Evaluating Strategies for Wide Scale Replacement of Human Inspection with Machine Vision

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Abstract

A stable and cost-effective workforce is key to manufacturing life-saving medical devices. However, an ongoing global labor shortage is causing national economic challenges and causing companies to have significant workforce shortages, delaying operations and production activities. Additionally, human visual inspections of medical devices are less reliable and effective than new technological inspections with machine and artificial intelligence vision systems. This research explores the efficiency of human visual inspections, the impact new technology, such as machine and AI vision, can add, how to lead technological change, and an approach to implementing this change at a medical device manufacturing company.

Specifically, it examines best practices and a specific strategy for identifying machine and AI vision opportunities at a large manufacturing company where quality is extremely important. It also examines strategies to quickly identify improvement areas and get manufacturing excited about new technology. Finally,it compares a traditional field visit approach to a data driven opportunity identification approach. Ultimately, it proposes a data-driven approach using visual tools to communicate opportunities to management in order to get the buy-in to proceed with these technological improvements.

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Acronyms

AI Artificial Intelligence.

AIA Automated Imaging Association.

BSC Boston Scientific.

CAPA Corrective Action / Preventative Action.

CGMP Current Good Manufacturing Practices.

EMAI Everyone Makes and Impact.

FDA Food and Drug Administration.

HVI Human Visual Inspection.

NCEP Nonconforming Events Prevention.

PPE Personal Protective Equipment.

RD Research and Development.

ROI Return on Investment.

SPC Single Point of Contact.

SQP Strategic Quality Process.

VIP Value Improvement Project.

VOP Value of Production.

WSVA Workstation Vulnerability Assessment.

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Chapter 1

Opportunity Statement and Overview

Currently, a national labor shortage is causing national economic challenges. According to the US Chamber of Commerce, in June 2021,there were approximately half as many available workers for every open job across the country as there have been on average over the past 20 years, and the ratio is continuing to fall. (U.S. Chamber of Commerce)[14] Boston Scientific (BSC) is affected by this shortage, having open roles in a historically competitive market and relying on labor to make their life saving medical devices. Across all BSC sites, over $140 million is spent annually on human inspections. The high volume of inspection tasks and long training time required to certify new employees on inspections results in an inability to respond to labor market shortages. Additionally, human inspection is less consistent than machine vision. BSC's goal is to eliminate human inspection tasks, with machine vision and artificial intelligence (AI) being two tools that can aid in this elimination.

However, globally launching new technology requires a lot of training, time, resources, and infrastructure that must fit into competing priorities and business needs at each manufacturing site. In order to achieve their technology platform goals, BSC created a Digital Factory initiative, with each site piloting a key Industry 4.0 principle. The Maple Grove, MN site was chosen to pilot the machine and AI vision component, aiming to reduce human visual inspections (HVIs) To date, BSC has successfully launched multiple AI vision inspections as part of a pilot program at their Maple Grove, MN site. Further work must be done to expand this pilot to BSC's global manufacturing platform. This project aims to create a strategy and best practices for scaling the machine vision and AI Vision program across all BSC sites, with focus on the Maple Grove, MN and Spencer, IN sites as initial pilots. Other sites were engaged for input and learning sharing as their availability throughout my project timeline allowed.

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Chapter 2

Background

2.1 Medical Device Industry Overview

According to the International Trade Administration, "the medical technology industry, commonly referred to as medical devices, consists of articles, instruments, apparatuses, or machines that are used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure of function of the body for some health purpose." The US leads the global market in consumption, accounting for 40%, $156 billion, in 2017. The industry accounts for over 2 million jobs in the US, of which 300,000 of these jobs are associated with direct employment. (The International Trade Administration) [2]

The medical device industry market size was $423 billion in 2020, corresponding to a 3.7% decline in year-on-year growth compared to the 2017 - 2019 periods. This is due to the impact of COVID-19 reducing medical procedures. It is projected to be a short-term impact, with the growing prevalence of chronic disease and increasing emphasis on preventative healthcare, including diagnosis, driving long term growth in the medical device industry. Additionally, the main companies, such as Johnson & Johnson, are continuing to increase their R&D investments in the space. (Fortune Business Insights) [11]

Competitively speaking, the industry is comprised of about ten key players and was led by Medtronic, Johnson & Johnson, Abbott, and Stryker in 2020. The market can be segmented into twelve categories, shown in Figure 2-1 below, with In Vitro Diagnostics (IVD), Cardiovascular Devices, Diagnostic Imaging, and Orthopedic Devices being the lead market segments. (Fortune Business Insights) [11]

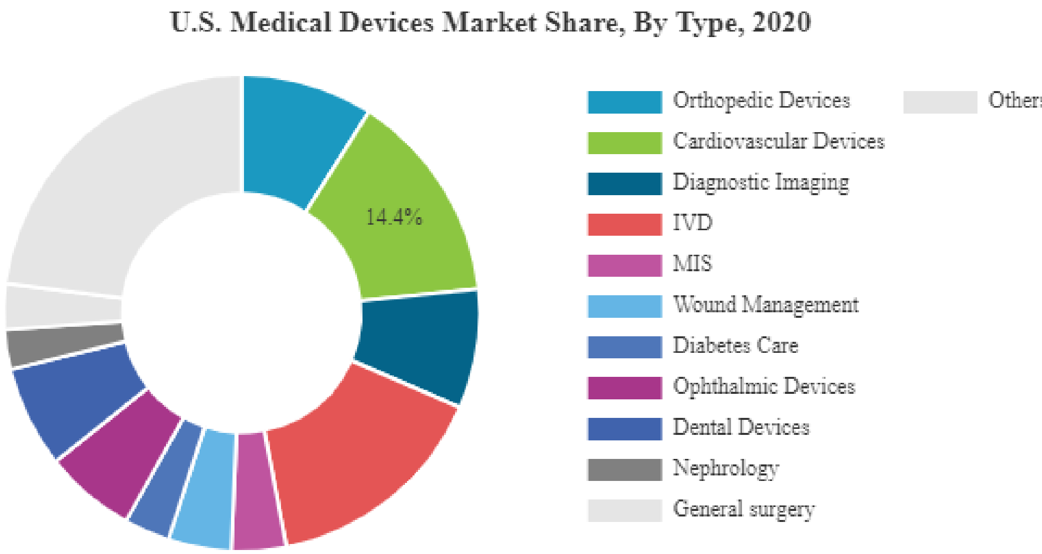

Figure 2-1: Breakdown of US Medical Devices Market Share in 2020 from Fortune Business Insights [11]

Industry profitability is driven by product differentiation, regulatory price approval (Medicare, Medicaid, and other country equivalents), cost-cutting, and relationships with care providers who choose which devices to use on their patients. Medical Device manufacturers must pay for labor, raw materials, services, and sterilization. Federal regulation causes the time to bring new devices to market costly and time intensive.

Within this industry, Boston Scientific primarily focuses on manufacturing implantable devices and scopes across six key business segments including Endoscopy, Interventional Cardiology, Neuromodulation, Peripheral Interventions, Rhytm Management, Urology and Pelvic Health.

2.2 Implants and Scope Manufacturing

2.2.1 Manufacturing Methods

Medical devices can be manufactured through a variety of methods including metal rolling, extrusion, forging, casting, and punching; attachment methods including grinding and joining; polymer processes including injection molding, thermoformoing, and extrusion; ceramic processing; additive manufacturing; CNC and other machining, and hand assembly amongst other methods. (Raymond H.W. *et al.*)[12] BSC deploys a lot of these methods, depending on the device they are making. However, hand assembly is most often used to turn the individual device parts into a final component. The cardiac rhythm management device, Acuity X4, shown in Figure 2-2 below, provides a great example of hand built assembly. The leads for this and similar devices are built using hand assembly at one location, another manufacturing plant might build the housing, and a third location assembles all of the components into a final product. This allows the company to specialize at its manufacturing sites and train their employees assembling the product to be very skilled on specific tasks.

Figure 2-2: Acuity X4 Cardiac Rhythm Management Device, Courtesy of Boston Scientific [21]

An illustration of how the hand build assembly looks throughout fabrication is shown in Figures 2-3 and 2-4 below. In the first image, a technician is working on fabricating a wire component similar to the the electrical leads that go into cardiac rhythm management devices. In the second image, a team of technicians are working on assembling the same type of equipment, in stages, indicative of how their skilled assembly lines operate.

Figure 2-3: BSC Employee Hand Assembling a Wire Component, Courtesy of Boston Scientific [20]

Figure 2-4: BSC Employees Assembling Wire Components in Assembly Line, Courtesy of Boston Scientific [19]

I interviewed a BSC Senior Process Engineer, Seth McIntire, about why BSC builds many of their product components by hand. Seth highlighted that most of the decisions regarding manufacturing are driven by product safety, product quality, and speed to market. With those drivers in mind, there are three key areas that lead to hand assembly being chosen for a product: time to specificity, economies of scale, and priority alignment. (Seth McIntire) [13]

The first area is time to specificity. In order to achieve speed to market with quality, specifications for a product must be established. It is easier and faster to make a specification of "no bubbles," versus doing a research study to determine the specific bubble size that is permissible. You can give a human a specification of "no bubbles" and know they will understand what that means and successfully inspect for it. However, a computer algorithm has to be given more measurable specifics to do the same inspection, and getting those specifics requires a lot more time than aligning upon "no bubbles".

The second area that impacts manufacturing decisions is economies of scale. Initially most products do not have enough estimated volume to justify a fully automated assembly or to purchase machines to build the parts. BSC has a large product portfolio. Across that portfolio there is a high mix of product sub-types due to some products coming in various sizes that scale with body size. The volume and mix leads to hand assembly most often being selected as the manufacturing method.

The final area that impacts manufacturing decisions is priority alignment across the manufacturing and process development teams. Once an item is in production, the margins exist to allow hand assembly and have a profitable product. At the same time, new products or improvements to existing products are being developed and need their manufacturing processes established. The process engineering and manufacturing teams can either automate existing processes that are achieving good margins and having good quality performance, or use the same resources to help bring new products to market. In most cases, bringing new products to market is the priority and old processes are kept as-is.

While these factors usually lead to hand assembly being chosen, there are some instances where machine assembly and automation are a better approach, in which case BSC chooses that option. Examples of this include metal part punching, such as for battery casings and housing for devices such as the Acuity X4, battery fabrication by robots, adhesive assembly by co-bot, and packaging on mechanized lines.

BSC carefully reviews each product and chooses the right manufacturing method. Due to the large volume of hand assembled items, I chose this as the focus area for my research, which seeks to bring those automation techniques into products currently made by hand. One area to start is removing humans from inspection.

2.2.2 Quality

Quality is a top priority for the medical device industry in general and Boston Scientific specifically, as the quality of medical products can have a significant impact on the success of a therapeutic regime and on patient safety. (BSC Global Quality Manual) [17] The Food and Drug Administration (FDA) mandates that Current Good Manufacturing Practices (CGMP) must be followed when producing medical devices, and codifies this under the Code of Federal Regulations Title 21 Part 820 Quality System Regulation. (Food and Druge Administration) [8] Similar European standards exist for companies selling their devices abroad. Quality systems enable companies to ensure they are the meeting customer needs and the multiple regulatory requirements of each sales location. Quality, or lack thereof, also has a major impact on companies' profits and valuation. According to a 2013 McKinsey study on medical devices, in the period from 2003 - 2013 an average of one company per year experienced a ten percent drop in share price after a single, major quality event, such as a recall. (McKinsey Center for Government) [9] The same report estimated that the total cost of quality for the medical device industry was $17 to $26 billion annually.

In order to help all employees feel personally invested in the impact BSC has on the 30 million patients its products help treat each year, the company hosts and annual Everyone Makes an Impact (EMAI) event. Its 35,000 employees are connected to the patients the company reaches. The employees are able to hear personal stories from patients and caregivers about how BSC products helped improve and save people's lives.

The company also has a Strategic Quality Process (SQP) that reinforces their quality policy and covers areas including operations strategy, management systems, continuous improvement, cascading metrics, and recognition and engagement. (BSC 2020 Performance Report) [15] All BSC manufacturing sites use the overarching SQP to ensure cohesive quality at an enterprise level.

The Global Quality Process is comprised of eight pillars (BSC 2020 Performance Report) [15]:

1. Quality system management
2. Documents, records and data control
3. Design controls
4. Product approvals
5. Material controls
6. Production and process controls
7. Post-market support
8. Corrective action, preventive action

These quality systems enable BSC to make products that reliably improve people's quality of life and save lives. In order to achieve this, McKinsey found that the average total quality costs for the industry are 12 - 18% of revenues and the day-to-day costs are 10 - 14% of revenues. (McKinsey Center for Government) [9] BSC earned $9.913 billion in revenue in 2020. (Boston Scientific Announces) [16] Using the McKinsey estimate, BSC spent approximately $1.18 billion on day-to-day quality efforts in 2020. One of the key components of this day-to-day cost is inspections.

2.2.3 Inspections

Inspections play a crucial role in risk management of medical device manufacturing. One of the fastest, easiest, and most cost effective ways to mitigate risk is to add an inspection step. In order to prioritize speed to market, human visual inspection is often added during the research and development (R&D) stage to ensure product quality and prevent 'escapes', events where a product or component not meeting specifications makes it into the downstream work flow. Due to the large volume of hand assembled products, multiple inspection steps are added to account for the previously discussed reliability issues with human inspections. At BSC, these inspections can range from examining a small sub part of an individual component, as shown in Figure 2-5, to a multi-dimensional inspection of a finished component or product. Each inspection requires the technician to be trained and certified. BSC currently has nearly 4000 HVIs globally and spends $140 million annually on labor to complete these inspection tasks. It can take weeks to months of training for an employee to pass a proficiency test. Additionally, the current labor shortage is leading to internal attrition rates of up to 75% at some locations. This results in recruiting, on-boarding, and training one person to be approximately five times more expensive than a base analysis. None of these costs are currently included in the cost of inspection analysis or in the cost savings calculations for inspection alternatives.

Figure 2-5: BSC Employee Inspecting a Medical Device Component, Courtesy of BSC [18]

2.3 Machine Vision and Artificial Intelligence for Inspection

2.3.1 Machine Vision

According to the Automated Imaging Association, AIA, and Cognex, a leading machine vision equipment manufacturer, machine vision encompasses all industrial and non-industrial applications in which a combination of hardware and software provide operational guidance to devices in the execution of their functions based on the capture and processing of images.(Cognex Machine Vision Introduction) [7] Industrial machine vision requires low cost solutions the deliver acceptable accuracy and high reliability. These systems use digital sensors, located inside of industrial cameras, to acquire images and then pass those images to computer hardware and software which processes, analyzes, and measures various characteristics for decision making. An example of a machine vision system for bottle fill-level inspection is shown in Figure 2-6 below.

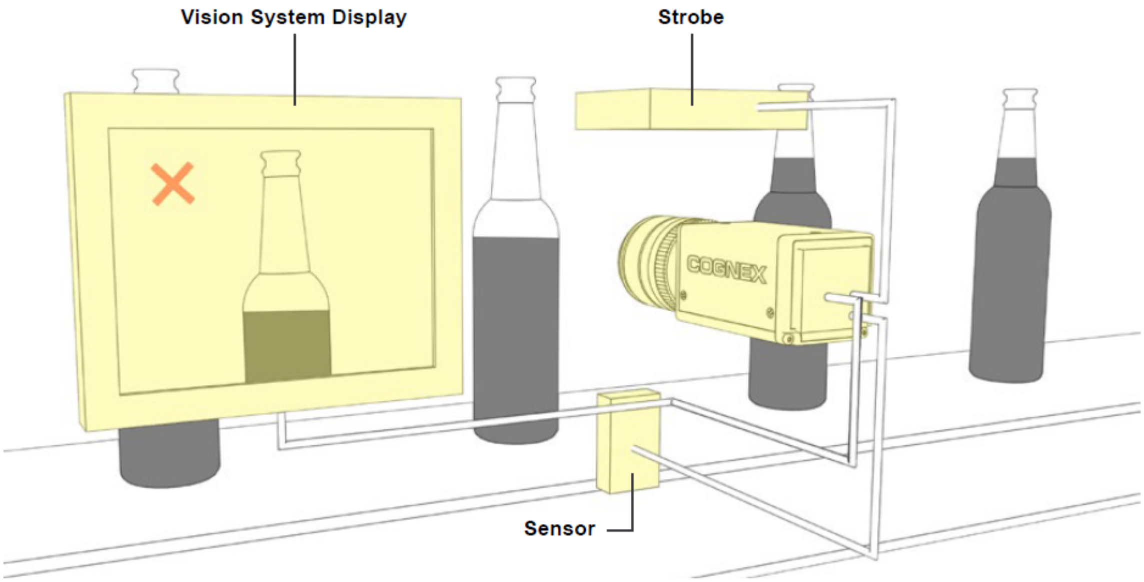

Figure 2-6: Machine Vision Example, Bottle fill-level inspection, Courtesy of Cognex [7]

Machine vision is a great resource to use for several different image identification categories: guidance, identification, gauging, and inspection. (Cognex Machine Vision Introduction) [7] Guidance refers to machine visions' ability to locate the position or orientation of a part and compare it to a specific tolerance. This is used to help align parts on an assembly line or as a precursor to further machine vision or artificial intelligence applications, which require the part to be in a specific orientation to complete their analysis, such as a measurement assessment or to help guide a robotic arm to work on the right location of the part. An example of machine vision guidance applications is shown in Figure 2-7 below.

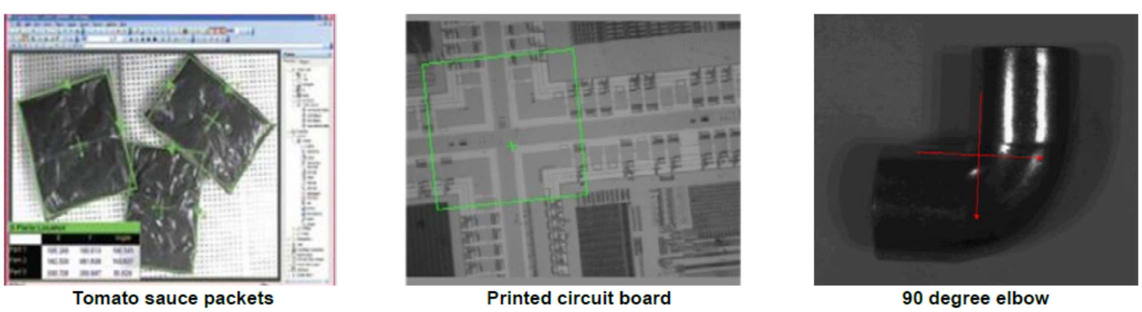

Figure 2-7: Machine Vision Image Guidance Example, Courtesy of Cognex [7]

Image guidance can also involve pattern matching, where the machine vision application looks for a specific pattern in order to identify the part. An example of this is shown in Figure 2-8.

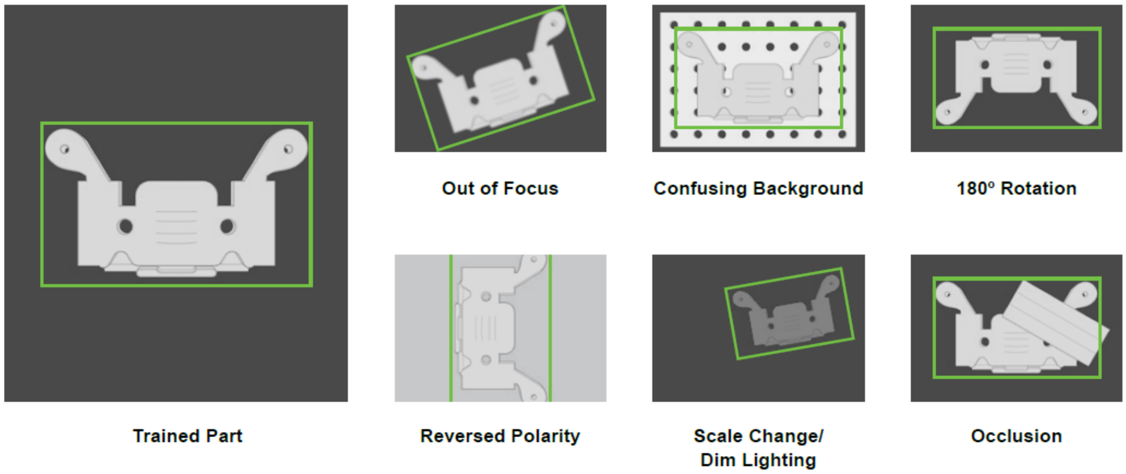

Figure 2-8: Machine Vision Pattern Matching Example, Courtesy of Cognex [7]

The next area machine vision can be applied is for identification, where the cameras and software work together to identify a specific object such as reading bar codes or other characteristics on the part.

A widely used application of machine vision is for gauging, where the machine vision system calculates the distance between two or more points and determines if the distance meets the part specifications. Figure 2-9 below shows an example where gauging is used to measure part tolerances within 0.0254 millimeters. (Cognex Machine Vision Introduction) [7] The machine vision system then takes action to identify bad parts that do not meet specifications, either by sending a message to the assembly person, in the case of hand assembly, or rejecting the part from the line, in the case of automated assembly line production.

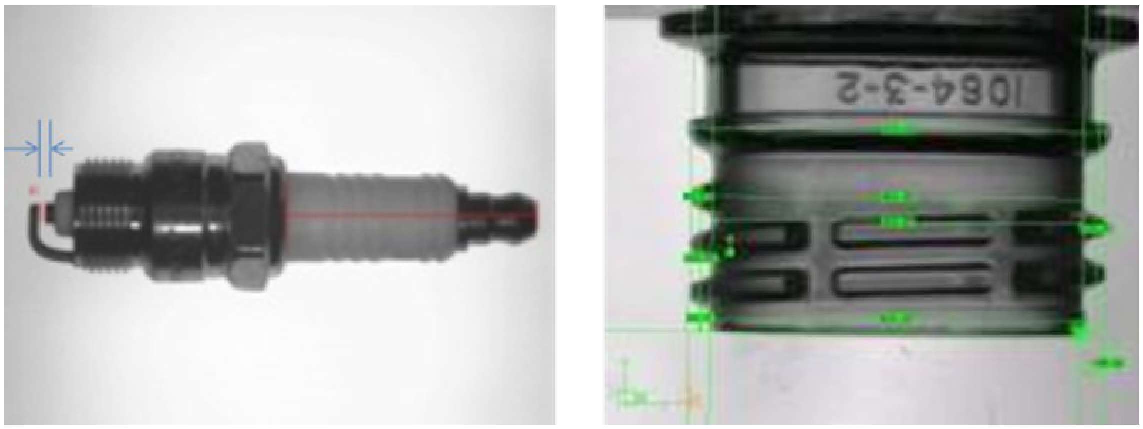

Figure 2-9: Machine Vision Gauging Example, Courtesy of Cognex [7]

The final key application for machine vision is for inspection of defects, contaminants, or other irregularities. Figure 2-10 below shows two examples of this, the inspection of a medicine tablet for flaws and the inspection of a display to ensure the right pixels are present.(Cognex Machine Vision Introduction) [7] This application is often deployed at final acceptance to perform a quality control review on a part or product.

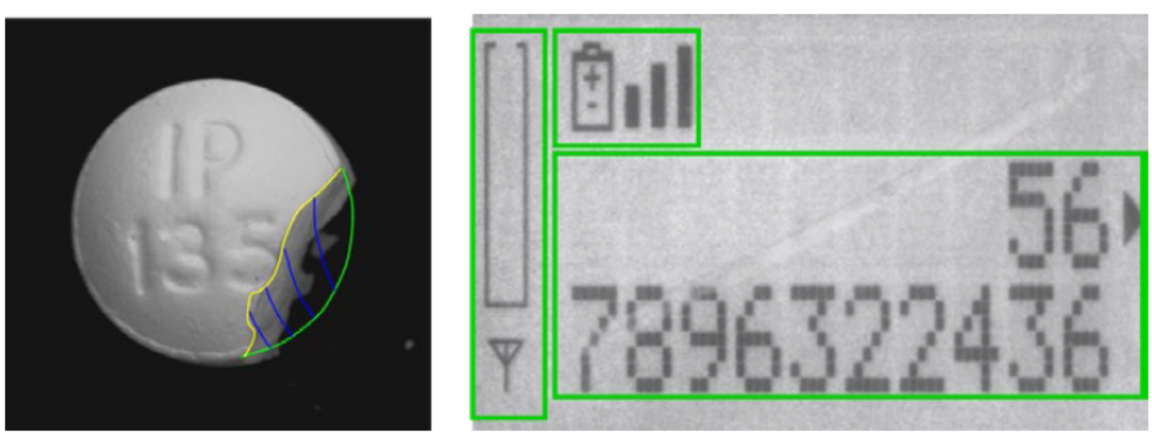

Figure 2-10: Machine Vision Inspection Example, Courtesy of Cognex [7]

In order to have a successful machine vision system, several main components must be present including lighting, lens, image sensors, vision processing software, and communication hardware (Cognex Machine Vision Introduction) [7]. A complete machine vision system set-up is shown in Figure 2-11 below.

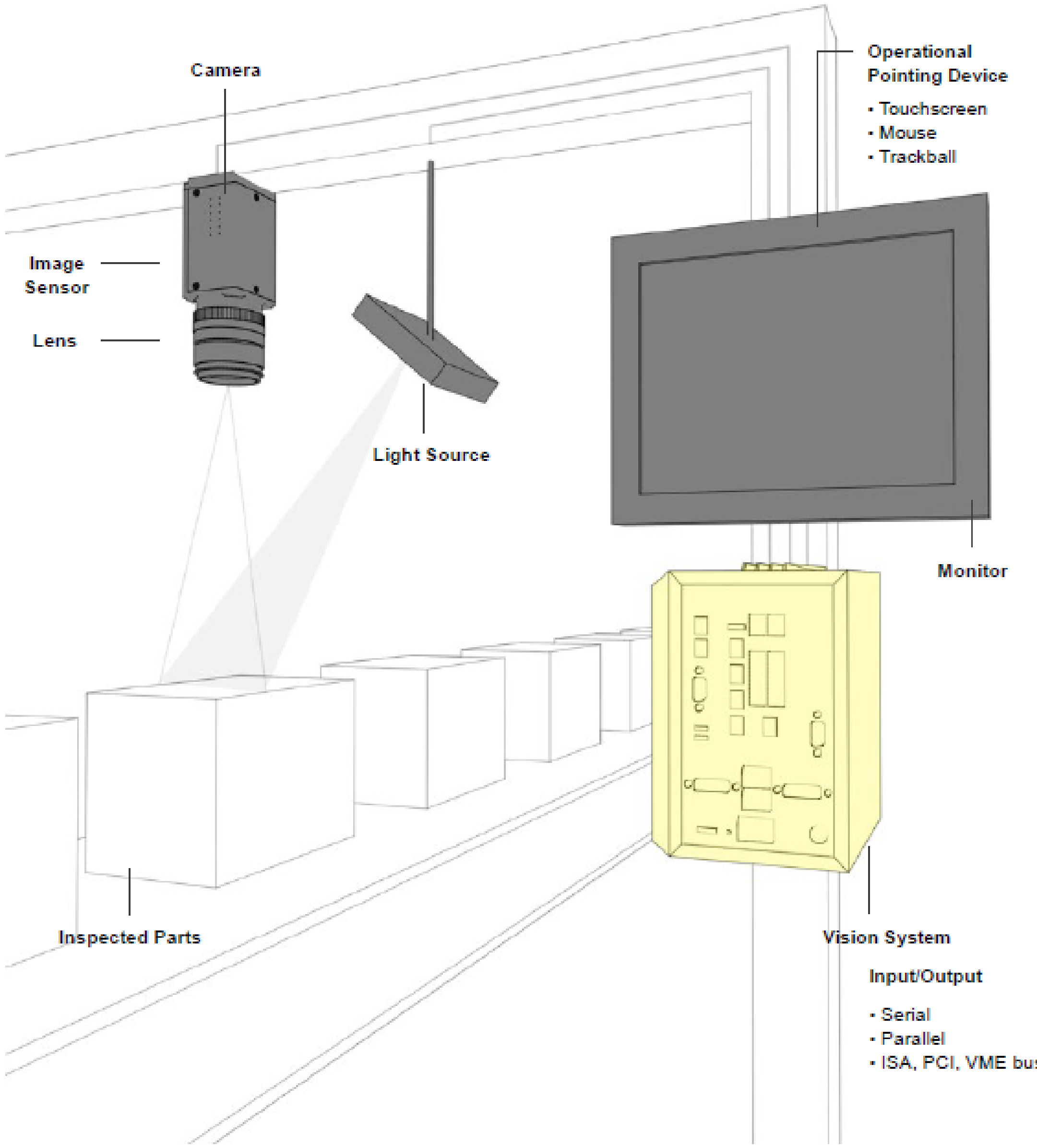

Figure 2-11: The Main Components of a Machine Vision System, Courtesy of Cognex [7]

The lighting provides the illumination needed for the lens to properly capture the image, which is then sent to the sensor in the form of light. The sensor converts the light into a digital image which is sent to the vision processing software for analysis. The vision processing software is comprised of algorithms that review the image, extract the right information, run the necessary comparison model, and make a decision regarding pass or fail (Cognex Machine Vision Introduction) [7]. For traditional machine vision this software is normally sold as a part of the overall vision system, from vision system manufacturers such as Cognex, and does not require AI programming by the company. Cognex and similar companies provide machine vision packages that make training the models very easy and often use point and click user interfaces. These systems are usually the starting point for companies looking to implement machine vision into their manufacturing lines, and can be further enhanced with custom applications, such as artificial intelligence.

2.3.2 Artificial Intelligence Models with Machine Vision

According to Britannica, artificial intelligence is the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings. (Copeland Britannica) [3] When applied to machine vision systems, artificial intelligence usually refers to models that work beyond the techniques of traditional machine vision, and involves self-teaching models that learn by example. According to Cognex, deep learning artificial intelligence models can precisely and repetitively solve complex vision problems, distinguish unacceptable defects, tolerate natural variations in complex patterns, and be adapted to new examples without re-programming the base algorithm. (Cognex Deep Learningfor Factory Automation) [5] Compared to traditional machine vision, artificial intelligence vision can solve more complex problems such as classification and location based applications that are not possible with classic rules-based machine vision. Additionally, artificial intelligence differs from machine vision in its ability to conceptualize and generalize a part's appearance based on distinguishing characteristics that might deviate or vary, which is beyond the ability of traditional machine vision. Figure 2-12 below shows the five main categories machine learning artificial intelligence algorithms can be classified as.

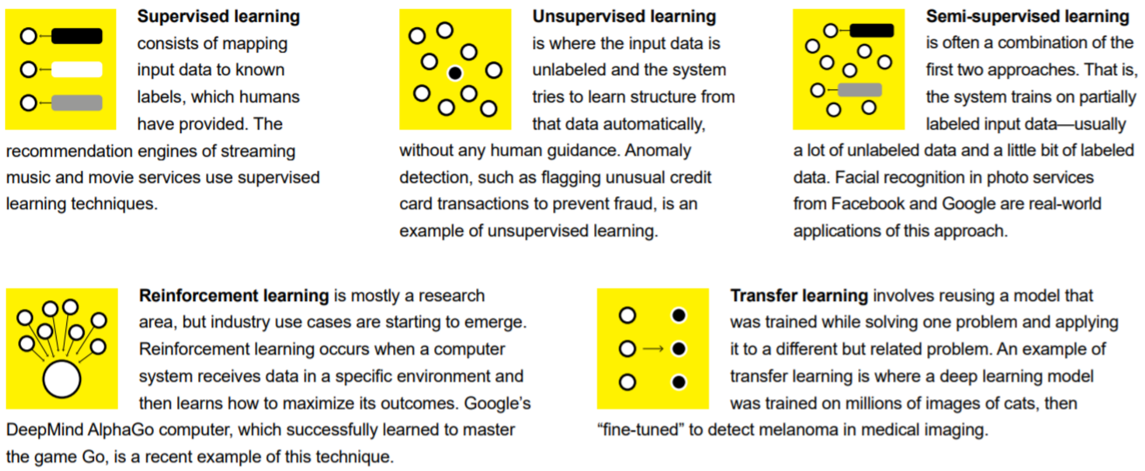

Figure 2-12: Five Categories of Machine Learning Algorithms, Courtesy of Cognex [6]

When the power of artificial intelligence is combined with traditional machine vision applications, companies can tackle more advanced inspection applications.

2.3.3 AI Vision's Role in Replacing Human Visual Inspections

Compared to human visual inspections, artificial intelligence vision applications are more consistent, being able to operate for 24 hours a day, 7 days a week while maintaining the same level of quality and accuracy. When properly trained, they are more reliable, and are able to be trained and tuned to hit a specified tolerance rate. They are also faster than humans. Additionally, machine vision systems have lower error rates than human vision. This will be elaborated on in the literature review. Where possible, replacing human inspection with machine vision systems will enable companies to reallocate their workforce to jobs humans are required to do while improving the reliability of their inspection processes. This will help lower cost by improving yield, reducing the risk of undetected quality issues, and helping to optimize the workforce.

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Chapter 3

Literature Review

3.1 Leading Technical Changes and Digital Transformations

George Westerman, Deborah L. Soule, and Anand Eswaran published an article in MIT Sloan Management Review titled "Building Digital-Ready Culture in Traditional Organizations." Their research discussed how a company can become more agile and innovative without alienating their employees or the best existing practices. Per their research, it is important to understand the four critical values of digital culture, "impact, speed, openness, and autonomy". (Building Digital Ready Culture) [10] Additionally, it involves adopting a set of digital ready practices that will shape employee actions. In order to understand how to share a digital ready culture, necessary to lead a technical change, culture must first be defined and understood. Westerman *et al.* define culture as "what happens when the boss leaves the room...it's present in the espoused values of management, the unspoken assumptions of employees, and the commonly accepted behaviors that have helped an organization succeed in its chosen environment." [10] A company has to understand its prevailing culture before trying to change it and must change the culture slowly so as to not alienate long time, high performing employees who are needed for a successful change. Additionally, leaders must understand what digital values and practices they hope to embrace in order for the change to be successful. (Building Digital Ready Culture) [10] The principles required to create a digital ready organization are highlighted in Figure 3-1 below.

BUILD these digital practices: Digital companies are typically stronger at *rapidly experimenting, self-organizing,* and *driving decisions with data* than are traditional organizations. The first two practices are associated with significantly better performance than peers and are impossible without the last.	• Encourage employees to conduct experiments quickly and often. • Insist that experiments are well-designed, with control groups, clean treatments, and before/after measures. • Encourage failing fast and sharing learnings. • Give people the autonomy to create or participate in teams as they wish, including with external partners. • Replace intuition with intentional testing.
PRESERVE these traditional practices: *Acting with integrity* and *seeking stability* don't hurt performance. In fact, these practices turn out to be critical to attract and retain talent, shore up customer loyalty, and earn stakeholder confidence.	• Create guidelines that enable speed and autonomy without sacrificing integrity. • Develop processes to rapidly identify places where guidelines are not being followed. • Create easy ways to suggest changes to guidelines. • Help employees keep their skills current through training and stretch assignments.
REORIENT these practices: The fast pace and connectedness of today's digital environment require a fresh perspective on how to *meet and anticipate customers' needs, drive accountability for results,* and *set rules* that prevent abuses.	• Move from meeting stated customer needs to innovating to delight the customer. • Think broadly about who your customers are — or could be. • Focus on results continually, not just in annual or quarterly performance reviews. • Ensure that everyone understands the performance goals. • Be transparent about performance at all levels, sharing information as broadly as possible. • Instead of requiring formal compliance reviews of every action, grant people the autonomy to act quickly within clear guidelines. • Adjust processes and tools to make it easier to act within guidelines than without. • Encourage accountability at all levels. • Actively and visibly discourage people who use rules to hold up necessary action.

Figure 3-1: Principles for Creating a Digital Ready Culture, Courtesy of MIT Sloan Management Review [10]

Once the digital transformation objectives are identified, companies should promote rapid experimentation while preserving practices that promote integrity and stability. In order to achieve this, companies should reframe the vision around radical impact, visibly promote new values and practices, be selective in choosing where to start, give people the chance to make an impact, look to IT where possible, provide the right tools, and be transparent about goals and performance. (Building Digital Ready Culture) [10]

3.2 Human Visual Inspection Reliability

Sandia National Laboratories in Albuquerque, New Mexico, conducted a literature review of visual inspection research. The research highlighted the large differences between human visual inspection and machine vision inspection. According to their analysis, "inspection processes require a large amount of mental processing, concentration, and information transmission, along with extensive use of both short-term and long-term memory." (Judi E. See) [22] Short term memory is used to determine what areas have and have not been inspected while long term memory is required to recall the inspection requirements. These inspection tasks are inherently stressful to the human inspectors who must be required to work quickly and not make mistakes. (Judi E. See) [22] Additionally, the stress is enhanced by the fact that defects tend to be rare occurrences but the cost of missing them is high.

Human inspection error is a fact of life that can be reduced with interventions but cannot be eliminated. (Judi E. See) [22] According to the Sandia report, inspection errors are more likely to be omissions (missing a defect) rather than commissive errors. Many factors lead to these human errors, and a summary of common factors is listed below. [22]

1. Task: the task pacing may not enable the inspector to have sufficient time to thoroughly inspect each item.

2. Environmental: time spent continuously inspecting items may lead to lapses in attention.

3. Individual: the inspector may lack the capability needed to preform the job or have biases based on past experience.

4. Organization: the training provided may be insufficient .

5. Social: pressure from manufacturing to reduce the number of items not passing inspection may lead to accepting items that are borderline.

As shown in Table 3.1, When performing an inspection there are four outcomes that the inspection can result in. A hit is the correct detection of a defect and a false alarm is when a good item is incorrectly identified as defective. A miss is when a defective product is incorrectly identified as good and a correct accept is when a good product is correctly identified as good. The inspection criteria, and the difficulty in measuring or detecting that criteria, will affect the relative frequency of the four outcomes.

Response	**Actual Condition**	
	Defective (Signal-Plus-Noise)	**Good Product (Noise)**
Reject	Hit (H)	False Alarm (FA)
Accept	Miss (M)	Correct Accept (CA)

Table 3.1: Four Possible Decision Outcomes in Detection Situation [22]

Per the Sandia National Laboratories review, the primary highlights of human inspection literature are "that human inspectors are imperfect, large individual and group differences in performance exist, and multiple differences in performing inspection tasks have been observed." [22]. Additionally, Sandia's summary provides some recommendations to improve human inspection reliability, including incorporating up to six independent inspections to increase accuracy; having two inspectors inspect every item and classify it as defective only if both inspectors reject it; reducing reliance on memory by using standards for comparison; and using overlays or templates to organize complex products. (Judi E. See) [22]

An article on Human Factors in Visual Quality Control, authored by Angieszka Kujawinska and Katarzyna Vogt, published in the Management and Production Engineering Review Journal, researched visual inspection from a human and machine vision standpoint. Their review summarized the multiple studies done measuring the effectiveness of visual human inspection and found effectiveness rates ranging from 45 to 100 percent accurate, highlighted in Table 3.2 below. (Human factors in visual quality control) [1]

Researcher	Process	Effectiveness of inspection [%]
Jacobson (1952)	Inspection of soldering defects	45–100
Heida (1989)	Aircraft landing gear inspection	57–98
Drury et al. (1997)	Aircraft visual inspection	68
Leach and Morris (1998)	Visual inspection of subsea structures and pipelines	53
Graybeal et al. (2002)	Routine inspection of highway bridges	52

Table 3.2: The effectiveness of visual inspection in actual process example [1]

Kujawinska and Vogt also concluded that the visual inspection error rate in humans ranges from 20 to 30 percent incorrect. (Human factors in visual quality control) [1] Additionally, "according to the FMEA (Modal Analysis of Failures and Effects) inspection process guidelines, the human visual inspection is effective, reliable in only 80% of cases based on the observation of multiple factors such as different points of sight or operators, reduced cycle time, visual fatigue and defects not detected by the human eye, among others." (Jorge Broto) [4] Machine Vision, when properly implemented, eliminates most of the factors that lead to missed inspection and can be fine tuned to have a target acceptance rate at or near zero.

3.3 Maximizing Return on AI Initiatives

Laks Srinivasan and Thomas H. Davenport, from the Return on AI Institute presented a webinar, in partnership with MIT Sloan Management Review, in October 2021 on *Critial Success Factors for Achieving ROI from AI Initiatives*. This presentation highlighted the key ways companies can maximize their return on invest on AI projects and help ensure they are picking projects that add value for the company. Their research focuses on large, non-digital native companies that have made heavy investments in AI and have a high risk of business model disruption. (Laks Srinivasan *et al.*) [23] They conducted over 45 qualitative interviews across six sectors. Their work highlights that the greatest challenges in deploying AI solutions arise from defining a path to value delivery. Additionally, leaders of AI journeys at the companies they interviewed tended to be isolated, which is not optimal for positive outcomes. To get value out of AI projects, business models must be transformed to create strategic versus operations returns.

In order to achieve this strategic intent, Srinivasan and Davenport recommend companies make three crucial decisions [23]:

1. Strategic Intent for AI: A company must commit to AI as a capability for achieving corporate goals

2. AI Money Map: A company must establish and align on a prioritized list of high value, defined use cases

3. Return-on-AI Governance: A company must define the results of AI, in a measurable manner, that is consistent with the company's financial management control framework.

Strategic intent for AI is required in order for a company to take their AI projects from research and experimentation to a strategy that can be acted upon at scale. This strategic intent should work well with the existing goals of the company. Starbucks used this methodology to turn their entrepreneurial goal of, "driving convenience, brand engagement, and digital relationships," into their AI strategy of "becoming world class at AI will ensure Starbucks will continue to be world class at creating shared experiences that drive human connection." (Laks Srinivasan *et al.*) [23] This combined entrepreneurial goal and strategic intent led to an overall AI solution of Starbucks DeepBrew, an AI based tool, which enables personalizing, improves operational efficiency, engages customers, and improves sales.

The next crucial decision a company must make is to deploy a Money Map, which shows the critical qualities including linking to an attractive value pool, having a willing executive sponsor or profit and loss owner, and having the ability to model the use case. An example of the AI Money Map is shown in Figure 3-2 below. In this example, the boxes represent the individual use cases, the size of each box represents the value proposition, and the colors represent another dimension such as the functional area or region etc. (Laks Srinivasan *et al.*) [23]

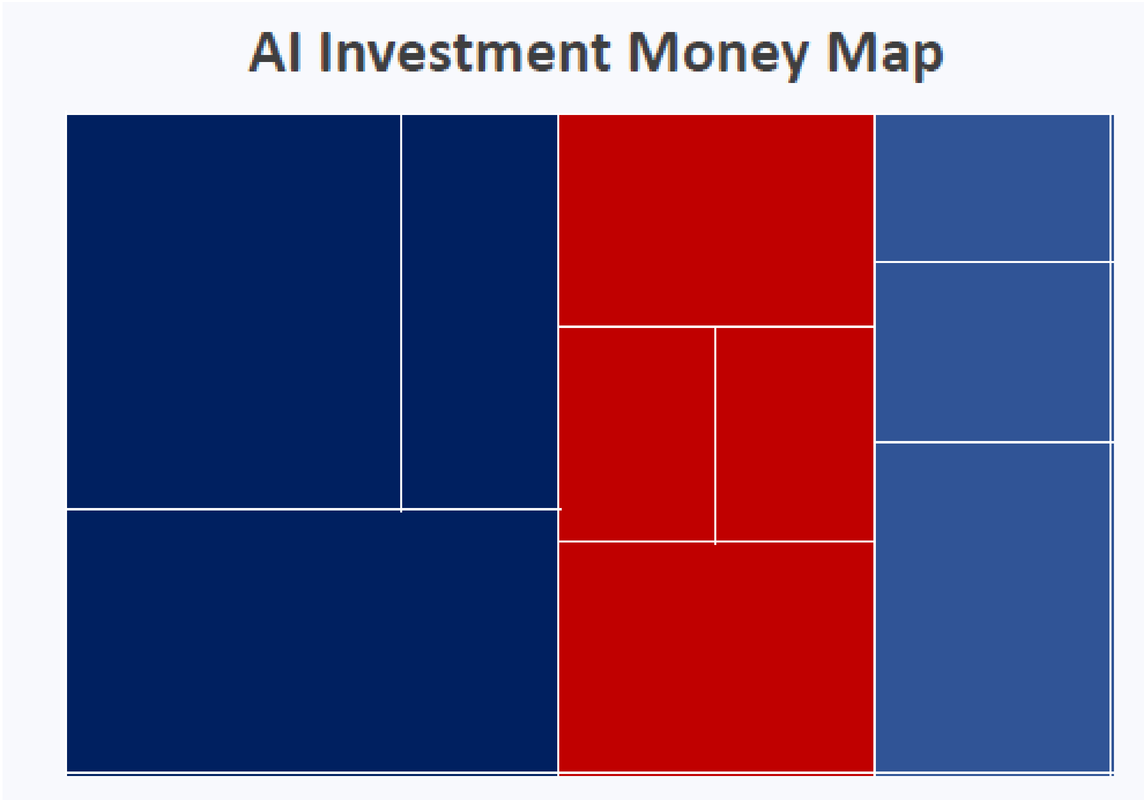

Figure 3-2: Example of AI Opportunity Money Map, Courtesy of the Return on AI Institute [23]

Once an organization uses a Money Map to find the right AI opportunities to pursue, it needs to take the necessary steps to maximize its return on those AI investments. The Return on AI Institute also researched how to have a successful AI implementation and determined the following three catalysts that lead to a successful implementation: (Laks Srinivasan *et al.*) [23]

1. Analytical Quotient: An organization must have cultural awareness and the ability to shape sub-cultures that create more localized opportunities to capture value on AI

2. Analytic Ready Data: An initiative should start with available now data and collect and build historical data first. Then it can move to centralize the capture of data from use cases in production.

3. Enabling Capabilities: The implementation team should focus on three critical areas: Personnel and Interface, the AI Technology Stack, and a Functional Organization.

Combining the three decisions and three catalysts together leads to a road map that the institute proposes to successfully implement AI projects, shown in Figure 3-3 below.

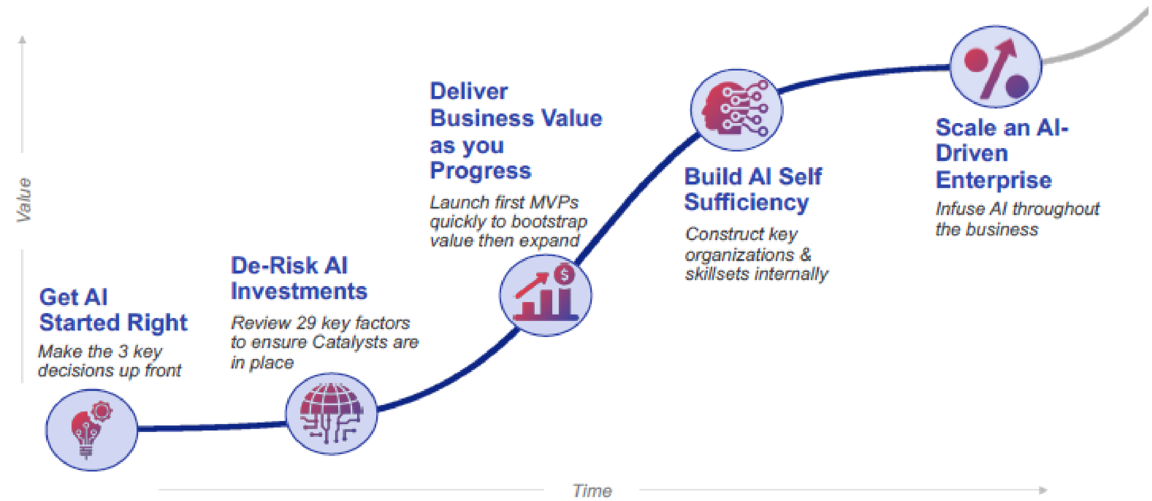

Figure 3-3: Return on AI Institute Recommended Road Map for Successful AI Projects [23]

Chapter 4

Methodology and Initial Findings

In order to develop an Operations Strategy for the deployment of machine and AI vision at BSC, I first had to understand the existing state of machine and AI vision at the company and the factors that were holding sites back from perusing projects in this area. Through a series of interviews, site visits, and data source screenings I was able to identify the best path forward for the project. The majority of my internship was remote, meaning I had to conduct my interviews with Microsoft Teams and only had access to salaried employees versus the hourly technicians assembling the medical devices outside of the few field visits I was able to participate in. The Digital Factory AI Vision team was established prior to the start of my internship, and already had contact people at all participating sites. I engaged with this group to initially conduct interviews and schedule site visits.

4.1 Problem Area and Best Practice Identification

I started by interviewing employees at the sites that had successfully implemented machine and AI vision projects to identify best practices and then followed the subject matter experts on line walks to understand the current state of this initiative.

4.1.1 Gemba Walks

Gemba is a Japanese word meaning the actual place, and in Lean Manufacturing, Gemba refers to the place where value is created. In the first month of my research the Digital Factory AI Vision core team and I had the opportunity to visit the Dorado, Puerto Rico site to conduct line walks and identify potential opportunity areas to implement machine and AI vision projects. During this visit, site leadership provided us with an overview of the site business model and key products. The AI vision team provided the Dorado leadership and engineering team with an overview of success stories, ways they can assist the sites, and the resources required to implement a machine or AI vision project. We then went on line walks using a potential opportunities list developed by a lead R&D engineer. The list covered seven different areas of the plant and took two full business days to explore with a team of seven engineers and vision experts. Through field visits to these seven areas, we identified over 90 potential machine and AI vision projects and had to reduce this list down to ten potential opportunities to do further analysis on. This list reduction process took approximately eight hours over a series of meetings, and required multiple follow-up activities to determine if there was a business need paired with the technical opportunities we identified. This line visit process identified that the opportunities for AI projects existed and that a streamline approach was needed to find these opportunities more efficiently.

4.1.2 Employee Interviews

Co-current with the Dorado, PR site visit planning and execution, I conducted interviews with AI model creators and the Digital Factory initiative leads at several sites to determine the current best practices and areas for improvement. There were three main sites that had started work on finding and implementing AI and machine vision projects: Arden Hills, MN; Maple Grove, MN; and Galway, Ireland. The goal of these interviews was to determine the role of this initiative at each site, the resources currently in use, the intra-site relationships, the best practices each site established, and what sites would like improved. A full list of the questions asked in the interviews is included in Appendix A.

The first people I spoke with were my work directors and the Digital Factory AI Vision initiative leads, Joe Mabis, Project Manager I in Maple Grove Operations, and Eric Wespi, Data Scientist Fellow in Maple Grove Operations. They outlined their work process for identifying opportunities. First, they educate and engage each site or business unit. They lead a road show with quality, manufacturing engineering, and production present. They visited each site in the global network to provide education on machine and AI vision, the Digital Factory initiative, the ways their team has added value at Maple Grove, the assistance they could provide, and what next steps were to find machine and AI vision projects at each site. Second, each site developed a business case for their projects. This occurred through business unit meeting with leaders, subject matter experts, and process development leaders for the site to determine where the sites machine and AI vision value is. Finally, they evaluated the complexity of the opportunities through line tours, or Gemba walks, with the subject matter experts. After the line tours, the business units conducted formal calculations to determine if the return on investment existed to move forward with the project. This effort was initially performed across the different Maple Grove business units over the initial two-year Digital Factory site roll-out. Joe and Eric are both Maple Grove employees who had an established reputation and network at the site.

Next, I spoke with the process development and equipment engineering teams at Maple Grove to get a better understanding of the current state of the technology. The Principal Data Scientist in Maple Grove Process Development, discussed the work his group was doing to make a single source software to use for AI model creation and deployment. This software is very useful when launching a model across multiple production lines or pieces of equipment, as it greatly reduces the amount spent on third-party licenses. Additionally, using a common software will better enable sharing of models to apply to future production lines or similar uses at other sites. The Principal Data Scientist also spoke about the importance of using a common image labeling software and library. For future transfer learning to be possible, having all of the labeled images in on repository was ideal. However, most sites were not at the point to deploy these commonalities and did not have the resources to support these efforts. Each site needed to reach the maturity and project count of Maple Grove before technology became the key barrier and improvement area.

Steve Maves, Principal Software Engineer in the Maple Grove Equipment Engineering group, discussed the key work the group does, including specifying vision equipment, building models using third party software, and deploying their own models along with open source models made by the data science group. The Equipment Engineering group has existed at the site for a long time, working on things outside of AI vision, and has built up a lot of trust with Maple Grove operations. The manufacturing team now comes to the Equipment Engineering group to show the equipment group engineers areas they want their help on and potential machine or AI vision improvement ideas. This relationship is a crucial as the technology the team works to implement. According to Steve, the site manufacturing teams he has spoken to believe in the power of the machine and AI vision technologies and trust it. The barriers to implementation lie in other areas of the process outside of the existing technology.

In addition to speaking with the team directly implementing these changes, I also spoke to senior management to understand their perspective. I had the opportunity to interview an Operations Senior VP. They highlighted that forty percent of BSC's direct labor is allocated to jobs involving humans looking at things and determining if they are acceptable. When you start to look at the use of smart technology and smart equipment, human inspection is a great first place to start because machines are much better than humans at visual identification. Their goal is to have zero HVIs by 2025 because it reduces BSC's reliance on direct labor; labor markets; and the labor rate, and it improves quality. Their belief is that this initiative will help the sites grow the skills they need to be leaders in smart factory technologies, and the sites will then start to come up with other improvement ideas on their own. Additionally, for machine and AI vision, the real driver is a quality of service and time basis. Humans are 95% effective, at best, and all manufacturing processes have product escapes due to failed HVIs. To meet the companies' growth rates while maintaining quality, BSC needs to reduce the number of HVIs. They have officially made the 2025 target part of all of the sites' goals and deployed a global initiative team to work on the strategy and execution.

Seeing that there was such strong senior leadership support for the machine and AI vision efforts and zero HVI initiative, I asked each site about the support they were receiving for their projects. Most sites expressed that they heard this support at the senior leadership level, however they remarked that there was passive support at the management level, especially with the manufacturing teams overseeing the production lines. As the 2022 strategies were established, the Operations Senior VP's drive for zero HVI by 2025 became more prominent and this passive support is likely to turn to active in the coming years.

Across interviews with all three sites, multiple employees at each site stressed that not having a return on investment, ROI, was the key reason projects didn't get approved. BSC calculates savings and ROI through a system know as VIPS, Value Improvement Projects. These 'VIP' projects must then compete with the site's project portfolio to move forward. AI vision projects are typically identified by technical feasibility first and then the VIP credits are calculated. These early, low risk projects can often not compete at the site level and when they are approved, they are lower on the priority list. Per Jayce Oxton, a Principal Manufacturing Software Engineer at Arden Hills, their team had a hard time getting the operations team to gather the data needed for VIP calculations and perform the calculations due to the perceived low priority and value of the machine and AI vision projects. Julio Zanon, a Principal Engineer in the Galway Equipment Engineering group remarked that Galway's biggest constraint is getting expert support from production engineers as this cohort of professionals is already overstretched trying to keep up with ever increasing volume demands. At Galway, automated inspections are seen as a high-risk, long payback initiative and therefore they tend to be deprioritised when competing with other, faster and less complex initiatives that can also achieve the site's VIP goals. These interviews indicated that a key barrier to this program is finding the value in the projects and starting with a value driven approach might be a good way to get sites on-board and grow the machine and AI vision initiative successfully.

The final area I inquired about was project opportunity identification. As discussed, Maple Grove met with business units at their site to find parts of the plant with need, and then conducted line walks to see if machine or AI vision could improve those areas. Interestingly, when they expanded this effort to new sites, they usually coordinated with one to a few people at the site to determine where to do line walks, versus specific business units, which led to longer, more complex line walks that saw a larger portion of the manufacturing site at once.

The Dorado site visit outcomes provide a good overview of the pros and cons of this approach. The Arden Hills site used a two-tiered approach. They met with the manufacturing teams and gave them a presentation to educate them on the benefits of machine and AI vision projects, areas the technology could help, and whom to contact if they thought there was an opportunity in their area. They would then follow-up these inquiries with targeted line walks. Additionally, they invited the Maple Grove AI Vision team to do multiple unstructured line walks, like at Dorado, to see what they found. These sites are less than 30 minutes apart making site visits very economical. These visits produced some follow-up projects but were time consuming and the projects ended up not having a high enough VIP to move forward.

Finally, Galway has a third approach to opportunity identification, believing that line walks are not the right starting approach. Galway has a technology proof of concept strategy and review team, which was created prior to the launch of the Digital Factory strategy. This team believes that scaling technology is similar regardless of the technology, and the machine and AI vision projects were wrapped into this team, amounting to a small fraction of the projects evaluated each year. Galway's technical department feels line walks, without collaboration with manufacturing, signal a lack of trust in the manufacturing teams that is counter to relationship building with manufacturing. Instead, they find projects using the technology scaling team, where ideas are brought forth by a multi-disciplinary team, and then the team assigned to the project conducts a multi-disciplinary line visit.

These three different approaches highlighted that there are multiple ways to successfully identify projects and helped solidify my belief that starting with the value proposition, rather than the technical opportunity identification, was the right strategy to gain support and resources for the machine and AI vision initiative.

4.1.3 Data Collections

In order to lead with a value proposition based approach, I needed to identify the right sources of data that would be a good proxy for likely value improvement. I looked at the existing project portfolio of Maple Grove projects, the site with the most completed and in-execution projects, to determine the basis on which they were approved. The BSC Digital Facotry Machine and AI vision initiative has implemented four projects including 24 AI models across 40 automated systems to date. There was a clear trend in this data, with projects falling into one of four categories:

1. Labor Reduction
2. Quality Improvement
3. Off-specification Product Escape Risk Reduction
4. Scrap Reduction

I then began interviewing employees in the departments that worked with this information and looked at various sources of site data to determine the best data sources to show the need in these four areas.

Choosing the Right Data Sources and Trade-offs

My second round of employee interviews were conducted with employees working on manufacturing oversight, industrial engineering, and quality improvement in manufacturing. Through these interviews I reached three main conclusions: BSC has a lot of great data available to track production and quality, the data is decentralized with each site using its own approach, and most of the data is hard to understand unless you are very familiar with the specific site's manufacturing. A lot of work is ongoing at BSC to standardize the data and and put it in a common repository, but this work was not ready at the time of my internship. Understanding that there would be trade offs between site-specific, detailed data and global data sources, I worked with each group to determine what the best choice for this application was.

4.1.4 Labor Reduction

Twenty-five percent of the projects implemented by the Maple Grove team have targeted labor reduction, and this is the key driver of this initiative from a senior leadership standpoint. Therefore it was very important to identify a good data source that provided an estimate of the time humans spent inspecting things and where to look for potential machine and AI vision projects. Through employee interviews I determined that each site's Industrial Engineering group kept work content graphs breaking down the tasks required to manufacture a device or sub-component, and what tasks each person was assigned. This provided great quality data with a lot of detail. However, each site was responsible for making these data sources and all used their own format. Additionally, this data was kept on site network drives or Microsoft Teams sites, and was not search-able by anyone in the company. Furthermore, in order to read and correctly interpret the work content graphs, one had to be familiar with the site product portfolio, terminology, and manufacturing steps. Using the work content graphs would include site buy-in, a close partnership and time commitment from the site to help analyze the data, and a tailored approach to analyze the data due to each site's unique formatting.

The global data approach came from the cooperation of Industrial Engineering managers and the foresight of the Digital Factory AI Vision team. In the first quarter of 2021 this team asked each site's Industrial Engineering manager to compile a list of all of the production lines, the time spent conducting human visual inspections, and the annual production volume from each work station, making a summary of the work content graph data. This data was available when I began my internship and was used to determine which areas of the manufacturing site spend the most time annually on human visual inspection. Because we already had this initial data, no further input from the sites was required to do an initial labor analysis, making this data source favorable to the site-specific data.

4.1.5 Quality Improvement

One-hundred percent of the projects implemented by the Maple Grove team have targeted quality improvement as a secondary driver, and this is a key focus area for the quality department and senior leadership. Similarly to the Industrial Engineering data, each site also has its own way of stewarding detailed quality information. There is a common database, eCAPA, that all quality incidents of a certain severity must be entered into. eCAPA stores all Corrective Action / Preventative Action, CAPA, reports and all Nonconforming Events & Prevention, NCEP, reports. Often sites use additional processes and databases to look at all of their quality data as well as implement early detection processes. These systems have more detailed information relating to each specific event. However, they also require site specific knowledge to know where the data is stored, how to access it, and how to correctly interpret the details provided in the reports. For instance Maple Grove has a system designed to track all reports, from multiple sources, that show process quality indicators. This database is very powerful and shows all of the quality data available for the Maple Grove site in one place. It pulls from eCAPA, the Manufacturing Execution System, scrap data, manufacturing complaints, and other sources. However, it is unique to Maple Grove and other sites likely have their own compiling systems. Using this would require reworking the quality data approach for each site to tailor to its unique data architecture.

Of the incidents logged in the eCAPA system, NCEPs are the most frequent due to their lower range of severity. The eCAPA system proved to be a good place to get data for a global project due to its consistency and scope. All quality incidents of a certain type had to be entered into this global system. Additionally, the system was programmed to run standardized reports that generated the same data frame for each site and allowed any BSC employee to view and download this data. While a site-specific contact person was required to further analyze the data and ensure it was being classified properly, this resource provided a great tool to get the initial data set to analyze and the consistency in classification made it easier to analyze the data.

4.1.6 Risk Reduction

Twenty-five percent of the projects implemented by the Maple Grove team have targeted risk reduction. This project aimed at reducing mis-counts by operators, saving approximately $150 K annually. This area is harder to define and therefore find projects for. However, it was included in this assessment framework due to the data sources available in this area. An Operations VP recommended that I look into the Workstation Vulnerability Assessment, WSVA, tool, which is targeted at minimizing the nonconforming product escape risk. The assessment was required to be completed by each site, although some have only done so for a faction of their workstations. This assessment has multiple questions asking specifically about human visual inspection, and was therefore a good data source to use to understand where in the manufacturing site HVIs were occurring.

4.1.7 Scrap Reduction

Scrap reduction was a key value driver for machine and AI vision projects, with fifty percent of the projects implemented by the Maple Grove targeting this area. The estimated scrap reduction for these projects totaled $1.5 M annually. Additionally, one of the projects reduced downstream labor requirements by reducing the amount of downstream scrap that required processing. A lot of projects created in conjunction with the manufacturing teams and the Maple Grove equipment engineering group were to help improve the accuracy and efficiency of product builds, reducing scrap. For example, projects were implemented to deploy AI visual aids over the manufacturing microscope image the technician looks at during assembly. These visual aids can help do counting tasks or show when a part is configured properly. This helps speed up the technician while improving the accuracy of the build, and in some cases, can help ensure a sub-component is properly assembled while rework is still possible, before going to a point when a defect could not be corrected. These projects have led to savings of $100 thousand to $250 thousand per project. While scrap reduction does not directly address the zero HVI initiative, it was still included in the assessment scope due to the value these projects added to production.

Site specific scrap data is available with a deep level of data, including scrap codes with reasons attributed to the scrap. However, like the other site specific data, great knowledge of the manufacturing line, products, sub-components, and assembly methods must be known to properly analyze these codes. Additionally, the scrap codes are all kept in varying data programs across each site, including Tableau, PowerBI, and ClickView. Getting access to these data sources requires multiple user licenses and each site controls their own data. The scrap code information gets compiled into a total scrap cost, which is reported monthly for both scrap variance, versus annual operating plan, and as scrap as a percent of the value of production, VOP. This information is calculated by the site or business unit financial analyst on a monthly basis and is readily available to get for an entire year with limited additional work. It took about an hour for the financial analyst to compile the monthly data for our team to use. Consistent with the other data categories, global data was chosen for the scrap analysis.

4.1.8 Global versus Local Data

After looking at all of the data sources available across the global manufacturing sites, I choose to start with a global data analysis for consistency between sites and due to the availability of the data. My hypothesis was that a global analysis that took limited time, targeting 8 hours of work, would enable the team to get a snapshot of a manufacturing site. This snapshot could be used for initial discussion and to highlight the key value improvement areas for the site. We would then engage with a site contact and use the locally available data for this specific area, or business unit, to dig deeper into the specific manufacturing processes driving the need for value improvement. Once we had that list narrowed, Gemba walks could be conducted to see if machine and AI vision were the right tool to help drive value in these areas.

Chapter 5

Data Analysis

5.1 Initial Analysis

I started the data analysis by gathering the available 2021 data for Maple Grove, capturing 8 months' of data. Maple Grove was chosen as a target site because of my work directors' tie to Maple Grove and because the ongoing work at Maple Grove provided a data set I could check the results of my analysis against.

5.1.1 Labor Data

I started the Maple Grove labor analysis by using the summary of the work content graph provided by the industrial engineering department. Maple Grove is divided into nine business units and consistently used these units to break-down their various data sources. The work content graph summary included the business unit, area name, industrial engineering contact, manual inspection time per line, and annual volume for each line. Using this data I was able to multiply the manual inspection time by the annual volume to get the annual inspection hours per line. I then sorted this data to get a descending list of the highest inspection time lines at the site, as shown in Table 5.1 below.

Business Unit	Area Name	IE Name	Manual Inspection Time per Line (total sec per unit)	Annual Volume (units)	Annual Inspection Time (Hours)
BU 6	Area 1	IE 6	68.0	3537371	66817
BU 2	Area 2	IE 2	20.0	7385943	41033
BU 7	Area 3	IE 7	57.0	2502607	39625
BU 4	Area 4	IE 4	22.5	3371000	21069
BU 6	Area 5	IE 6	233.0	271745	17588
BU 2	Area 6	IE 2	86.0	575196	13741
BU 9	Area 7	IE 9	129.0	243540	8727
BU 9	Area 8	IE 9	376.4	81675	8540
BU 9	Area 9	IE 9	89.0	271745	6718
BU 2	Area 10	IE 2	198.4	98453	5426
BU 2	Area 11	IE 2	11.0	1092661	3339
BU 2	Area 12	IE 2	70.3	141632	2766
BU 4	Area 13	IE 4	58.0	168600	2716
BU 4	Area 14	IE 4	121.6	80300	2712
BU 2	Area 15	IE 2	80.0	120479	2677
BU 7	Area 16	IE 7	86.0	110617	2643
BU 4	Area 17	IE 4	32.0	273100	2428
BU 9	Area 18	IE 9	32.0	247091	2196
BU 7	Area 19	IE 7	160.0	49342	2193
BU 9	Area 20	IE 9	89.6	85758	2134

Table 5.1: Work Content Graph Analysis

5.1.2 Quality Data

The eCAPA NCEP report took an hour to download. It provided forty-two unique columns of data and for each NCEP entry and over 1300 entries for the first eight months of 2021. Upon reviewing the data, I decided to use a Pivot Table to summarize the top quality improvement areas. The data included a unique NCEP number for each event, the business unit, if the event was operations related, the work stream, the product family, a description of the event, and other key identifiers. Initially, I hoped to use text filtering to identify all NCEPs that were inspection related. However, through interviewing manufacturing and quality employees, I determined that there were no requirements to enter this information in the NCEP system and the right level of text details were only available in a small percentage of the entries, making the text filtering an unreliable analysis. With the data available, I proposed we pivot the data to look for unique NCEP entries that were operations related and then do a descending list of the work stream, which represented the nine business units, and product families with the most entries. My work directors agreed that this was the best approach for the data. I then filtered out the work streams and product families that would not be related to human visual inspection, such as defects in the raw materials arriving from a supplier. The NCEP pivot table analysis is shown in Table 5.2 below.

Operations Related?	Yes
Unique ID?	1
Initiation Date	(All)
Work Stream	(Multiple Items)

Row Labels	Count of No.
BU 4 - Product Family A	50
BU 7 - Product Family B	40
BU 7 - Product Family C	35
BU 4 - Product Family B	30
BU 4 - Product Family C	28
BU 1 - Product Family A	25
BU 9 - Product Family D	25
BU 7 - Product Family E	20
BU 3 - Product Family F	19
BU 7 - Product Family G	19
BU 1 - Product Family H	19
BU 8 - Product Family A	18
BU 6 - Product Fmily I	18
BU 4 - Product Family I	17
BU 6 - Product Famly J	16
BU 4 - Project Family K	16
BU 8 - Product Family L	13
BU 9 - Produt Family M	13
BU 3 - Product Family E	12
BU 2 - Product Family K	12
BU 5 - Product Family N	12

Table 5.2: Nonconforming Events & Prevention Analysis

5.1.3 Risk Reduction Data

According to the BSC Lexicon, an internal reference library for BSC,the workstation vulnerability assessment is "a tool used at BSC manufacturing and distribution sites to help identify and mitigate process vulnerabilities at each manufacturing workstation, in order to reduce downstream quality issues." It is comprised of forty-three questions that span a range of categories and focus areas including people control, measurement control, and equipment control and inspection types, automated equipment accuracy, and process setup respectively. Each question is very specific and has a range of answers, called "risks" from one to five. Each "risk" score corresponds to a specific answer for that question. For example, question one is in the category of *people control* with a focus area of *inspection type*. A risk one answer for question one indicates that *no inspection takes place at this work step or no defects are inspected* while a risk five answer indicates that *sample and/or human inspection with manual equipment occurs*. A risk one and five answer for a different question have their own unique text to explain the risk scale for that specific assessment.

Upon reviewing the forty-three questions with the Digital Factory AI Vision team, we aligned on eight questions that indicate if the workstation has a high risk related to HVI.

1. Are defects inspected as part of this work step's inspection activities? What type of inspection method's are used at the work step (automated/monitor/manual/sample)?

2. Does the product builder complete inspection on their own work that is being processed at this work step or at a work step further downstream?

3. Is this an automated acceptance activity (vision system) making a quality decision? Is there a periodic check to ensure ongoing accuracy of the measurement?

4. Can you physically distinguish processed and unprocessed or inspected and uninspected at the workstation?

5. Is part positioning a critical input to process, print, downstream operations, or performance output?

6. Can the processing or inspection steps at the workstation be bypassed?

7. Are visually similar components/materials stored locally at this work step, or stored offline in a communal setting prior to being brought to this work step?

8. Is there a likelihood of wear due to moving parts within the process work step that impacts product quality (i.e. functionality of equipment or transfer of metallic, plastic FM on to product)?

We then reviewed each of these eight questions to pick the proper risk scores, and corresponding question answers, that should be used. Once this question and answer set was created, I added logic to the Microsoft Excel workbook containing the WSVA answers for the site. I then created logic columns to indicate if a workstation answered the proper risk score for one of these questions, and flagged those workstations accordingly. The WSVA also contained a column for the business unit and a column for the workstation. Additionally, the workstation data contained an overall score calculated from looking at the "risk" answer for each question, the impact score, and an occurrence score, where the impact score is a *measure of the overall impact of the error and/or defect occurring* and the occurrence score is *a measure of the likelihood of the error and/or defect occurring*. I created a pivot table to look at only the workstations that had been flagged based on the answers to the eight questions, and summarized it by business unit - workstation combinations. The overall score was used to rank the business unit - workstation combinations in descending order based on overall score, shown in Table 5.3 below.

Follow-up?	1

Row Labels	Sum of Score
BU 9 - Workstation 1	402
BU 7 - Workstation 2	360
BU 8 - Workstation 3	270
BU 9 - Workstation 4	237
BU 7 - Workstation 5	229
BU 2 - Workstation 6	229
BU 1 - Workstation 7	225
BU 3 - Workstation 8	214
BU 2 - Workstation 9	212
BU 7 - Workstation 10	202
BU 1 - Workstation 11	196
BU 9 - Workstation 12	195
BU 3 - Workstation 13	194
BU 9 - Workstation 14	190
BU 3 - Workstation 15	190
BU 3 - Workstation 16	190
BU 9 - Workstation 17	187
BU 5 - Workstation 18	184
BU 9 - Workstation 19	184
BU 1 - Workstation 20	180
BU 1 - Workstation 21	180

Table 5.3: Workstation Vulnerability Assessment Analysis

5.1.4 Scrap Data

The Maple Grove scrap data for the first eight months of 2021 was provided to me by a financial analyst. This data was already sorted into the nine key business units and included scrap as a percent of VOP and scrap variance. I used this data to find the rolling average of scrap as a percent of VOP and the total annual variance to date. Both of these data sets were then put in descending order by business unit and are shown in Table 5.4 below. The scrap data required the least additional analysis due to the work previously done by the financial analyst.

Average Monthly Scrap % by BU	
BU	2021
BU 8	39%
BU 1	23%
BU 9	16%
BU 2	12%
BU 5	11%
BU 7	10%
BU 6	9%
BU 4	9%
BU 3	7%

Total Scrap Variance (Annual)	
BU	2021
BU 8	$ 6,605,191.00
BU 6	$ 1,004,863.00
BU 2	$ 102,114.00
BU 1	$ 29,931.00
BU 7	$ (350,001.00)
BU 5	$ (746,669.00)
BU 9	$ (923,035.00)
BU 3	$ (1,366,100.00)
BU 4	$ (1,387,063.00)

Table 5.4: Scrap Analysis

5.1.5 Checking Data with Site Resource

After I completed the initial data analysis I verified that it took less than a business day to collect and analyze all data. I then met with my work directors to quality check the data and make any site-specific adjustments I would not be aware of. This screening step involved removing product lines that were about to be discontinued and adjusting for any other areas that did not fit within the human inspection realm but were not labeled in an obvious manner. After the final adjustments were made, I recorded the top 10 highest areas from each data source analysis, as shown in Table 5.5 below.

Source	Description	Bucket	Rank
WCG	BU 6 - Area 1	BU 6	1
WCG	BU 2 - Area 2	BU 2	2
WCG	BU 7 - Area 3	BU 7	3
WCG	BU 4 - Area 4	BU 4	4
WCG	BU 6 - Area 5	BU 6	5
WCG	BU 2 - Area 6	BU 2	6
WCG	BU 9 - Area 7	BU 9	7
WCG	BU 9 - Area 8	BU 9	8
WCG	BU 9 - Area 9	BU 9	9
WCG	BU 2 - Area 10	BU 2	10
NCEP	BU 4 - Product Family A	BU 4	1
NCEP	BU 7 - Product Family B	BU 7	2
NCEP	BU 7 - Product Family C	BU 7	3
NCEP	BU 4 - Product Family B	BU 4	4
NCEP	BU 4 - Product Family C	BU 4	5
NCEP	BU 1 - Product Family A	BU 1	6
NCEP	BU 9 - Product Family D	BU 9	7
NCEP	BU 7 - Product Family E	BU 7	8
NCEP	BU 3 - Product Family F	BU 3	9
NCEP	BU 7 - Product Family G	BU 7	10
WSVA	BU 9 - Workstation 1	BU 9	1
WSVA	BU 7 - Workstation 2	BU 7	2
WSVA	BU 8 - Workstation 3	BU 8	3
WSVA	BU 9 - Workstation 4	BU 9	4
WSVA	BU 7 - Workstation 5	BU 7	5
WSVA	BU 2 - Workstation 6	BU 2	6
WSVA	BU 1 - Workstation 7	BU 1	7
WSVA	BU 3 - Workstation 8	BU 3	8
WSVA	BU 2 - Workstation 9	BU 2	9
WSVA	BU 7 - Workstation 10	BU 7	10
Scrap %	BU 8	BU 8	1
Scrap %	BU 1	BU 1	2
Scrap %	BU 9	BU 9	3
Scrap %	BU 2	BU 2	4
Scrap %	BU 5	BU 5	5
Scrap %	BU 7	BU 7	6
Scrap %	BU 6	BU 6	7
Scrap %	BU 4	BU 4	8
Scrap %	BU 3	BU 3	9
Scrap Var	BU 8	BU 8	1
Scrap Var	BU 6	BU 6	2
Scrap Var	BU 2	BU 2	3
Scrap Var	BU 1	BU 1	4
Scrap Var	BU 7	BU 7	5
Scrap Var	BU 5	BU 5	6
Scrap Var	BU 9	BU 9	7
Scrap Var	BU 3	BU 3	8
Scrap Var	BU 4	BU 4	9

Table 5.5: Top Areas for Each Data Source

5.2 Communication Methodology for Data Analysis

5.2.1 Site Alignment of Strategy

Once I had the top priority areas for each of labor, quality, risk, and scrap, I needed to find a way to clearly communicate this to the site. The list made it too difficult to find overlapping areas, as there was too much data to look at and it was hard to quickly see the difference between business units frequently at the top of the lists versus the bottom of the lists. Considering that the business units and management were familiar with looking at score cards for various corporate metrics, we decided to focus on a similar visual approach. I tried a grid approach, putting the five data categories on the x-axis and the business units, Maple Grove has 9, on the y-axis. I then recorded the rank each business unit had for each category, shown in Table 5.6 below.

Import Rank Here, Enter ranks for each category by Business Unit or other group

Do Not Delete

	Labor WCG	Quality NCEP	Risk WSVA	Scrap % VOP	Scrap Var		Rank	Assigned Value
BU 1		6	5 9	2	4		1	10
BU 2	2 6		4 6	4	3		2	9
BU 3	7	9	8 10	9	8		3	8
BU 4	4	1 4 5		8	9		4	7
BU 5				5	6		5	6
BU 6	1 5			7	2		6	4
BU 7	3	2 3 8 10	1 3 7	6	5		7	5
BU 8			2	1	1		8	3
BU 9	8 9 10	7		3	7		9	2
							10	1

Converted Score (1=10, 10=1)

	Labor WCG	Quality NCEP	Risk WSVA	Scrap % VOP	Scrap Var
BU 1		4	6 2	9	7
BU 2	9 4		7 4	7	8
BU 3	5	2	3 1	2	3
BU 4	7	10 7 6		3	2
BU 5				6	4
BU 6	10 6			5	9
BU 7	8	9 8 3 1	10 8 5	4	6
BU 8			9	10	10
BU 9	3 2 1	5		8	5

Table 5.6: Data Classification for Analysis Visual

Looking at this data table, an obvious issue came to rise. Business units without representation in the top ten list for each category had the lowest score of all, which conflicted with the business units having the most items in the first place, and therefore the most room for improvement, having the second lowest score. To resolve this conflict, I applied a reverse ranking to the data, where items in the first place were assigned a score of 10, and items in the tenth place were assigned a score of 1, shown in red in the Data Classification for Analysis Visual table above. This converted score table is the bottom graph in Table 5.6 above. I then summed the converted numbers for each score, and used that to create a table of the combined score for each category, shown in Table 5.7 below. Upon review with the Digital Factory AI Vision team, we were concerned people would put a lot of meaning into the scores and give them more merit than they had. This led us to consider using an approach similar to the Money Maps discussed in the literature review. Because we coded the data based on the scores, we called this approach a heat map.

	Labor WCG	Quality NCEP	Risk WSVA	Scrap % VOP	Scrap Var	Total
BU 1	0	4	8	9	7	28
BU 2	13	0	11	7	8	39
BU 3	5	2	4	2	3	16
BU 4	7	23	0	3	2	35
BU 5	0	0	0	6	4	10
BU 6	16	0	0	5	9	30
BU 7	8	21	23	4	6	62
BU 8	0	0	9	10	10	29
BU 9	6	5	0	8	5	24

Table 5.7: Data Analysis Visual with Total Scores

5.2.2 Heat Map Creation

To switch from a scored table to a heat map, I used the conditional formatting feature in Microsoft Excel to put each x-axis category on a color gradient scale, with higher numbers getting the darkest color, as shown in Table 5.8 below.

	Labor WCG	Quality NCEP	Risk WSVA	Scrap % VOP	Scrap Var	Total
BU 1	0	4	8	9	7	28
BU 2	13	0	11	7	8	39
BU 3	5	2	4	2	3	16
BU 4	7	23	0	3	2	35
BU 5	0	0	0	6	4	10
BU 6	16	0	0	5	9	30
BU 7	8	21	23	4	6	62
BU 8	0	0	9	10	10	29
BU 9	6	5	0	8	5	24

Table 5.8: Data Analysis Visual with Color Gradient Overlay

Next, I sorted the data to rank the business unit with the highest total score first, and removed the numbers so the final heat map only had a color gradient, shown in Figure 5-1 below. This final heat map was used to move forward with the analysis and as the primary communication tool for the operations strategy.

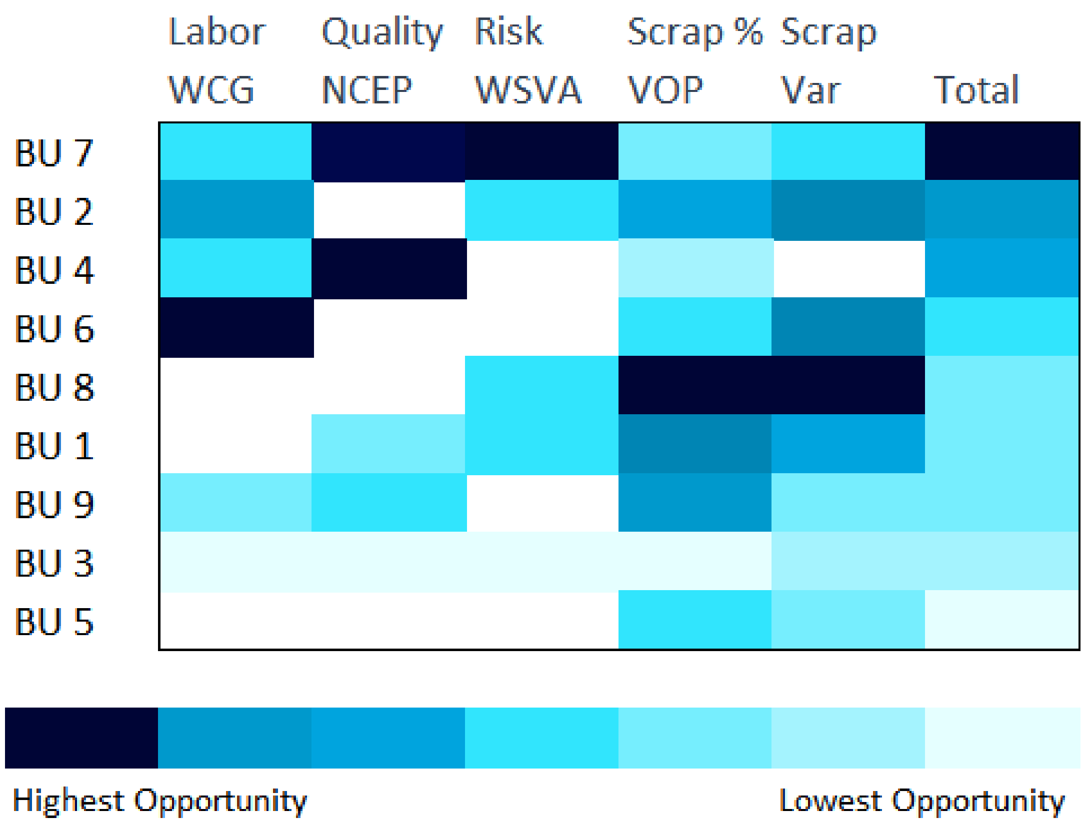

Figure 5-1: Final Heat Map for Maple Grove

5.3 Bench-marking with Existing Opportunities

In order to determine if this proposed heat map methodology was a good analysis to use for finding machine and AI vision opportunities, I next compared it to the projects the Digital Factory AI Vision team at Maple Grove had discovered through their past two years of work. According to the heat map the top labor opportunities were in business units six and two, and Maple Grove had discovered and implemented labor reduction projects in both of these areas, shown in purple in Figure 5-2 below, through their process of meeting with individual business units and conducting line walks. The top quality areas were in business units seven and four, and the Maple Grove team had independently discovered a seal inspection quality improvement project in business unit four, also shown in purple in Figure 5-2 below. Business unit eight had the greatest scrap contribution, and there were multiple scrap reduction projects underway in this area, also shown in purple. Of all of the high opportunity areas shown in the assessment, business unit seven was the only one that did not have active projects, shown in red in Figure 5-2. Upon speaking to the Maple Grove team, they had not yet engaged with business unit seven and started working with them to find quality and risk reduction opportunities as a result of this assessment. Based on the high overlap between the heat map assessment and the opportunities the Maple Grove Digital Factory AI Vision team had found independently, we decided to proceed with this analysis as the primary assessment tool for the Digital Factory machine and AI Vision operations strategy.

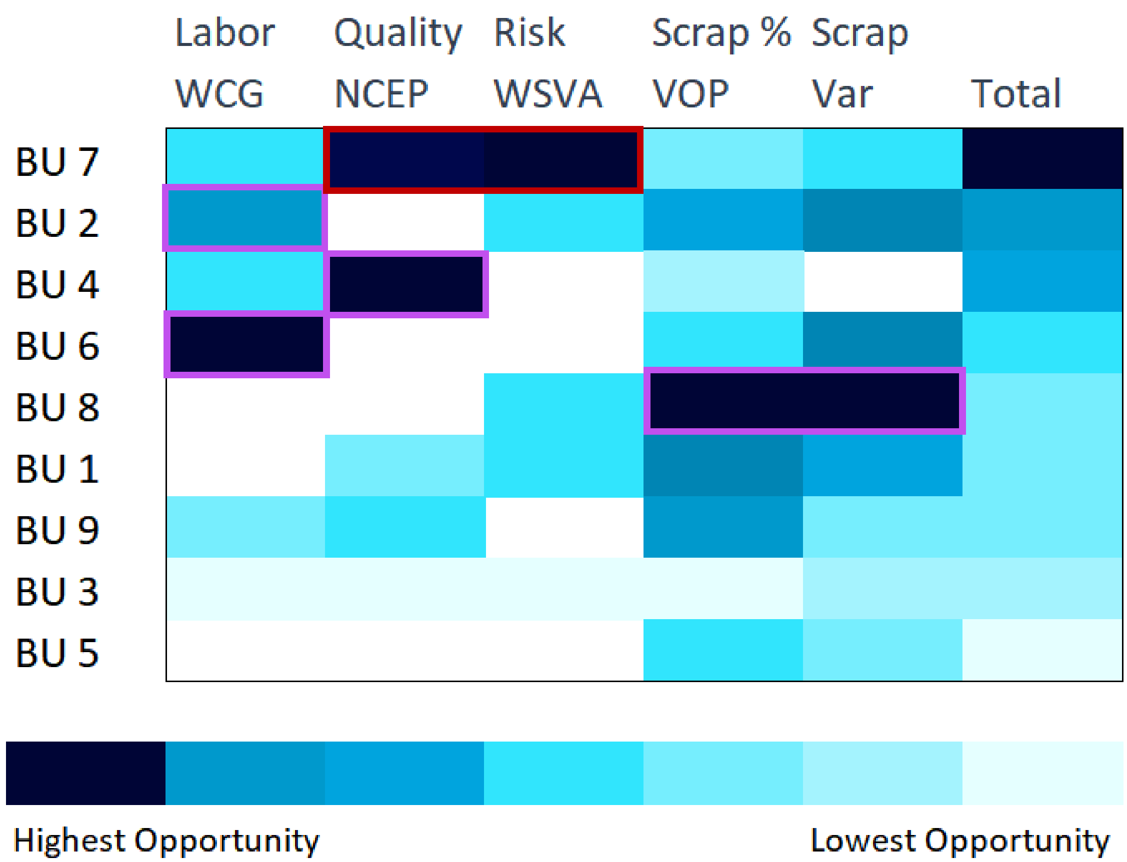

Figure 5-2: Final Heat Map for Maple Grove with Opportunity Overlap

To further validate this assessment, Arden Hills, who was also actively identifying projects through their own methodology, provided me with their data set to benchmark against. The Arden Hills heat map is shown in Figure 5-3 below.

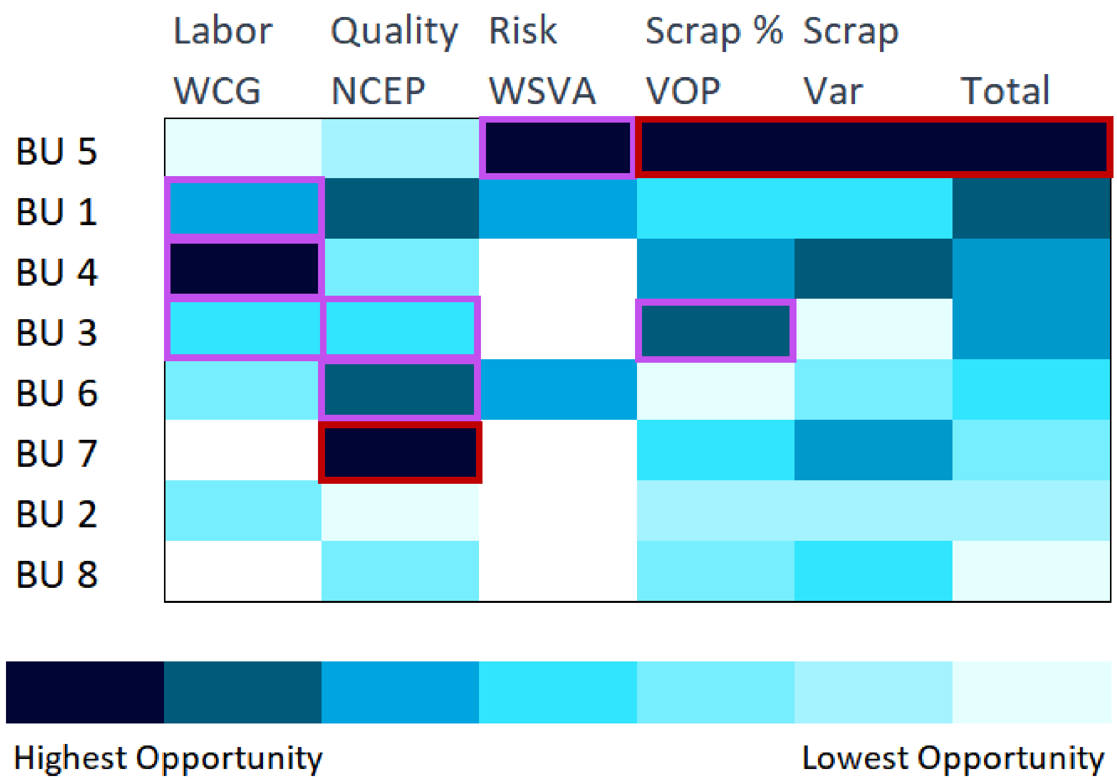

Figure 5-3: Final Heat Map for Arden Hills

The Arden Hill heat map overlay did not match as well as the Maple Grove comparison did, however, there was a strong enough correlation to show that this analysis helped highlight the areas the sites were finding on their own through a much more time consuming process. Through their own analysis, Arden Hills identified potential machine and AI Vision labor improvement projects in business units one, three and four, which matched the heat map well. In the quality improvement opportunities there was overlap in two of the top four categories, and in one of the top categories for risk and scrap. Due to an upcoming assembly relocation to another manufacturing site for a large part of business unit five, Arden Hills had decided not to pursue the scrap reduction potential in this area. Finally, the Arden Hills team had not yet assessed business units seven and eight. Overall the Arden Hills data showed significant overlap for all of the high opportunity areas and furthered our confidence in proceeding with this analysis.

5.4 Application of the Heat Map

5.4.1 Target Area Selection

The heat map is just the first step in finding machine and AI Vision opportunities. This tool helps the technical team target their approach to the right business unit, and then engage in a deeper analysis with that unit. Using the heat map, the Digital Factory AI Vision team meet with the site teams to determine which of the high opportunity, dark blue, areas was best to pursue based on current site activities and ongoing work. In the Maple Grove case, there were already projects underway for all of the high opportunity areas except business unit seven, so we chose to engage with them. Once the business unit(s) is selected the team can engage in a deeper analysis using site-specific data to get more details on what parts of that business unit to conduct manufacturing line walks at.

5.4.2 Additional Analysis Steps

The additional analysis step usually starts by seeing what analysis is possible using the data already in the assessment. The quality NCEP data and the risk WSVA data both have additional levels of data that can be filtered and pivoted to find the top product families contributing to high NCEP count and the top workstations contributing to the high risk. These areas are then used to create a business unit specific seriatim. For scrap data, the business unit is asked to provide their site-specific scrap data including scrap codes, so this data can be analyzed to make a seriatim. Finally, for labor data, industrial engineering is engaged to take a deeper analysis of their work content graphs and find the workstations with the highest individual inspection times and volumes. The top opportunity areas from each of these additional analysis was then turned into a list to do a targeted site visit and line walk to assess for machine and AI vision opportunities. Because the line walks were now focused to areas of known value, if a project was found the team had much more confidence that it would have the VIP to get approved and would be a priority for the manufacturing site.

By doing this work after the heat map is created, only a few business units are asked for each type of information, taking the total number of site-specific data analysis from forty-five to six in the Maple Grove case, based on their nine business unit grid. This greatly reduces the time requirements of the site personnel who have conflicting priorities. Additionally, when speaking to these business units about the specific high opportunity areas, they were very receptive to our help because we were addressing a high priority for them as well. For instance, when the team set up meetings with the quality team for business unit seven, they were naturally aware of their business units quality issues and were happy to discuss a collaboration. They had not been aware that machine and AI vision could improve quality issues and therefore had not thought to partner with this team. Our proactive engagement with a group's common issue led to a lot of support, a productive meeting where they highlighted their biggest quality issues, and the scheduling of line walks to see if AI vision could help solve some of these issues.

5.4.3 Workflow to Opportunity List

The heat map was just the initial step to identify areas of a manufacturing site to look for opportunities. However, to get sites on-board to execute this process and ensure there was proper ownership so it did not get ignored, a workflow needed to be established. I worked with the Digital Factory AI Vision team to create the workflow shown in Figure 5-4 below. All of the steps in this workflow are led by the Digital Factory AI Vision team.

Figure 5-4: Workflow from Data Analysis to Line Walk

We started by having a kickoff meeting with the site we were working with, and asked them to identify a site single point of contact, SPC, to work with us on the analysis. Some sites provided us with this person, while others named multiple people to this role. In all instances where a single person owned this relationship for the site, more progress was made during my internship and responses were received faster than the sites that appointed a team and had shared ownership. At the kickoff meeting we reviewed a slide deck and proposal showing the value of machine and AI vision projects, the four data sources I proposed we examine, and the results of the Maple Grove heat map to demonstrate the plan we were proposing to execute at the new site. We also went through this workflow to show the required commitment.

After the kickoff meeting I conducted the initial data analysis, working with the site SPC, and developed the heat map. The site SPC was a crucial team member for the proper heat map generation because they helped provide site-specific knowledge and helped establish the categories for the y-axis of the heat map. Not all sites had their data classified into consistent business units or labels like Maple Grove did, and site expertise was required to establish heat map categories that made sense to the site manufacturing was set-up. The site SPC helped with quality checking the information and reviewing the final heat map.

Once the heat map was finalized we held a follow-up meeting with the same team that attended the kick-off meeting. At this follow-up meeting we decided which business units to focus on based on the high opportunity zones and ongoing work at the site. We then discussed what data sources would be used to conduct the additional data analysis discussed in the previous section. The site SPC and I conducted the additional data analysis and met with the target business units to gain any insights they had regarding the opportunities in their area. We then analyzed the new seriatims and created a list of ten to thirty workstations to visit, with the objective of spending one day doing line walks at the site looking at these targeted areas. Finally, line walks at the site were scheduled and conducted.

At the end of my internship, we had only executed the workflow through the line walk. However, we established the post line walk workflow shown in Figure 5-5 below. Post line walk, the site owns the workflow and the Digital Factory AI vision team supports the process. This is a critical part of the process as potential projects need assessed and taken through to the approval phase in order for solutions to be implemented.

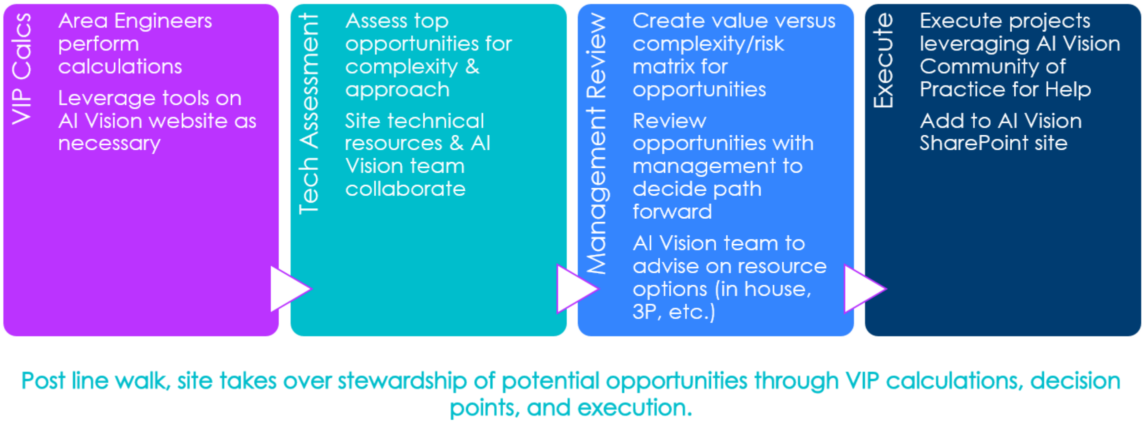

Figure 5-5: Workflow Post Line Walk

After line walks are conducted, the site must start gathering the required data to do a VIP calculation. These calculations are led by the area engineer, who has the required knowledge about the area. We created tools, discussed in Chapter 7, that help simplify the VIP calculations. In addition to the VIP calculations, a technology feasibility assessment is also conducted to understand the complexity of the project. The Digital Factory AI Vision team assists with this assessment as much as the site needs them to, and can help advise on the type of solution, the resources required, and the equipment required. Factors that are considered are if the part is fixtured during inspection / assembly or moved by a technician, if a camera is already present, if a measurement is being made or a visual judgement, and how quantifiable what is being measured is. Once the VIP calculations and technical feasibility assessments are completed, the site can make a list of the potential opportunities and plot them on a complexity versus VIP scale, shown in Figure 5-6 below.

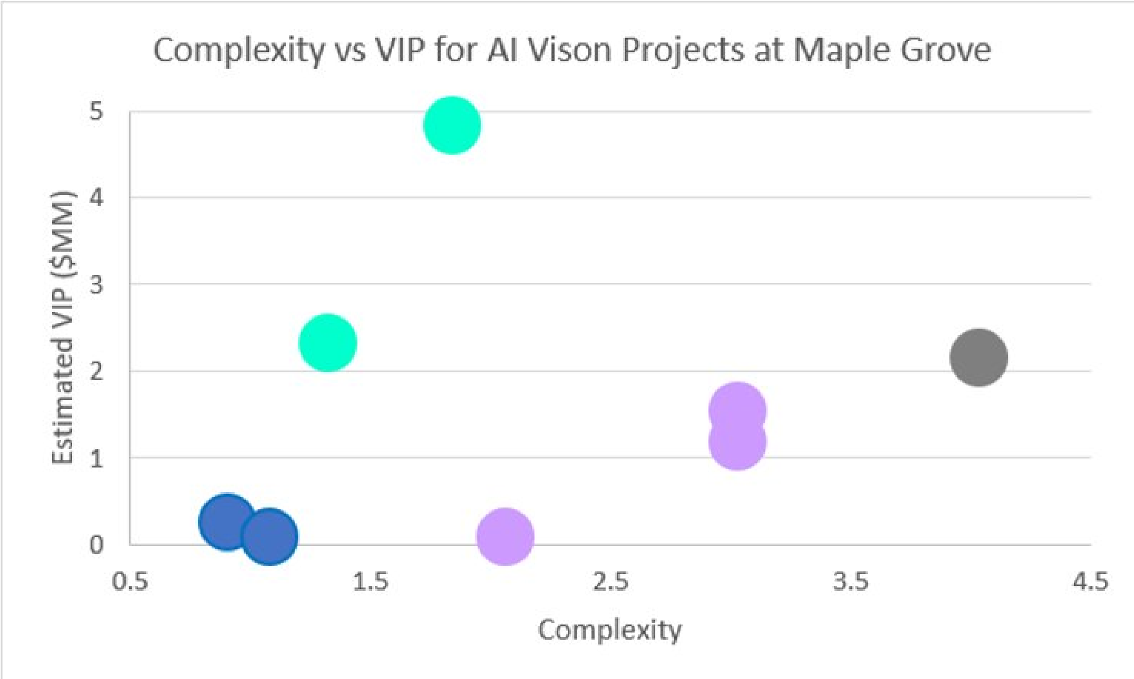

Figure 5-6: Example of Complexity Versus Value Map for a Site

Finally, the site takes the opportunity list through the management review process to get projects approved and incorporated into the active project list or included in the next year's annual operating plan. The site then begins planning and executing the projects and sharing their learning's with the Global AI Vision Community of Practice. Upon completion the projects are logged on the AI Vision SharePoint site, discussed in Chapter 7, so future sites and project teams can reference it as applicable.

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Chapter 6

Results

6.1 Site Reception

The first test of the AI Vision Operations Strategy was site adoption. Before proceeding from the initial test heat map, using Maple Grove data, to testing it at a site without an active AI Vision team and project portfolio, I had to see if sites were receptive to the heat map process. I presented the heat map and workflow at an AI Vision Community of Practice meeting, which is attended by representatives from all of the manufacturing sites. The sites had positive reception and seven additional sites were interested in working with our team to get heat maps created for their sites. Ultimately I created heat maps for the following sites:

1. Arden Hills, MN, USA
2. Clonmel, Ireland
3. Cork, Ireland
4. Coyol, Costa Rica
5. Galway, Ireland
6. Heredia, Cost Rica
7. Maple Grove, MN, USA
8. Spencer, IN, USA

6.2 Test Site - Spencer, IN

Of all the sites I worked with, Spencer had the most resources available and agreed to partner with me to get to the line walk process before the end of my internship. They were also one of the sites that appointed a single point of contact to help with the assessment.

6.3 Identified Opportunities

During the last week of my internship, a member of the Digital Factory AI and Machine Vision team was able to visit the Spencer site to do a line walk of the areas the heat map process identified. However, results from this walk were not available at the time of my departure. In the time since my internship Spencer has begun pursuing two projects identified during the December site visit. The heat map process helped by targeting the line walks so the team ended up taking a close look at approximately fifteen percent of the factory versus the previous method of taking a cursory glance at one hundred percent of the factory. Additionally, one of the projects identified and being pursued was missed during a May 2021 visit to Spencer before this assessment methodology was developed. While this is only one data point, it provides strong evidence that the assessment method helps improve the time requirements and impact of line walks and helps to identify viable machine vision and AI projects to replace human inspection.

Chapter 7

Other Implementation Considerations

7.1 Cultural Impacts

As discussed in Chapter 3, Literature Review, culture is a very important part of leading a digital change. This was apparent from the start of my project and was also addressed in some of my interviews. It was important to address each sites' culture and ensure the communication and approach from the the corporate Digital Factory team was tailored to the site and programs needs. The end goal was to have a pull strategy where the manufacturing teams were aware of the machine and AI vision tools and sought out help to partner with the technical team to solve manufacturing problems. However, we had to start with a push strategy, because many sites did not know about these resources, while building the framework to transition to a pull strategy at a later date.

In order to achieve this, the Digital Factory team made a road show style presentation to present the technology, its successes within BSC, and how their team could help. They presented this, virtually, to all of the manufacturing sites and offered to work with the sites on next steps to develop an opportunity list. Through the Gemba walks we aimed to identify those opportunities and also help build awareness on the manufacturing floor.

Additionally, we leveraged a training presentation the Arden Hills team made, targeted towards manufacturing teams, which explained how machine and AI vision add value, gave example projects, and discussed how to get help for consultations on these projects. We put this tool on the AI Vision intranet website in order for all sites to use it to help train their teams and build awareness.

One issue I expected to arise throughout the project was technicians being wary or against the machine and AI vision projects, out of fear of being automated out of their jobs. However, this ended up not being an issue. In the geographic locations where removing humans from tasks makes economic sense, there are ongoing labor shortages where more skilled labor is needed than is available. At these sites, when a human is removed from an inspection task they are placed on a new open job. Because the employees are aware of this, and no employees have lost their jobs thanks to automation, to date, the cultural trust in seeing automation and AI technologies as a partnership and job aid exists.

The final cultural item we considered was the role of a global Digital Factory team providing guidance to the technical teams at other sites. This had to be approached delicately to not insult the sites. In order to do this we formed partnerships and offered help versus mandating what the sites do. Additionally, we asked sites to share their experiences and included their learning's with the global tools. Finally, if a site did not want to partner with us we did not force them to.

7.2 Tools for Successful Technology Launch

Through my interviews I determined that most sites had great tools but everyone was making their own and not collaborating. Some sites had great tools for one area but needed help in another. It became clear that the tools to find these projects, plan them, and execute them were just as important as finding the opportunities was. Additionally, the tools were required to have a successful technology launch and make the work I did sustainable for the future. I worked with the AI Vision Digital Factory team leads to understand what tools were required and build out the AI Vision intranet site to be a single source resource for future projects. We also created a model reference library on this site so everyone could see what projects had been completed and find contact people to collaborate with for similar projects.

7.2.1 Resource Alignment and Requirements

One of the key questions the AI Vision Digital Factory team was frequently asked was what resources were required to execute a project, how long it would take, and what information they should put in their annual business plan to secure these resources and be able to do a future project. This was a very difficult question to answer when sites did not have a project list identified let alone scoped. In order to assist with this I gathered information on the Maple Grove completed projects to make reference resource tool. New project teams could use this tool to assist with estimation. This tool included the complexity, VIP savings, existing equipment such as cameras, if the project was executed in-house or by a third party, time required to execute, and the hardware cost. It also included the labor required for the project by job role and full time equivalent hours,such as AI/Machine Vision Engineer, Software Programmer, Project Manager, Quality Engineer, etc. Finally, it included the number of systems the project addressed. By looking at this table and finding a project similar to the one a site thinks they identified, they can quickly get a rough estimate of what it would take to execute the project. As more projects are completed this table will continue to be updated to become a better resource, in the future, hopefully, an actual estimation tool capable of extrapolating estimates within the data set range.

7.2.2 Timeline

Another question the AI Vision Digital Factory team was often asked was how long the process takes from having a site kickoff meeting to working through the sites top few priority opportunities. Using the Maple Grove and Spencer sites as models, I created a timeline, shown in Figure 7-1 below, to highlight the workflow and time requirements. I modeled a moderate situation where a site cannot devote full time resources to these efforts but does make a single point of contact and meets up to once a week to progress these issues.

This timeline shows that it takes approximately three months to get an initial project list and have a project ready for management review and approval, listed at "Management Opportunity Review" in Figure 7-1. After the initial process has been kicked off and one key focus area has been assessed, it takes approximately two additional months to analyze a new focus area and get additional projects approved in these areas, highlighted by a color change in Figure 7-1.

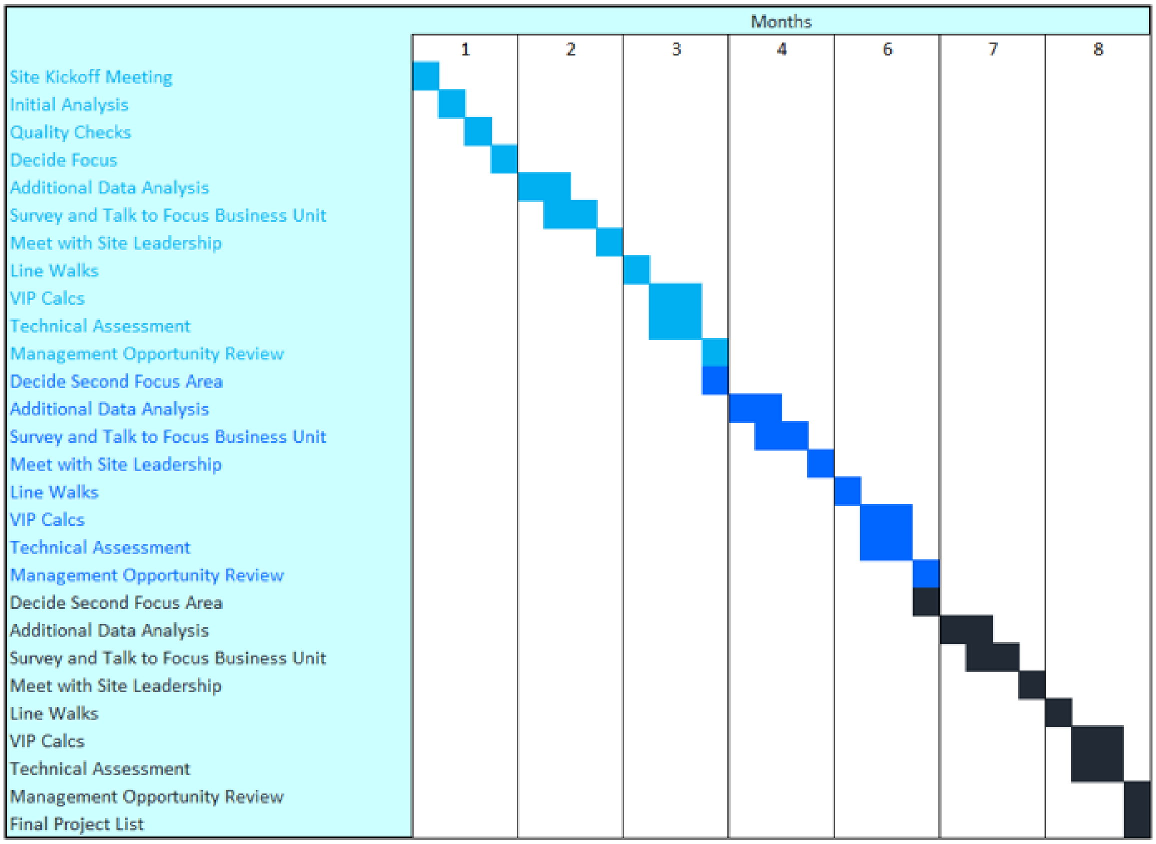

Figure 7-1: Timeline to Complete Opportunity Identification Process

7.2.3 Value Proposition Calculation Tools

Value Proposition calculations, or VIP calculations in BSC terminology, were a repeated area of concern and difficulty for the machine and AI vision projects, as quality at an individual workstation is difficult to assign a cost to. If we can reduce the percent of product escapes at one workstation, but the product still goes through many more workstations downstream, how much value was added? This is a question that is difficult to address. Additionally, scrap value is often not assigned at a specific workstation and is also hard to address. Finally, the savings of a project is not always known at the estimation stage, often only an indication that the project will improve the outcome is known. Through my interviews I identified that the Arden Hills site had made a great VIP calculation spreadsheet that included important questions to ask to understand the complexity of a project, such as if the part was fixtured, if rework was still possible at this stage, and what equipment such as cameras were already present. Additionally, the spreadsheet had a tab that included standardized company financial estimates to use for the things like an ergonomic improvement, a quality improvement, and other key items. This tool made calculating the VIP value for a project much easier and helped standardize the way these projects are evaluated across the company. We added this spreadsheet to the AI Vision website so everyone had access to it.

7.2.4 Technology Readiness Assessment Tools

The final tool that multiple sites needed but only one had was the Technology Readiness Assessment Tool, created by the Galway site's technical team. This tool helps take an inspection standard and translate it into the information needed for the machine and AI vision engineers to turn it into an automated inspection via code. This tool streamlines the process and makes getting the right information to the project team easy, preventing potential project delays and rework. It also helps a project work through the technical challenges early on, before they get too far along the project pipeline. The tool helps document key information so all project members have access to the same information such as ambiguities in the pass/fail criteria, tactical steps required during the inspection, post inspection handling requirements, image acquisition complexity, example inspection images, reference inspection documents, and a list of all product varieties subject to this inspection specification. When this tool was demonstrated at an AI Vision Digital Factory Community of Practice meeting, all of the sites in attendance were very excited to start using the tool to assist them with their project scoping and implementation.

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Chapter 8

Recommendations for AI and Machine Vision Launch in Global Manufacturing

8.1 Recommendations

This project enabled me to network with most of BSC's manufacturing sites, job functions, and departments. Through this work and the third party literature review there were several key areas that led to improvement or could have improved the effectiveness of the AI and Machine Vision efforts.

First, sites with Equipment Engineering groups seemed better prepared than sites without this group to handle technical changes, implement new innovations, and have a collaborative relationship with the manufacturing team. The Equipment Engineering group regularly works with the manufacturing team and the technicians assembling the BSC products. This relationship fosters trust and helps the manufacturing team know whom to go to when they see areas for improvement. In turn, more improvement areas are identified faster, and the Equipment Engineering group and manufacturing teams can collaboratively solve the problems. The on-site Equipment Engineering group model should be considered at all manufacturing sites, especially as BSC continues its work to bring Digital Factory capabilities to its manufacturing lines.

The next recommendation is to have sites communicate better with each other, continuing to share their tools and projects with the rest of the AI Vision Community of Practice. When I spoke with sites about the tools they developed, such as the

VIP calculation tools, some sites had unknowingly spent valuable time duplicating work already done by other sites. When these tools were shared by various parties at Community of Practice meetings, the other sites in attendance were very receptive and started using these tools themselves. As BSC continues to lead technology changes, they should further utilize the Community of Practice structure to encourage sharing of tools and resources to avoid duplicating work and instead foster collaboration to strengthen the ability of each tool.

A lot of the projects discussed during my internship had strong technical potential and long term impacts, however, the initial return on investment and corresponding VIP valuation was low, which made the project not get chosen versus others in the portfolio. Per section 3.3 of this thesis, Maximizing Return on AI Initiatives, companies must commit to AI as a tool for achieving corporate goals. In order to get some of these AI projects started, so the company can meet its long term manufacturing technology goals, BSC should develop a way to provide funding for these projects from a different source than the standard project review process and funding. If these projects have to compete with the site VIP list, they will have a difficult time getting approved. BSC should consider treating these projects as an intermediary between the early stage research partnerships and normal manufacturing projects, and use this separate funding to approve projects with high technological improvements or returns and a longer pay-back period. The same logic can be applied to lines moving to other sites, which end up in an odd holding pattern in the year leading up to the move, where improvements do not have the appropriate returns for the site to pursue, but then the new location inherits issues the company was aware of and could have fixed.

The final recommendation is to review the work content graph labor data and consider doing a deeper analysis. If the inspection reduction work continues, the existing data does not provide the right level of detail to effectively identify and address solutions. The current work content graph data has inspection times available at the line level. However, the total inspection time could be evenly spread out across multiple work stations or all concentrated at one workstation. The workstations with most of the inspection tasks are great candidates to remove the inspection from or automate. However, if the work is spread across all workstations, and the technicians are only inspecting for a small percentage of each task, the returns from pursuing these projects are not competitive. If the Industrial Engineering team re-does their time studies at the workstation level, the data set helping identify areas for improvement will have much more impact.

8.2 Lessons Learned

In addition to learning about BSC culture, medical device manufacturing, and machine and AI vision, several key lessons were reinforced regarding project approach and implementation:

1. Take time to understand the problem upfront so you reach the right problem and solution

2. Choose the right level of data for the problem

3. Lower the barrier to entry to get more stakeholders on-board

4. Design the project and solution with job hand-off in mind

The first lesson I had reinforced was that it is worth taking the time to understand the true problem upfront, not just the stated problem. For this project, there was a business objective for the global team to increase the use of machine vision and AI in inspections and reduce the number of HVIs. However, upon speaking to the key stakeholders and sites, I determined that there were underlying problems, such as corporate goals, resource availability, and lack of tool sharing leading to barriers in project identification and approval. By adjusting my project to fit this problem, I was able to address the root problem of finding opportunities and sharing resources, hopefully leading to a larger project list.

The next lesson learned involved choosing the right level of data for a problem. BSC has a lot of site-specific data and can use it to answer almost any question. However, due to the unique characteristics and tools used to track this data at each site, it is not standardized and requires a large time commitment of a knowledgeable site employee to analyze. By pivoting to global data available for all sites, I was able to analyze the data more efficiently and do this analysis for all manufacturing sites. However, because the data was in a standard global tool, it was not formatted in a way to maximize site value and lacked a lot of details available in other site-specific databases. This degraded the quality of the analysis and was something that had to be considered when moving forward with this path. For future projects, always strive to understand the pros and cons of the data sources and pick the one that best fits the project.

The final lessons I learned was that creating a low barrier to entry enables sites with low bandwidth to get on board with the initiative. Companies often launch these large technology initiatives and work groups have a hard time balancing the new priorities. Before the heat map, getting sites to follow-up on the machine and AI vision efforts to reduce HVIs was very difficult, as the sites were busy and the effort required a lot of work. Additionally, our requests were for the entire site, which were vague. When we shifted to a work group specific request and spoke to common concern areas with the site leadership, reception greatly increased and nearly all of the manufacturing sites wanted to be involved in our work process. Lowering the barrier to entry and starting with a phased approach is a strategy I will deploy for change management in the future.

Appendix A

Interview Questions

A.1 Questions asked to Maple Grove, MN Team Members:

1. Can you describe your role in the AI vision development and implementation at Maple Grove
2. Technical
   (a) What parts are transferable
   (b) What parts should be done from scratch
   (c) Any recommendations on how to share learnings with other sites
3. Organizational
   (a) Any recommendations on how to share learnings with other sites
   (b) What is working well from project management, alignment standpoint
   (c) How do you get alignment with line that AI will go on
   (d) What would you change if doing again
   (e) How do you think groups should be set up across sites
   (f) Should this team remain as center of excellence or let each site have their own infrastructure
   (g) Have you been involved in VIP calculations
   (h) Any standardization recommendations

4. Political
    (a) Have sites been open to adopting this technology
    (b) What do you see as the biggest hang-ups
    (c) What has worked to get alignment
5. Other ways to approach reduction in human inspection
    (a) Traditional machine vision
    (b) Improved process controls / less person handling
    (c) Can we use risk tree / decision tree approach to implementation

A.2 Questions asked to employees from non Maple Grove sites:

1. Can you describe your role in the AI vision development and implementation at your site
2. Did your site have machine vision prior to the digital factory push
3. What was your site's / group's reaction to digital factory AI inspection
    (a) Supportive
    (b) Needed or forced
    (c) What do you see as the biggest hang-ups
    (d) What has worked to get alignment?
4. How have you found the existing resources and collaborations with the Maple Grove team
    (a) AI vision website
    (b) Line walk program
    (c) Connections to Vidi and other third party programs
    (d) Open source software and labeled data sets
    (e) Guidance document
5. Organizationally

(a) What is working well from project management, alignment standpoint

(b) How do you get alignment with line that AI will go on

(c) What would you change if doing again

(d) How do you think groups should be set up across sites

(e) Should this team remain as center of excellence or let each site have their own infrastructure

(f) Have you been involved in VIP calculations

(g) Any standardization recommendations

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