0	0	**0**
3	2	7/16/19	600	CONT	CONT	0	0	0	**0**
3	3	7/16/19	600	CONT	CONT	0	0	0	**0**
4	1	7/16/19	600	CONT	1.1*CONT	0	0	0	**0**
4	2	7/16/19	600	CONT	1.1*CONT	0	0	0	**0**
4	3	7/16/19	600	CONT	1.1*CONT	0	0	0	**0**

Table 5-4: DI Water Removal Nozzle Replacement Run Plan and Results

The results indicate that replacing the damaged nozzles resolved sporadic failures. Given this realization, another DOE was executed to confirm the results while exploring new process space.

5.2.4 Two-Factor Design of Experiments

Moving forward, pressure was deemed statistically insignificant in ANOVA testing (reference Section 5.2.2 for ANOVA analysis); therefore, it was removed as an independent variable.

A Two-Factor DOE was executed to measure the heat seal process parameters outlined in Table 5-6. Compared to the Three-Factor DOE completed in section 5.2.2, the temperature values in the Two-Factor DOE span a lower target range while the time values span a higher target range. These value were also informed by physical constraints of the equipment. For example, the heat seal die was programmed not to apply temperature less than EXT_LOW°C as temperature lower than this value may not be sufficient enough to seal the foil onto the package.

The full ranges were categorized as follows:

	Two-Factor DOE Variable Range				
	Extreme Low	Low	Control Point	High	Extreme High
Temp (°C)	EXT_LOW	LOW	CONT	HIGH	EXT_HIGH
Time (sec)	EXT_LOW	LOW	CONT	HIGH	EXT_HIGH

Table 5-5: Two-Factor DOE Variable Range

Over the course of eight hours, a total of 9,000 sealed packages were collected with 7,650 submitted to the QC Lab for Package Integrity Testing and 300 submitted for peel-strength testing. It is important to note that these packages did *not* contain any contact lenses. This is because evaluating heat seal integrity at this stage did not require a lens in the package. Any package sample that was not submitted to PIT or peel-strength testing was reserved as a spare to be evaluated as needed.

Below is an abbreviated table of the run plan and results. Factor replicates were performed to improve model robustness:

Two-Factor DOE							
Run #	**Temp Target (°C)**	**Time Target (sec)**	**Start Date**	**PIT Sample Size***	**PIT Failures**	**Peel-Strength Sample Size**	**Avg. Peel Force (lbF)**
1	CONT	CONT	7/18/19	510	0	20	~1.3*AVG
2	EXT_HIGH	CONT	7/18/19	510	0	20	~1.7*AVG
3	LOW	LOW	7/18/19	510	1	20	AVG
4	LOW	HIGH	7/18/19	510	1	20	~1.5*AVG
5	CONT	EXT_LOW	7/18/19	510	1	20	~0.9*AVG
6	HIGH	HIGH	7/18/19	510	0	20	~2.1*AVG
7	LOW	LOW	7/18/19	510	0	20	AVG
8	CONT	CONT	7/18/19	510	1	20	~1.5*AVG
9	HIGH	LOW	7/18/19	510	0	20	~1.3*AVG
10	LOW	HIGH	7/18/19	510	0	20	~1.5*AVG
11	EXT_LOW	CONT	7/18/19	510	1	20	AVG
12	HIGH	LOW	7/18/19	510	0	20	~1.1*AVG
13	CONT	EXT_HIGH	7/18/19	510	0	20	~2.0*AVG
14	HIGH	HIGH	7/18/19	510	0	20	~2.1*AVG
15	CONT	CONT	7/18/19	510	0	20	~1.5*AVG

Table 5-6: Two-Factor DOE Run Plan and Results

*Note – the PIT sample size differs from the Three-Factor DOE due to now capturing the array location. For example, 170 samples were submitted from Array 1-5, Array 6-10, Array 11-15 respectively. Therefore, 170 x 3 = 510 total.

The Two-Factor DOE was centered around the newly proposed process settings for temperature and time. Informed by the results from the Three-Factor DOE, these new values were hypothesized to reliably produce strong heat seals with acceptable peel-strength results. Therefore, they were set to be the *CONTROL* values. Ultimately, there were only five PIT failures throughout Two-Factor DOE experiment. Figure 5-14 is a visual depiction of the PIT failures (referred to as ARO failures in the graph) separated by contact temperature:

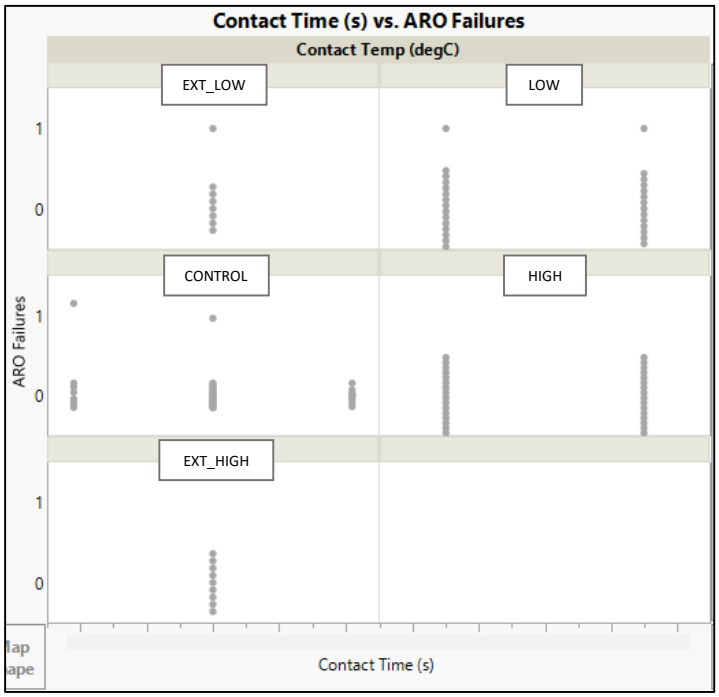

Figure 5-14: Two-Factor DOE PIT Failures

It is important to note that all variations of process settings tested meet the acceptance criteria as outlined in Section 5.2. These results gave confidence in the proposed process of *CONT*°C and *CONT* sec as well as in defining the worst case scenario values at *LOW*°C and *LOW* sec that were prescribed in the Two-Factor DOE.

The dataset from the Three-Factor DOE and the dataset from the Two-Factor DOE were combined to evaluate the larger process space simultaneously. However, it is difficult to analyze

the combined set due to the confounding factors that were present in the Three-Factor DOE due to the damaged DI Water Removal nozzles. As a result, there are more predicted failures at higher contact times and temperatures than should be expected. This was taken into account during the final analysis.

Below is a visual of the combined datasets. The red shaded area represents the points at which the Two-Factor DOE results predict a PIT failure. The green shaded area represents the points at which both the Two-Factor DOE and Three-Factor DOE results combined predicted a PIT failure. The blue shaded area represents the points at which the predicted average peel strength is *~2*AVG* lbF and above. Lastly, the blue dotted line represents the various combinations of time and temperature resulting in a *~1.5*AVG* lbF average peel strength. Therefore, the combinations of contact temperature and contact time that fall along the blue dotted line *and* are in the white region are the desirable process settings. The black crosshairs mark the intersection of the control values of temperature and time; thereby showing that these values are sufficient as the default setting.

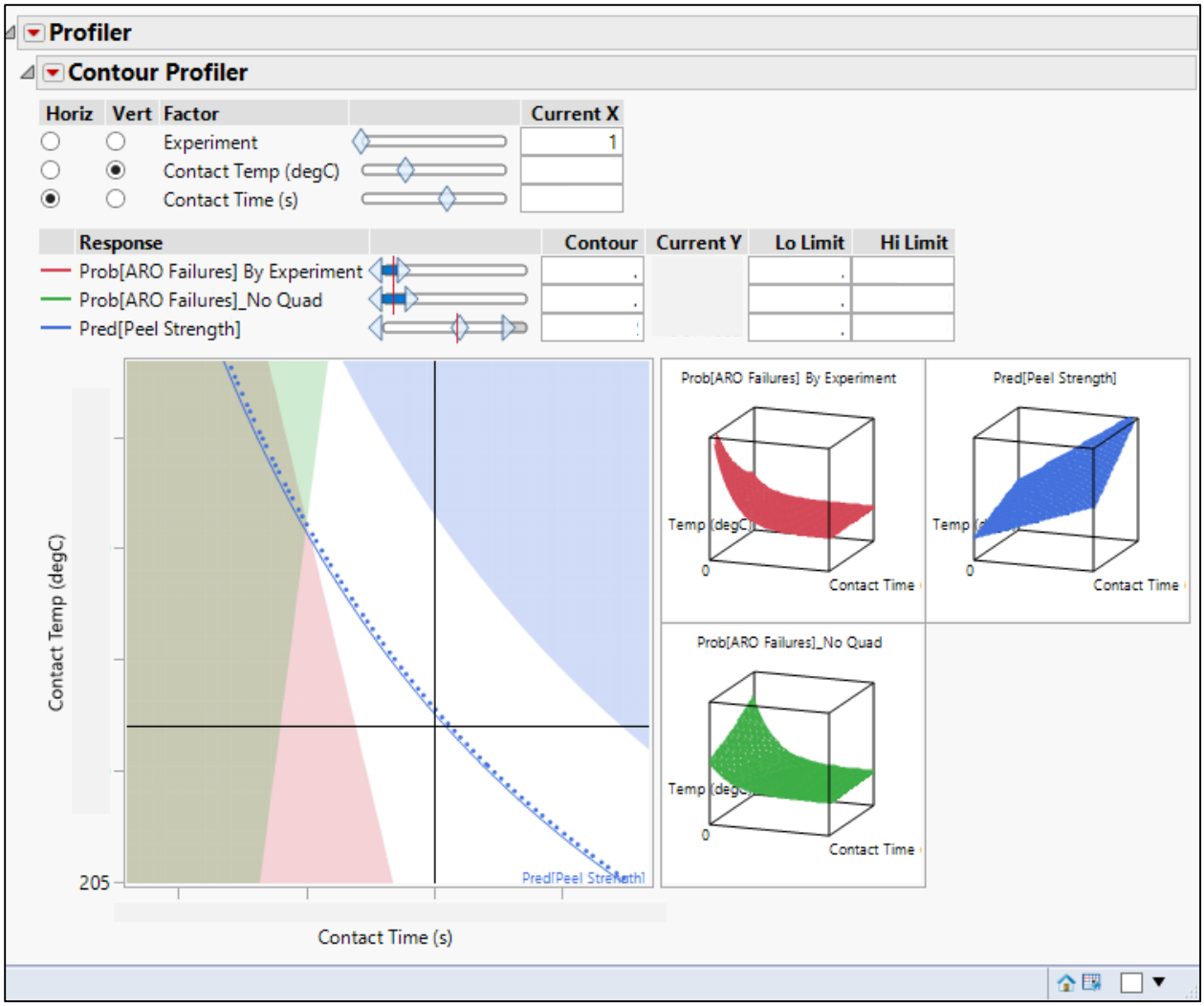

Figure 5-15: Two -Factor Contour Profile Map

5.2.5 Lens-Package Interaction Testing

Lens-Package Interaction (LPI) testing was executed to evaluate the rate of lenses folding and/or sticking to the packaging during ship testing. Ship testing is a method used to mimic the vibration and handling that packages would experience during actual transportation. Samples representative of the entire SKU range (-9.00 to +6.00 in sphere power) were collected while toggling RHSS on and off and toggling foil press on and off.

Table 5-7 shows the run plan:

Lens-Package Interaction Testing				
Run #	**Foil Press**	**RHSS**	**Sample Size**	**Sphere Power**
1	ON	ON	1800	-9.00
2	ON	ON	1800	-6.00
3	ON	ON	1800	-0.25
4	ON	ON	1800	+6.00
5	OFF	ON	1800	-9.00
6	OFF	ON	1800	-6.00
7	OFF	ON	1800	-0.25
8	OFF	ON	1800	+6.00
9	ON	OFF	1800	-9.00
10	ON	OFF	1800	-6.00
11	ON	OFF	1800	-0.25
12	ON	OFF	1800	+6.00
13	OFF	OFF	1800	-9.00
14	OFF	OFF	1800	-6.00
15	OFF	OFF	1800	-0.25
16	OFF	OFF	1800	+6.00

Table 5-7: Lens-Package Interaction Testing Run Plan

The results from this experiment were not able to be collected prior to the conclusion of the internship. Therefore, next steps for LPI analysis include placing the packages into 30-pack cartons and subsequently sending these cartons offsite for ship-testing. Ship testing is expected to span at minimum two weeks.

5.2.6 Failure Modes Worst Case Scenario

Finally, a worst case scenario was executed to evaluate heat seal integrity under potential worst-case conditions. These parameters are chosen so as to mimic the conditions that, when occurring together, are most likely to compromise the integrity of the heat seal. The conditions are defined in the “Worst-Case” column in Table 5-8 below:

Worst Case Scenario		
Characteristic/Variable	**Heat Seal Configuration and Process**	
	Proposed Process	**Worst-Case**
Heat Seal Temp Range (˚C)	CONTROL ± 4	LOW ± 4
Heat Seal Contact Time (sec)	CONTROL ± 0.3	LOW ± 0.3
Saline Dose Volume (mg)	CONTROL ± ~2.5%	~.025*Control ± ~2.5%
Lidstock Type	Final Product Foil	Similar Foil A and Similar Foil B
Reduced Headspace	Yes	Yes
Foil Press	Yes	Yes
Heat Stroke Count	0 to 5,000	0-1,000 and 5,000+
Sterilization Profile	Production	Worst-Case
Sterilization Cycles	One	Two
Lens Sphere Power	Entire SKU Range	-8.00 Low Add Power

Table 5-8: Worst Case Scenario Configuration

Table 5-9 outlines the worst case scenario run plan:

Run #	Lidstock Type	Saline Dose Volume (± 25 mg)	Temp Target (±4 °C)	Time Target (±.3 Sec)	Heat Stroke Count	Sterilization Profile	Steri Cycles	PIT Sample Size	PIT Failures
1	Similar Foil A	1125	Low	Low	0-1,000	Production	1X	1620	135
2	Similar Foil A	1125	Low	Low	0-1,000	Worst-Case	2X	1620	124
3	Similar Foil B	1125	Low	Low	0-1,000	Production	1X	540	56
4	Similar Foil B	1125	Low	Low	0-1,000	Worst-Case	2X	1620	86
5	Similar Foil B	1125	Control	Control	0-1,000	Production	1X	-	-
6	Similar Foil A	1125	Low	Low	> 5,000	Production	1X	1620	16
7	Similar Foil A	1125	Low	Low	> 5,000	Worst-Case	2X	1620	21
8	Similar Foil B	1125	Low	Low	> 5,000	Production	1X	540	13
9	Similar Foil B	1125	Low	Low	> 5,000	Worst-Case	2X	1620	28
10	Similar Foil B	1125	Control	Control	> 5,000	Production	1X	540	0

Table 5-9: Worst Case Scenario Run Plan and Results

Worst case scenario results revealed an outside influence causing unexpected PIT failures. During the Two-Factor DOE, a heat seal process setting of *LOW*°C and *LOW* sec was tested

resulting in only one package integrity testing failure. However, during the worst case scenario testing, a heat seal process setting of *LOW*°C and *LOW* sec caused nearly catastrophic failures.

Figure 5-16 depicts the results (note, ARO failures are the same as PIT failures):

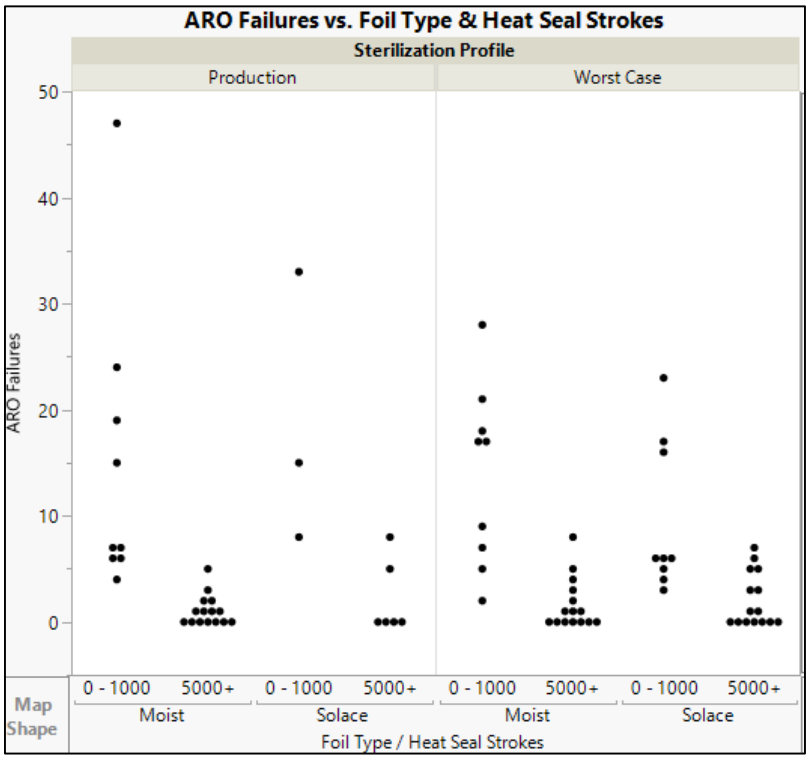

Figure 5-16: Worst Case Scenario PIT Failures

These results counter-intuitively suggest that a "dirty" heat seal die performs better than does a "clean" heat seal die. In other words, it suggests that the more strokes the heat seal equipment undergoes before it is cleaned, the stronger a seal it creates. Yet, this seems illogical. Unfortunately, there is daily variability in the FMP's performance making it difficult to measure the true effect of a worst case scenario. For example, initial investigation suggest that saline dose volume was initially too high inside of the package bowl, causing some packages to be overdosed above the stipulated limit. Too much saline in the package could plausibly cause a heat seal failure.

5.3 Heat Seal Conclusion and Next Steps

While the proposed heat seal process of *CONTROL*°C and *CONTROL* seconds should be sufficient, there are remain confounding factors that will need to identified and quantified. Potential factors causing heat seal failures requiring further investigation include:

- DI water removal process (pressure, blow time, etc.)
- Saline dose volume (filter clogging vs. dispensing accuracy)
- Sterilizing the package after it has been placed into a carton
- Switching between different types of foil

Each of these factors could be studied by conducting screening tests or by monitoring these values through passive sampling. The goal would be to better understand the tolerance around the current set points and the resulting impact.

When installing a new manufacturing line, the largest hurdle will be the unexpected obstacles. While the team can brainstorm potential risks and develop mitigation plans to minimize damage or delay, the technology still has never been used before and therefore will hold hidden hurdles. As such, best practice to characterize a new manufacturing line is:

1) Determine critical process parameters
2) Understand the effect of critical process parameters (and tolerance) through screenings
3) Define process edges and predicted failure rates
4) Confirm prediction through testing

Ultimately, FMP characterization started before the line was fully under control with all variables understood and minimal variation in output. This caused issues over time when interpreting results. Moving forward, it is recommended to continue conducting screenings around potential influences (e.g. saline dose volume and sterilization profile) as well as passively sample lots under the proposed process to monitor quality.

5.4 Chapter Summary

Overall, enough data was able to be collected to create a process capability model. Throughout the heat seal characterization study, the FMP was continuously undergoing tweaks and alterations. This caused inconsistency in day-to-day reliability. For example, the damaged DI Water Removal nozzles skewed a portion of the heat seal data. However, this is naturally a part of the process in installing a new manufacturing line that incorporates new technology. Ultimately, the heat seal setting of *CONTROL*°C and *CONTROL* sec were found statistically sufficient. This setting will continue to be monitored and evaluated to ensure viability.

6 Flexible Manufacturing Platform Current State Analysis

Performing the heat seal characterization case study allowed for daily observation of the FMP work processes, support systems, and organizational structure. There was daily interaction with the FMP team to align the schedule, gather resources, communicate recent results, discuss potential risks, etc. Additionally, challenges and disruptions to manufacturing process steps upstream of the heat seal step likely still impacted the seal integrity (see Section 5.2.3 for an example). Therefore, a full understanding of how FMP was functioning holistically was necessary. This chapter describes these observed current state operations.

6.2 Three-Lens Analysis

6.2.1 Strategic Lens

Vision Care is a matrixed organization that rotates individuals through various jobs frequently. Teams are formed around both products and platforms. In the case of the first contact lens product launch using the Flexible Manufacturing Platform, the launch team consists of representatives from many functions, including supply chain, marketing, finance, distribution, manufacturing, process engineering, as well as the team lead. Table 6-1 illustrates this matrix across multiple products.

	Supply Chain	Marketing	Finance	Distribution	Manu-facturing	Process Engineering
Product A	SC Person 1	Mkt Person 3	Fin Person 5	Dist Person 4	Mfg Person 2	PE Person 4
Product B	SC Person 3	Mkt Person 2	Fin Person 2	Dist Person 2	Mfg Person 2	PE Person 2
Product C	SC Person 1	Mkt Person 1	Fin Person 1	Dist Person 3	Mfg Person 1	PE Person 5

Table 6-1: Example of cross-functional launch teams

As a result of this matrix, it can be difficult to hold people accountable for various tasks. For example, if the same person is supporting multiple product launches, then he or she will likely

only be able to work on one at a time. Moreover, from a process flow perspective and as mentioned in Section 3.2, R&D traditionally transfers product ownership to manufacturing operations in Stage 3. This transfer is not so clear-cut with FMP because FMP is an R&D-owned asset and is meant to continuously fluctuate between 1) R&D pilot projects, 2) commercial scale-up for new product launches, and 3) supporting the existing manufacturing fleet in times of high-utilization. This lack of clarity creates opportunities for miscommunication and misalignment. However, there is also a valuable opportunity to restructure the new product design and development process around FMP to be more flexible and responsive to market demand.

6.2.2 Political Lens

As the Flexible Manufacturing Platform transitions from the equipment installation phase to the process characterization phase, there is a notable shift in influence from the FMP Operations Team to the R&D Process Engineering Team. This is because, in the beginning FMP Operations oversaw equipment installation efforts, debugged software issues, and performed troubleshooting activities whenever the manufacturing line unexpectedly stopped. Once the line reaches a certain level of continuous operation and has met minimum safety requirements, the R&D Process Engineering team starts to ramp up the process characterization work. During process characterization, each manufacturing process step of FMP undergoes a series of detailed experiments to determine the critical parameters needed to reliably produce a high-quality product. The Process Engineers create the daily agenda and prioritize resources accordingly. However, the Operations team still readily supports all efforts since all involved are working towards the shared end goal to ultimately validate the line. Following process characterization, the Operations team will then work to maintain equipment reliability, high line throughput, and final product quality.

Notably, while there is minimal conflict among upper management teams regarding the importance of investing in the Flexible Manufacturing Platform, there is disagreement over the long-term use of FMP. More specifically, R&D Leaders purchased FMP to execute a multitude of pilot projects to ultimately create new types of corrective lenses. However, in a capacity-constrained environment, Manufacturing Operations Leaders view FMP as another resource to manufacture and sell lenses for the legacy brands. Historically, these two groups have worked sequentially on product launches, but now they are working in parallel and this is causing

discordance in ownership. Both groups are aligned in the importance of innovation and regularly launching new product lenses into the market to remain competitive. However, the two groups disagree over how to get this done (i.e. does FMP spend half the year piloting multiple projects and the other half mass-producing one product).

6.2.3 Cultural Lens

All decisions at Johnson & Johnson are guided by the Credo, which captures the company's core values and mission. It ensures that all employees worldwide display the same levels of commitment to the patient, employee, local community, and shareholders in that specific order. The larger in size a company grows, the more important it becomes to share a sense of culture and be informed by the same set of values.

At Johnson & Johnson Vision Care there are additional factors playing on top of the fundamental Credo. These include 1) a deep passion and genuine enjoyment for helping the world to see better by producing quality contact lenses and 2) the southern hospitality that is readily found across Jacksonville, FL (Figure 6-1). The Credo guides individual and group decision making, while people's passion for the product ensure that they are actively engaged and always putting forth their best effort, and lastly the southern hospitality means people treat other with warmth and kindness. In the case of the FMP team, everyone works hard to keep the line steadily progressing towards milestone achievements. It is a supportive environment based upon strong relationships and a team-first mindset. This is a strength that will need to be leveraged to maintain future success.

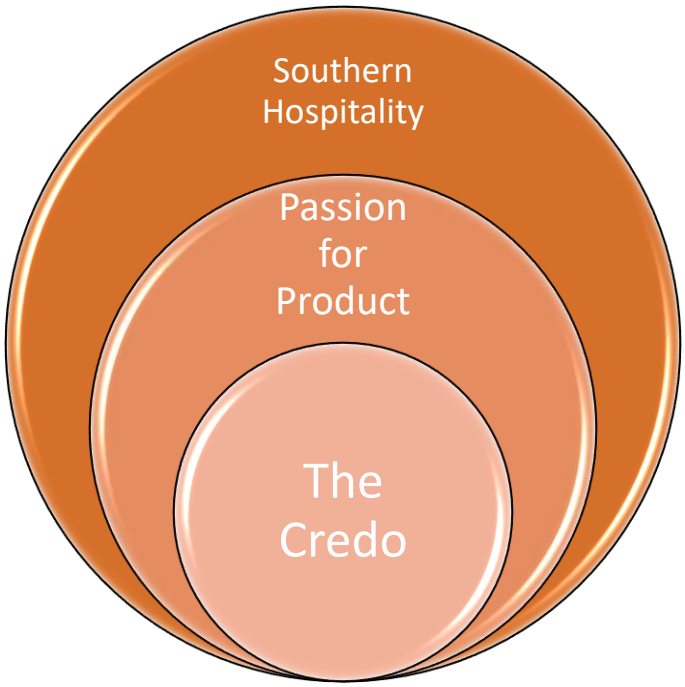

Figure 6-1: A simplified representation of the cultural make-up of Johnson & Johnson Vision Care

6.3 Task Management

6.3.1 FMP Internal Communication Methods

The daily morning meetings are "all-hands" style with FMP technicians, hardware owners, R&D engineers, quality engineers, and others attending the meetings to verbally discuss the day's objectives. The meeting is led either by the FMP Operations Manager or the FMP Design Engineer Lead, depending upon who is in the room at the start of the meeting. There is little use of visual aids when discussing the day's goals, nor is their clear accountability for who owns which item. These meetings are often quick, yet leave priority work unclear. For example, the software engineer may have ten action items on their agenda ranging in scope and importance. But the highest priority items were not communicated to the team and therefore the software engineer may be continuously distracted with ad hoc requests. If the team were aligned on which action items were most important then the software engineer would better be able to focus.

Presently, communication between day shift and night shift on FMP consists of passing information via either word-of-mouth or through writing onto a white board. First shift typically runs Monday through Friday 6am – 3pm while night shift typically runs Monday through Friday

3pm – 12am (sometimes these hours shift depending upon unique requirements throughout the validation process). While the line is being installed, no one is scheduled to work on the weekends; however, once the line is fully operational and producing contact lenses, there will be technicians servicing the line 24/7. At midnight, when night shift is shutting down the line and wrapping up, one technician will craft and send an email to day shift explaining what was accomplished that night. The amount of detail to include in this email is at the discretion of the author as there is no standard communication template. Such methods of communication leave room for misinterpretation due to the lack of standardization.

6.3.2 Visual Aids

There is one television monitor on the manufacturing floor space. This monitor displays the same general information that is displayed on each of the television monitors lining the main hallways, cafeteria spaces, and other common spaces. Such information includes Vision Care site news, encouraging healthy lifestyles, reminding employees to follow standard EH&S policies, and displaying company goals for the year. In other words, there is no unique information to FMP being shown here.

6.3.3 Manufacturing Floor Arrangement

The Flexible Manufacturing Platform is visited by different stakeholders daily. Even the CEO and Chairman of Johnson & Johnson as well as the Executive Vice President of Medical Devices visited FMP during the extent of this research. All of this activity creates a high demand for table space, desk space, and computer stations on the floor. Moreover, several of the available tables are covered with contact lens samples, spare parts, tooling, and other hardware, meaning they cannot be used as workspaces. Further observation revealed that there do not exist any tool tracking measures on the manufacturing floor. If a tool were to get lost, there is no way to know who had it last and at what time. Nor is their shadow boarding so it would be difficult to be sure a tool was missing in the first place. For example, there was a moment on day shift when one technician spent more than twenty minutes looking for a hand mirror that was not in the toolbox. In the end, this hand mirror was found by the night shift sitting inside of one of the modules. Lastly, the toolboxes themselves are often cluttered and scattered about the floor.

6.4 Line Operations

While the manufacturing line is capable of producing high-quality lenses, the technicians and engineers are still constantly working to improve reliability and total throughput. Whenever the line suddenly stops due to an unforeseen issue, new problems may arise as a result of the pause in conveyor movement. This is due in part to the thermodynamics of the equipment. Metal parts heat up when in continuous motion; however, when the line stops suddenly and there is no movement for an extended period of time, these parts will begin to cool. These slight temperature changes are enough to cause shifts in the way the hardware interacts with each other and can ultimately cause disruption when the line is restarted to achieve steady state again. In these cases, issues experienced when restarting may take even longer to resolve than the initial cause for downtime. As a result, oftentimes sections of the manufacturing line that are unaffected by any troubleshooting issue will continue to run to avoid issues upon a restart (lenses produced during this time are automatically discarded). This start and stop behavior induces unpredictability in the process characterization results. For example, if one thousand samples need to be collected from heat seal continuously and there is a sudden line halt upstream of heat seal, then that would introduce time as a factor in the experiment. Whereas, originally, time was a non-factor. This unpredictability can make it difficult to produce repeatable results in the long term.

6.5 Chapter Summary

The cross-matrix organizational style employed by JJVC is effective; however, the traditional knowledge transfer from R&D to operations may not be readily applied to FMP. FMP is an R&D-owned asset that has considerable implications for manufacturing capacity, so there will need to be discussion and decisions as to FMP's long-term use. Those who currently work at FMP are very team-oriented but they are also currently consumed by a fire-fighting mentality that disallows them from executing operational improvement tasks. It appears that once the line is stable with few unplanned interruptions, the attention can be turned to improving work-flow processes.

7 Flexible Manufacturing Future State

Now that the current state of the Flexible Manufacturing Platform has been described, Chapter 7 will outline where FMP could improve in the near term. This chapter will suggest operational

changes and other recommendations that could aid in the overall goal to make FMP a reliable, flexible, and efficient manufacturing resource. First steps are to standardize various processes so that process outcomes become more predictable, and then implement subsequent improvement projects.

7.1 Ideal Future State

The ideal future state of FMP includes leveraging the line to conduct early stage research, execute both small and large scale product launches, and support the existing manufacturing lines in meeting growing demand for existing product. All of this would be made possible due to the Flexible Manufacturing Platform's ability to quickly changeover between products across the entire ACUVUE® Brand portfolio (Figure 7-1). Determining how much time is spent in each segment will ultimately be a leadership decision. Knowing "which process control system to switch, when to switch, and how to switch" (Jose-Fernando Jimenez et al. 2015) is a common issue when incorporating flexible manufacturing. This is because there will be many options available and paths forward to take at any given time, but ultimately a final decision must be made that is in alignment with the company's overall strategic objectives. However, there are a few areas of immediate improvement that will need to take place regardless of FMP's long term use.

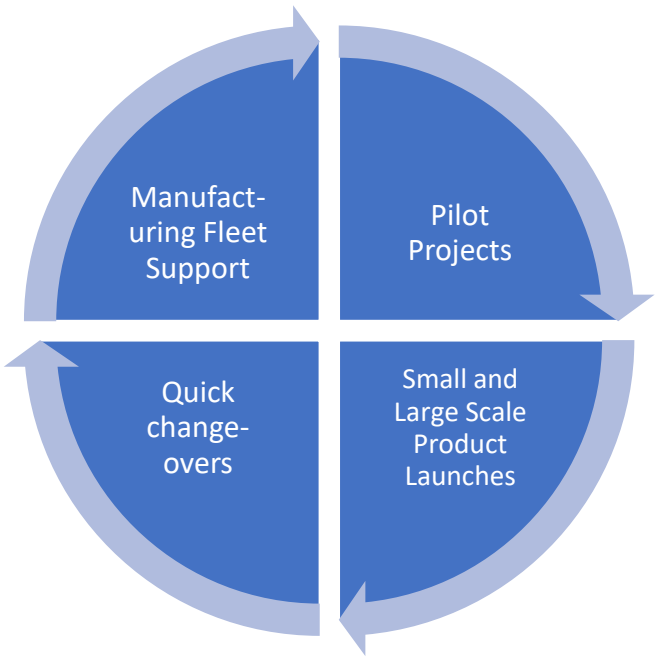

Figure 7-1: The Flexible Manufacturing Platform will routinely cycle among several capabilities

7.2 Opportunity Areas for Improvement

Communication between the FMP day shift and night shift can be improved by creating a standard shift carry-over template. This will ensure that the same amount of information is not only documented and conveyed but also to the same level of detail between each shift (Figure 7-2). To start, the carryover, also referred to as a "daily story", captures the date and shift information. Subsequent details fall into one of three buckets: 1) What has been done? 2) What needs to be done next? 3) What are our long-term goals? The first section captures all of the work that took place during the shift and outlines troubleshooting methods and results. The second section is the "To-Do" list which tells the upcoming shift exactly where to start their work and how to prioritize their efforts. Lastly, the third section of the shift carry-over provides project milestones in both the near-term and long-term. This is to ensure team 32alignment in that all members are working toward the same vision.

FMP Daily Story
Thursday, May 16, 2019
Day Shift

Completed

- Resolved lens sticking in lens transfer
  - Replaced nozzles
- Finished sterilizer SAT
- Resolved "No Result" ALI defects
  - Altered Demold settings

Action Log To-Do

Date Raised	Action	Owner	Due Date	Status	Priority Level
5/13/19	Troubleshoot misaligned foil	David R.	5/16/19	Complete	
5/13/19	ALI edge tears	Xavier W.	5/14/19	Working	High
5/14/19	Sterilizer load tray	William S.	5/20/19	Working	Low
5/16/19	FC/BC IMM	William S.	5/24/19	Hold	Medium

Project Schedule

Milestone	Date Completed By	Status
PP Loop SAT Complete	5/30/19	Working
Protocol XXX12345 Complete	6/7/19	Working
Protocol XXX12345 Complete	6/14/19	
Overnight Line Run	7/2/19	

Figure 7-2: An example of a Shift Carry-Over Template

Daily morning meetings should also be held around a 'communication board', acting as a large visual aid showing the day's objectives and accountability for particular action items as need. Communications boards are common lean implementation tools used to guide team briefings and inform team leads in the day's activities. Not only do they enable performance management, but they also aid in linking operational improvement to overall strategy. This is because communication boards allow information to quickly be understood at a glance. Team leads and team members use visual aids to evaluate current performance, identify and prioritize problems, and inspire improvement in alignment with strategic goals. (Bateman, Philp, and Warrender 2016). Preferably, communication boards should be physical boards. Parry and Turner (as cited in Bateman, Philp, and Warrender 2016) "advise against the use of technological tools such as software- and computer-based systems because they allow too much information to be accessible – not focusing on the 'vital few', and familiarity with software can create 'operator experts' taking, 'control of a board from the team and places it into the hands of a single or small number of people', limiting opportunities for improvement across teams." Moreover, the monitor screen on the manufacturing floor could be utilized to display live line performance data, progress towards short-term and long-term goals, and also display the action items list with ownership accountability.

In addition to communication improvements, tool tracking methods such as shadow-boarding (Figure 7-3) or electronic tool tracking will aid in the efficiency of the Flexible Manufacturing Platform team. According to M. Tap *et al.*, "Great variety of tools, unavailability of tools, difficulties in the tracking and control of tools, the large size of the total tool inventory, lack of tool services and the high cost of tooling are found to be the most important tooling problems. This and other surveys point to the need for a good tool-tracking system in order to implement an efficient tool management system." This is because a reliable tool-tracking system will prevent technicians from wasting valuable time chasing lost tools (see Section 6.3 for an example story). Moreover, tool-tracking methods such as shadow-boarding provide a way to view a tool rack and quickly determine which tools are present or missing. In one quick glance, an operator can determine what is available and what is not. On the other hand, electronic tool-tracking takes this one step further by not only identifying which tools are missing, but tracking which technician

"checked out" the tool and at what time. This is because the toolbox will only unlock once someone scans his/her badge. Thus when a tool is removed from the box, it will be documented (via RFID) and assigned to the badge number accordingly.

Figure 7-3: Example of tool shadow-kitting. Source: osaapamerica.com/products/kitting

Lastly, implementing 5S methodology on the manufacturing floor will assist with floor organization. In this way, items such as portable toolboxes, wheel carts, portable white boards, trash bins, etc. will have a clear, identifiable location, making it obvious if the item were to be moved out of place. This can be accomplished using both colored tape and clearly printed labels.

7.3 Determining Metrics of Success

For FMP to be deemed successful, the line will need to accomplish the strategic benefits outlined in Section 4.2. However, these goals are not weighted equally depending upon the current business needs. Additionally, missing certain goals would drive higher costs more quickly than would missing other goals. These prioritized targets are:

- Quick change-over processes
- Shorter propagation periods
- Minimizing disruption to the manufacturing fleet

If either one of the above targets are missed, FMP significantly loses value and importance as a manufacturing asset. This is because the costs of investing in this new technology will not be fully recouped as FMP would ultimately operate similarly to existing manufacturing lines. Therefore, in order for FMP to meet the aforementioned targets, it will require a dedicated team of R&D engineers, manufacturing operations, and supply chain management to weigh the costs and benefits of FMP against Vision Care's long-term strategic goals.

As a company, Vision Care has recently implemented the Flawless Project Execution (FPX) model, which closely mimics strategies taught in the Project Management Professional (PMP) license. However, FPX is only nine years old in the company, so not everyone is familiar with the concept. Yet still, FPX is a powerful tool due to its ability to provide structure when executing various projects that range in both complexity and amount of time required. Essentially, FPX methodology allows a Project Leader to plan for complex projects, gain support for the project across multiple levels in the company, identify risks and subsequently create mitigation plans, and create communication channels for the Project Team. FPX has a large potential to be impactful. As it is continued to be used, and with success, these tactics will be engrained across the company, including FMP.

7.4 Chapter Summary

The Flexible Manufacturing Platform has the capability to conduct early stage research, execute both small and large scale product launches, and support the existing manufacturing lines in meeting growing demand for existing corrective lens products. Yet, to be efficient in these goals, the team must first incorporate physical, communication boards to improve team alignment, introduce standard shift carry-over communications, accurately track their tools, and lastly adopt the Flawless Project Execution strategy.

8 Conclusions and Recommendations

A company must be agile in today's manufacturing world to maintain pace with variable demand, increased product variety, shorter windows for product launches, and the ever-changing available technology. In other words, a company, regardless of its size, must *think big, start small, and scale fast.*

Johnson & Johnson Vision Care's commitment to continued innovation means that it must launch new contact lens products each year. Doing so will not only raise brand awareness, but it will also ensure competitiveness with niche players in the long-term. Yet, this is currently difficult to achieve in today's capacity constrained environment.

The New Product Introduction process is comprised of Stage Gates that require a product to meet all quality and testing requirements before advancing to the next stage of product development. This creates a system of checks and balances. Likewise, cross-functional core teams continuously work together throughout the product development process. Doing so helps to maintain smooth transitions between stages while estasblishing product manufacturability and repeatability in the long run.

The Flexible Manufacturing Platform's value proposition includes its ability to enable large-scale clinical builds, small market launches, shorter product development cycles, decreased impact on producing lenses for sale, and improved technical knowledge transfer. To better evaluate its technical capability, a heat seal characterization case study was performed. The case study was comprised of a series of experiments to ultimately determine the values for the critical process parameters that would ensure a strong seal while maintaining an acceptable experience when opening the package. The cross-functional heat seal core team consisting of a project lead, software engineer, validation quality engineer, process engineer, and a statistician subject matter expert. The results of the experiments revealed that out of the three input variables – contact time (sec), contact temperature (°C), and contact pressure (lbF) – contact pressure was statistically insignificant. Additionally, relatively longer contact times at lower contact temperatures yielded the most repeatable results. Therefore, sealing the package at a relatively lower temperature for a longer amount of time was the proposed solution. Moving forward, the heat seal will need to be closely monitored and product should be randomly collected and sent to the lab for testing to measure reliability over time. This is because the line is still working through early stage software and hardware troubleshooting, which has the potential to affect the heat seal integrity.

In New Product Introduction, the traditional knowledge transfer from the R&D team to the operations/manufacturing teams will not be as straightforward on FMP. This is because FMP has

the ability to fluctuate between R&D pilot projects and manufacturing commercial products. In the short term, FMP is likely most impactful as a manufacturing line to help the company meet current demand and increase buffer stock. Over the long term however, FMP should be used primarily to scale-up one or two new products each year.

The FMP team is dedicated to making the line a success but is currently consumed by a fire-fighting mentality that disallows them from executing operational improvement tasks. Day-to-day operations such as intra-team communication, visual management, and floor arrangement will need to be improved. For example, rather than technicians sending emails to capture the shift's activities, they should leverage a standard template in which they simply "plug in" the relevant information. Additionally, using a white board or other similar visual tool will make daily morning meetings more effective and increase accountability.

Ultimately, the Flexible Manufacturing Platform is very promising. It not only resolves current manufacturing challenges, but also introduces new ways of operating entirely. This comes with numerous benefits but also presents unique challenges if not accounted for and managed proactively. Flexible manufacturing is a respectable strategic move for companies like Johnson & Johnson Vision that have high volume, high mix product lines. As the company continues to introduce new products into the market, the Flexible Manufacturing Platform will undoubtedly be a unique asset.

Acronyms:

ARO – QC lab test named after the company that first made the machine

DOE – Design of Experiment

ECP – Eye Care Professional

FDA – Food and Drug Administration

FMP - Flexible Manufacturing Platform

FPO – Final Project Objective

FPX – Flawless Project Execution

JJV – Johnson & Johnson Vision

JJVC – Johnson & Johnson Vision Care

NPI – New Product Introduction

PIT – Package Integrity Testing

QC – Quality Conformance

SME – Subject Matter Expert

R&D – Research & Development

RFID – Radio Frequency Identification

RHSS – Reduced Headspace Heat Seal

Glossary:

Changeover – the process of retooling and/or reconfiguring a manufacturing line from producing one type of contact lens to producing another

Characterization – a series of experiments conducted to determine the values for the process parameters that are critical to consistently producing viable product

Customer – the person or entity directly purchasing contact lens products from Johnson & Johnson Vision Care (e.g. Eye Care Professionals, 1-800-Contacts, etc.)

Manufacturing Fleet – multiple manufacturing lines comprised of similar technology and are typically situated next to one another

Manufacturing Line – a set of sequential, automated operations through which raw materials are processed and transformed into a high quality contact lens that is suitable for use. These lines are optimized for speed and efficiency

Package Integrity Testing – a test performed in a controlled laboratory environment to evaluate the integrity of the heat seal on a contact lens package

Patient – the individual who wears the contact lens on his/her eye (i.e. the wearer)

Peel-Strength Testing – a test performed in a controlled laboratory environment to evaluate the amount of force required to remove the foil from the plastic package by breaking the heat seal

Pilot Line – a small manufacturing line used to conduct research on new types of contact lens project ideas. Traditionally, pilot lines are located in the R&D building, produce few lenses per hour, have several manual steps, and are optimized for flexibility

Pilot Project – a small-scale experiment meant to assess the feasibility of a new type of contact lens product

Product Launch – the act of introducing a new contact lens product to the market

Propagation – The process of moving manufacturing capacity for a particular contact lens product from a validated line to another line that has yet to undergo validation. The receiving manufacturing line will meet validation requirements more quickly due to the bulk of quality testing having been previously met by the first line.

Validation – approves a manufacturing line with the Food and Drug Administration to make a particular product at commercial scale

List of Figures:

List of Tables:

References:

Bateman, Nicola, Lee Philp, and Harry Warrender. 2016. "Visual Management and Shop Floor Teams – Development, Implementation and Use." *International Journal of Production Research* 54(24): 7345–58.

Carr, Austin, and Kiley Roache. 2019. "Warby Parker Wants to Be the Warby Parker of Contact Lenses." *Bloomberg Businessweek* (4638): 50–53.

"Contact Lenses Market Size, Share | Global Industry Report, 2019-2025." https://www.grandviewresearch.com/industry-analysis/contact-lenses-market (December 28, 2019).

"Contact_Lens_Fast_Facts.Pdf." https://www.jjvision.com/sites/default/files/2018-09/Contact_Lens_Fast_Facts.pdf (December 23, 2019).

Curran, Jack. 2018. Contact Lens Manufacturing in the US. IBIS World. US Specialized Indusrty Report. https://my-ibisworld-com.libproxy.mit.edu/us/en/industry-specialized/od4155/about (April 19, 2020).

Efron, Nathan, Jason J. Nichols, Craig A. Woods, and Philip B. Morgan. 2015. "Trends in US Contact Lens Prescribing 2002 to 2014." *Optometry and Vision Science* 92(7): 758.

"History_of_ACUVUE_Brand_5.Pdf." https://www.jjvision.com/sites/default/files/media_center/History_of_ACUVUE_Brand_5.pdf (December 22, 2019).

Kimmel, Allan J. 2015. "People and Products : Consumer Behavior and Product Design." *People and Products : Consumer Behavior and Product Design*. https://lib.mit.edu/record/nlebk/961750 (April 25, 2019).

Linton, Jonathan D., and Steven T. Walsh. 2004. "Integrating Innovation and Learning Curve Theory: An Enabler for Moving Nanotechnologies and Other Emerging Process Technologies into Production." *R and D Management* 34(5): 517–26.

Swaab, Roderick I, Adam D Galinsky, Victoria Medvec, and Daniel A Diermeier. "16(1) 25–53 © 2012 by the Society for Personality and Social Psychology, Inc. Reprints and Permission:

Sagepub.Com/JournalsPermissions.Nav DOI: 10.1177/1088868311417186 Http://Pspr.Sagepub.Com." *Personality and Social Psychology Review*: 29.

Tap, M., J.R. Hewit, and S. Meeran. 2000. "An Active Tool-Tracking System for Increased Productivity." *International Journal of Production Research* 38(16): 3889–98.