Improving Shop Floor Visualization and Metrics

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

Master of Business Administration
and
Master of Science in Mechanical Engineering

In conjunction with the Leaders for Global Operations Program at the

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Abstract

Within the Technical Operations division of Novartis Pharmaceuticals, there is an aggressive vision to be the "Toyota" of the Pharma Industry by 2010. To accomplish this, PharmOps Switzerland has embraced operational excellence, IQP (Innovation, Quality, and Productivity). Still, there is more that the site, and more specifically manufacturing, can do to fully realize the benefits of adopting all aspects of IQP.

Currently, there is a lack of adequate visualization on the shop floor. The current status and schedule of production cannot be quickly seen at the tools where the work is being performed. This thesis focuses is on improving the visualization and creating a set of KPIs (Key Performance Indicators) and visual displays that will improve performance

Change, especially cultural, is difficult and takes considerable time and effort. Even when changes are implemented slowly with small iterations, it might not be well received. Without a strong culture of continuous improvement, teams may not perceive that there are things that can be improved. Historical metrics are comfortable and useful to the shop floor. Visual metrics have improved communication.

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Chapter 1: Introduction

LGO Program and Novartis AG

The Leaders for Global Operations (LGO) program is a partnership between the Massachusetts Institute of Technology (MIT) School of Engineering, MIT Sloan School of Management, and 23 supporting partner companies. LGO provides its Fellows with two degrees: an SM in Management or MBA, and an SM in one of several participating engineering disciplines.

Novartis AG is one of the LGO industry partners, and is a leading pharmaceutical company headquartered in Basel, Switzerland. Novartis AG has four divisions: Pharma, Vaccines & Diagnostics, Sandoz, and Consumer Health with over 100, 000 employees' worldwide and over $44B USD in net sales in 2009 (Novartis Group, 2009). This thesis is the result of a six-month internship within the technical operations group of the Pharma division. The Technical Operations group is a Global function of Novartis Pharma that is responsible for all production, distribution processes and facilities worldwide. The internship project is supported by technical operations and is supportive of the 2010 vision to be the "Toyota of Pharma Industry" Work was conducted at Pharmaceutical Operations, Switzerland (POCH) site in Stein, Switzerland. This project was specifically looking at the visual management system for the shop floor within their current Innovation, Quality, and Productivity (IQP) framework for operational excellence.

Thesis motivation

The purpose of the internship was to support the technical operations vision of becoming the "Toyota of pharma" by focusing on the visualization on the shop floor in one of Novartis' pharmaceutical operations sites. By working with the teams on the shop floor to develop a sustainable system to track performance as close to real time as possible, the idea would be to not only improve performance, but also increase empowerment of the work force. The 2010 vision that Pharma technical operations has encompasses all aspects of operational excellence. This includes lean tools, process orientated organizations (POO), and Enhanced Business Process Re-engineering (eBPR) (van Laar, 2007). Without a consistent set of relevant key

performance indicators (KPI) implemented throughout POCH packaging and processing lines, complete implementation of POO is not fully realized.

The shop floor visualization work was mostly focused on setting up a pilot line at one packaging line. First a thorough understanding of the current state was assessed in the packaging lines of a Process Unit (PU) and through many interviews of both PU management and shop floor workers; an initial plan was developed to increase visualization of the shift schedule. That initial thought was that if the shop floor can easily see what their shift production goals are, they will adjust behavior in order to meet those expectations and thus performance will improve. The shop floor visualization was then improved and adjusted through an iterative approach with feedback from the shop floor and with key stakeholders along the way. The approach is discussed in detail in Chapter 5

Finally, the question if improving visualization will in fact improve performance and empower the shop floor workers will be evaluated. The IQP framework will be evaluated as a framework for continuous improvement as well as the organization of the Pharma technical operations efforts as they work to realize their vision. Recommendations for improving their chance of success in reaching the vision will also be proposed.

Approach

The approach taken during the internship involved a combination of a Novartis-specific project management system and the application of analytical tools from statistical process analysis and Lean Manufacturing. Novartis' Innovation, Quality, and Productivity (IQP) is a four-step project management methodology to promote a science-based approach to process improvement across the Novartis manufacturing network and all of technical operations. This methodology was used to frame the progress of the project at POCH. IQP consists of four major phases and is similar to the DMAIC framework (Define, Measure, Analyze, Improve, and Control) (Womack J. P., 2003) and Deming cycle (Plan, Do, Check, and Act) (Walton, 1986). The four phases of the IQP framework is:

1. Scope
2. Seek
3. Solve
4. Sustain

Supporting the IQP methodology is a toolkit selected from Lean and Six Sigma. Some specific tools include; eBPR, POO, and QUALIMETRICS in addition to the traditional Lean and Six Sigma tools. During the scope phase, interviews with key stakeholder as well as direct observation of the shop floor was conducted to get a full understanding of current metrics that were being reported, how they were used on the front line, and understand what would be the most useful on the shop floor if different metrics were reported and visualized. In addition access to processing data was available and analyzed to get the baseline performance.

With the help and input from POCH management, PU management and pilot line personnel, I was responsible for the implementation of the visual management tools. An implementation plan is presented here, along with general information regarding change management. This discussion is intended to provide some understanding of how changes for process improvement can be handled.

Thesis Overview

This thesis is organized into the following chapters:

Chapter 1 provides an introduction to the thesis.

Chapter 2 provides background on the project: industry, company, and site context.

Chapter 3 provides a discussion about Lean and the pharmaceutical industry.

Chapter 4 is a discussion of metric selection and visual indicators in order to drive performance.

Chapter 5 is a case study in the implementation of visual management tool with recommendations.

Literature review

History of Lean

By going back and really understanding the origins of Lean and Lean thinking, this research builds on the ideas developed from studying Lean and the Toyota Production System (TPS). With the book The Machine That Changed the World, the concepts of Lean manufacturing and the principles associated with it were introduced. The authors coined the term that is still widely used today. The concepts that make up the idea of lean manufacturing were described as a company-wide focus on continuous improvement through the elimination of waste (Womack J. P., 1990). This focus on eliminating waste is echoed by Taiichi Ohno, the inventor of the TPS. He describes categorized the seven different types of waste inherent in manufacturing (and work in general) as follows:

- Overproduction
- Waiting
- Transportation
- Over processing
- Inventory
- Movement
- Defective products (Ohno, 1988)

The elimination of these wastes is the core of lean manufacturing, from which all other concepts and practices were driven. Countless companies have attempted to implement the TPS, but were unable to replicate their impressive results even with a focus on eliminating waste. Toyota has been open and allowed companies to learn and observe their operations, however, it seem very difficult for an outside organization to replicate their results (Spear S. &., 1999). It seems that companies attempting lean transformations implemented the tools and methods used by Toyota, but were unable to sustain the results and fundamentally change the company culture. The rest of the story can be attributed to the underlying principles of the TPS.

While the focus on waste, reliance on teamwork and use of simple yet effective tools are very important in lean, they are not sufficient for success. Rather, the company needs to have an

underlying foundation and reliance upon basic scientific principles in order to drive improvements through lean manufacturing. This theory on the core foundations of lean manufacturing was proposed by Spear and Bowen, who observed that "the rigid specification [of the Toyota Production System] is the very thing that makes the flexibility and the creativity possible" (Spear S. &., 1999). Due to their reliance on the scientific method for continuous improvement activities, "Toyota Production System [and thus true lean manufacturing] creates a community of scientists" (Spear S. &., 1999). In accordance with this theory, a lean transformation at any company should begin first with a focus on applying the scientific method to the way they conduct business. Further, the application of 'typical' lean tools and methods should occur in accordance with the following proposed rules:

> Rule 1 – All work shall be highly specified as to content, sequence, timing, and outcome.
> Rule 2 – Every customer-supplier connection must be direct, and there must be an unambiguous yes-or-no way to send requests and receive responses.
> Rule 3 – The pathway for every product and service must be simple and direct.
> Rule 4 – Any improvement must be made in accordance with the scientific method, under the guidance of a teacher, at the lowest possible level of the organization. (Spear S. &., 1999)

There are books and publications about the theories associated with lean principles, there are less about how work groups and managers should go about introducing and managing a lean transformation within an organization. To achieve Toyota's sustainable success, the ultimate goal of any organization embarking on a lean transformation, how can these principles and tools can best be put in place? This is not a simple question with one right answer, however, the research suggests that is must start with an unwavering commitment from the top leaders in the organization to follow through on the transformation to completeness in all aspects of the operations. Additional research on the underlying principles at Toyota has given rise to the following lessons for any manager or leader of improvement activities within a company.

Lesson 1 – There's no substitute for direct observation.
Lesson 2 – Proposed changes should always be structured as experiments.
Lesson 3 – Workers and managers should experiment as frequently as possible.
Lesson 4 – Managers should coach, not fix. (Spear S. J., 2004)

The reliance on the scientific method at all levels of the organization to drive improvement; in addition to the other principles outlined above is the true essence of lean manufacturing. If you pick up almost any book or guide that speaks about Lean manufacturing you will get most of the basic tools and practices, but that won't be enough to truly transform an organization. A true lean transformation is only possible when there is:

1) A company-wide focus on improvement
2) A reliance on scientific principles and
3) A trained and empowered workforce able to drive improvement activities. (Villa, 2008)

Chapter 2: Company, Division, and Site overview

This chapter provides background to help understand Novartis and the pharmaceutical industry. This will also provide additional context behind the project and drivers behind Novartis' shift toward operational excellence, including its continuous improvement efforts.

Novartis Corporation

Novartis is one of the leading pharmaceutical companies in the world with annual sales over $44B USD in 2009 (Novartis Group, 2009). Novartis AG is made up of 4 divisions: Pharmaceuticals, Sandoz (generic pharmaceuticals), Vaccines and Diagnostics, and Consumer Health (Over-the-Counter products). Novartis sells their products in both developed and developing markets around the world. Novartis was created in December of 1996 though a merger of Ciba-Geigy and Sandoz (Novartis A G) and is headquartered in Basel, Switzerland. Novartis' mission statement is: We want to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life (Novartis A G).

Tech Ops and Pharma Ops

The Technical Operations Group of Pharmaceuticals is responsible for all production, distribution processes and facilities worldwide. It Includes: ChemOps, BioPharmOps, PharmOps, Quality and Distribution. They have 24 Chemical, Pharmaceutical and BioPharma Plants with 350 brands, 20,000 finished product SKUs and 8 major 3rd parties with 9,000 employees worldwide (van Laar, 2007). Technical Operations has the vision to be the "Toyota

of Pharma", meaning they want to embrace and emulate the principals of Lean manufacturing and encourage a culture of continuous improvement (van Laar, 2007).

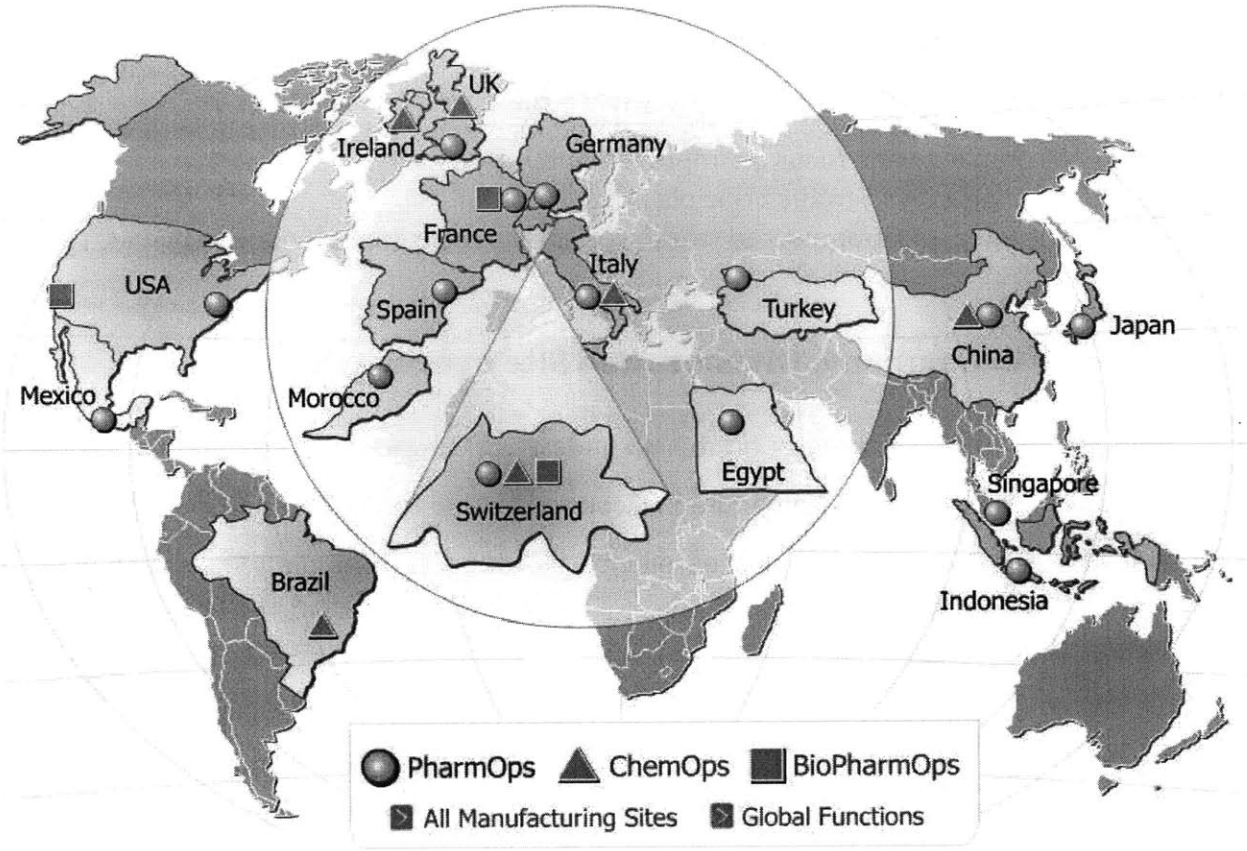


Figure 1 - Map of global technical operations network. (van Laar, 2007)

Stein, Switzerland

Pharmaceutical Operations, Switzerland (POCH) is the biggest pharmaceutical production site located in Stein, Switzerland, a short commute from the corporate headquarters in Basel, Switzerland. They are the launch site worldwide for sterile and solid dosage forms for the PharmOps network. POCH is also the global center for transdermal therapeutic systems. Storage and distribution center for active pharmaceutical ingredients worldwide are located in Stein.

Stein has embraced the POO organization since 2005 when they restructured their organization in alignment with POO vision and created Process Units and flattened the whole organization so there were only 3 layers of management between the ship floor operator and the site head.

They also have an IQP champion in place for the site to help coordinate, provide support and track progress for ongoing continuous improvement projects at the site level.

Chapter 3: Pharmaceutical Industry transition to Lean

Pharmaceutical operations historically

Currently the majority of pharmaceutical manufacturing consists of batch processing with fixed manufacturing set points. A typical pharmaceutical process consists of four key steps: manufacturing of crude material (creation of active substance), intermediate product (purification), drug substance (preparing IP for final processing), and drug product (final processing, i.e. tablet formation). Each of these steps is broken down into a multitude of sub steps such as crystallization, drying, milling, and wet-granulation. The process parameters, such as temperature, pressure, etc. are run at a specific set-point and must be controlled within a narrow, validated range. Statistical process control (SPC) methods are typically utilized to monitor the process (Kourti, 2006). Typically only a few tablets out of several million are tested at the end, so drug manufacturers are expected to conduct many in-process material testing. After each step, and sometimes after sub-steps, samples are collected and analyzed offline to ensure product quality specifications are met at each step. The batch will not proceed until the quality results are verified from the previous step. Generally, if any of the in-process or end of process testing is out of the specification, the entire batch is scrapped and typically not reworked (Yu, 2008). It could be said that the current strategy for pharmaceutical manufacturing is one of "quality-by-testing". The product quality is ensured by raw material testing, a fixed manufacturing process, in process material testing, and end product testing (Tozer, 2008).

Changes in the Industry and Health care pressures

The global pharmaceutical market is expected to grow at a 4-6 percent pace in 2010, compared with 2.5 – 3.5 percent in 2009, according to IMS Health's 2010 Global Pharmaceutical Market and Therapy Forecast (IMS Health, 2009). The forecast predicts global pharmaceutical sales to expand to $825 billion in 2010. Overall, market growth is expected to remain at historically low

levels, but stronger-than-expected demand in the U.S. is lifting both our short- and longer-term forecasts. There is a strong growth in the emerging markets. The term "pharmerging market" refers to the countries of China, Brazil, India, South Korea, Mexico, Turkey and Russia and those markets are expected to grow 12-14 percent in 2010. This growth is driven by an increase in access to healthcare and broader public and private funding. Growth is dampened due to significant imbalance between new product introductions and patent losses (IMS Health, 2009).

The pharmaceutical industry is highly competitive. The industry is dependent upon intellectual property protection to maintain market exclusivity for their products. Once a drug looses patent protection, generic manufacturers flood the market with cheap alternatives. The amount of generics in the market has been increasing steadily and was 54 percent in 2003, and jumped to 72 percent in 2008 (PhRMA Industry Profile, 2009).

For many drugs the first to market captures the majority market share. As a result of the intense pressure to capture market share, pharmaceutical companies aggressively sell and market their drugs, with most companies investing around 25% of revenues back into sales and marketing (Friedli, 2006). There is a high switching cost for most pharmaceuticals. If a drug is working well for a patient, they tend to stay with the therapy and are unwilling to try a different medication. Most pharmaceutical companies try to capture patients through intensive commercial launches including expansive direct to consumer marketing campaigns. In the U. S., pharmaceutical advertisements are widespread on TV, in magazines, and more recently online as well it is costly for a company to not take full advantage of the patent protection period to earn as much revenue as possible and gain the customer loyalty. Because many branded pharmaceutical companies are facing a gap in their product pipeline.

Historically pharmaceutical companies have relied on blockbuster drugs to achieve the double digit sales growth rates expected by analysts. However, the growth rate in the blockbuster market is expected to slow down in the upcoming years (Friedli, 2006). Many blockbuster drugs are scheduled to lose patent protection soon, and companies are working hard to have a solid pipeline for the future, but there is very little in the pipeline to replace lost revenue (IMS

Health, 2009). IMS expects new drugs to launch in 2010, but not with the same revenue as the products that will face generic competition (IMS Health, 2009).

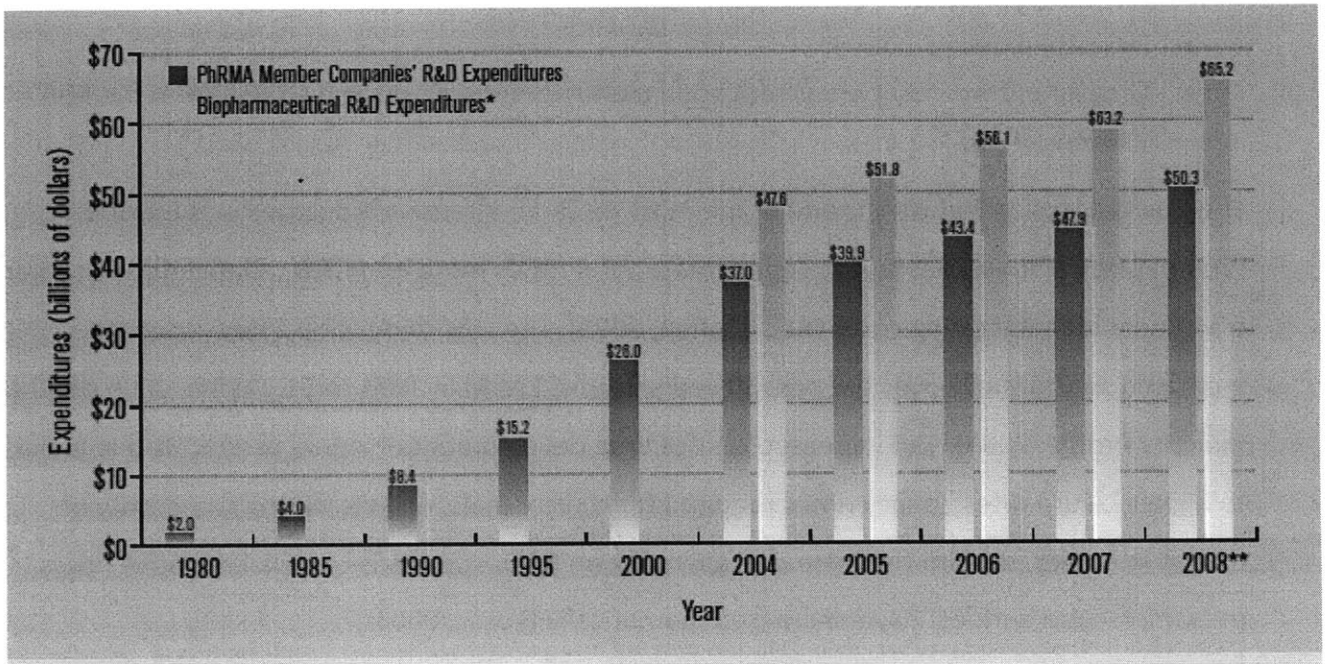
The profit margins in the pharmaceutical industry have historically been so high that there has been little incentive to invest in improving the manufacturing process (Tozer, 2008). According to industry analyst the industry average profits average 32 percent and blockbuster drugs can have over 80 percent profit margin (Staton, 2010). However, the pharmaceutical industry is now facing increasing pressure to reduce costs. Justin Neway describes these pressures as including:

- Skyrocketing R&D costs
- Rapidly decreasing periods of exclusivity
- Increasing pressure from the generics marketplace
- Increasing price scrutiny
- Greater enforcement of current good manufacturing practices(CGMPs) from the FDA (Neway, 2003)

The pharmaceutical industry is one of the most research intensive industries in the world. Pharmaceutical industries invest approximately 3-4 times more into R&D, relative to sales, than traditional manufacturing companies (Cohen, 2005). The cost to develop a new drug has increased substantially over the past 30 years, from $138 M in 1975 to $1.318B in 2006 (PhRMA Industry Profile, 2009). The increased cost of drug development of a drug product is due in part to higher failure rates, longer times required for clinical trials, and increasing complexity of drugs. However, despite the increased spending on R&D, approvals of new innovative drugs (new molecular entities) have decreased dramatically (Tozer, 2008).

In June 2003 President Bush signed a bill that limited patent extensions to pharmaceutical companies. The "Greater Access to Affordable Pharmaceuticals Act" limits the number of 30-month patent extensions that pharmaceutical companies can receive to only 1 (US House of Representatives, 2003). This eliminated a loophole in the 1984 Hatch-Waxman Act that that allowed companies to receive multiple extensions to their initial patents.

Patents of several blockbuster drugs have recently been lost, or will soon lose, patent protection. Between 2007 and 2012 more than three dozen drugs, equating to combined revenues of over $67 billion, will lose patent protection (Martinez, 2007). When a drug comes off patent, generic manufacturers can produce the drug at a fraction of the cost. In general, once the first generic enters the market the price for the drug falls by 20%, and then can drop by as much as 90% as other generics enter the market (Nocera, 2006). The industry is finally realizing that in order to remain competitive, they need to start investing in their manufacturing process. They can no longer afford to lose revenue from their products because of long start-up and scale-up times, lost batches, process instability, and product recalls.



*The "Biopharmaceutical R&D Expenditures" figures include PhRMA research associates and nonmembers; these are not included in "PhRMA Member Companies' R&D Expenditures." PhRMA first reported this data in 2004.

**Estimated.

SOURCES: Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2005–2009; Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Member Survey* (Washington, DC: PhRMA, 1981–2009).

Figure 2 shows the trends in pharmaceutical R&D expenditures from 1980 to 2008. (PhRMA Industry Profile, 2009)

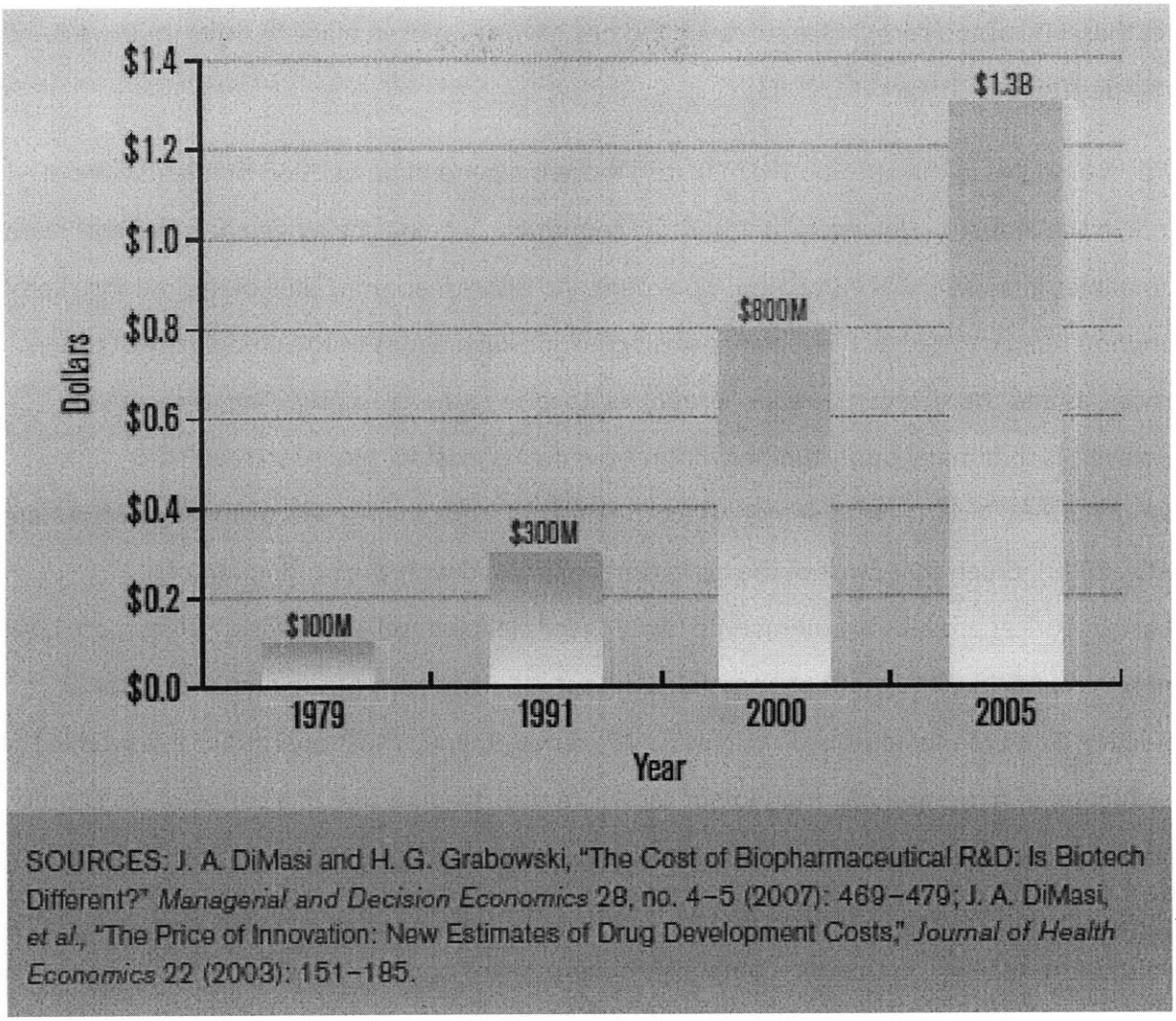


Figure 3 shows the trends in costs to develop one new drug from 1979 to 2005. (PhRMA Industry Profile, 2009)

Lean manufacturing in the Pharmaceutical Industry

Lean transformation efforts, or other continuous improvement programs, are fairly common in established industries. Companies within younger industries, such as the biopharmaceutical industry, have been slower to adopt these practices mainly due to their focus on establishing themselves in the initial market (Villa, 2008). The same can be said for traditional pharmaceutical companies as the combined industries face increased regulatory and cost pressures. A study conducted by Tefen, an international management consulting firm, and BioPharm International concluded the biopharmaceutical industry was just beginning to focus on operational excellence programs to sustain competitive advantage, as is evidenced by the

fact that 84% of the companies surveyed did not have systems in place to drive improvement activities (BioBenchmarkSM, 2003).

With the origins in the automotive industry, there is a general perception that lean will not work in the industry. However, that belief is continuously being challenged as more and more companies in a variety of industries implement and adopt lean principles of operations. Some common reasons cited as the incompatibility include such issues as the complexity of the processes and the strong regulatory pressures governing the processes. The simple truth, however, is that many opportunities for improvements exist within these regulated manufacturing facilities that do not affect the process steps themselves or the regulated steps (Villa, 2008). Given that most of the cycle time associated with the production of a pharmaceutical product is waiting time (waiting for cleaning, set-up, testing, release, etc.), vast improvements in throughput are possible without modifying any of the filed processes or affecting Good Manufacturing Practices (GMP) requirements. Most operations involved in the production of a therapeutic drug do not resemble the assembly line of a car plant, so in order to success with these concepts involves choosing tool(s) and adapting them to fit the need. Many successful improvement efforts begin with value stream mapping and simple organizational tools before moving on to more complex problem solving and analytical systems (Shanley, Merck's Lean Mission, 2006).

If one was to define operational excellence as ensuring the customer receives its product on time, at high quality while achieving a large gross margin, most of the pharmaceutical industry are top performers (Coffey, 2008). However, pharmaceutical operations are far from efficient as was first widely communicated by the Wall Street Journal in September 2003 when it revealed that "the pharmaceutical industry has a little secret: Even as it invents futuristic new drugs, its manufacturing techniques lag far behind those of potato-chip and laundry-soap makers" (Coffey, 2008). For the most part pharmaceutical operations can be described as having long cycle times, high inventory levels, lots of rework, low yields, and inflexibility.

Historically, manufacturing excellence was not a top priority. A pharmaceutical company's ability to discover new breakthrough therapeutics and sell and market those medicines at

premium prices enabled it to achieve very large profit margins. With high profit margins, companies focused on research and development as well as marketing and sales functions, ignoring operations (Coffey, 2008). This mindset seems to be changing in part due to changes in the competitive environment.

Pharmaceutical companies are increasingly focusing on reducing costs through improving operational efficiencies. In the pharmaceutical industry, costs attributed to manufacturing are a major part of the company's total expenses (Basu, 2008). Historically, manufacturing performance has been measured by a firm's ability to provide drugs to patients while meeting regulatory compliance requirements.

According to the international benchmarking study nearly 57% of the 100 pharmaceutical companies (including research based, contract manufacturers and generic manufacturers) have implemented parts of a JIT production system including pull systems, setup time reduction, planning adherence and layout optimization (Friedli, 2006). The following data are given for the bottom 10% (low performer) and top 10% (high performer) of the 100 companies surveyed. Even among these top performers few used lean pull system techniques (BioBenchmarkSM, 2003).

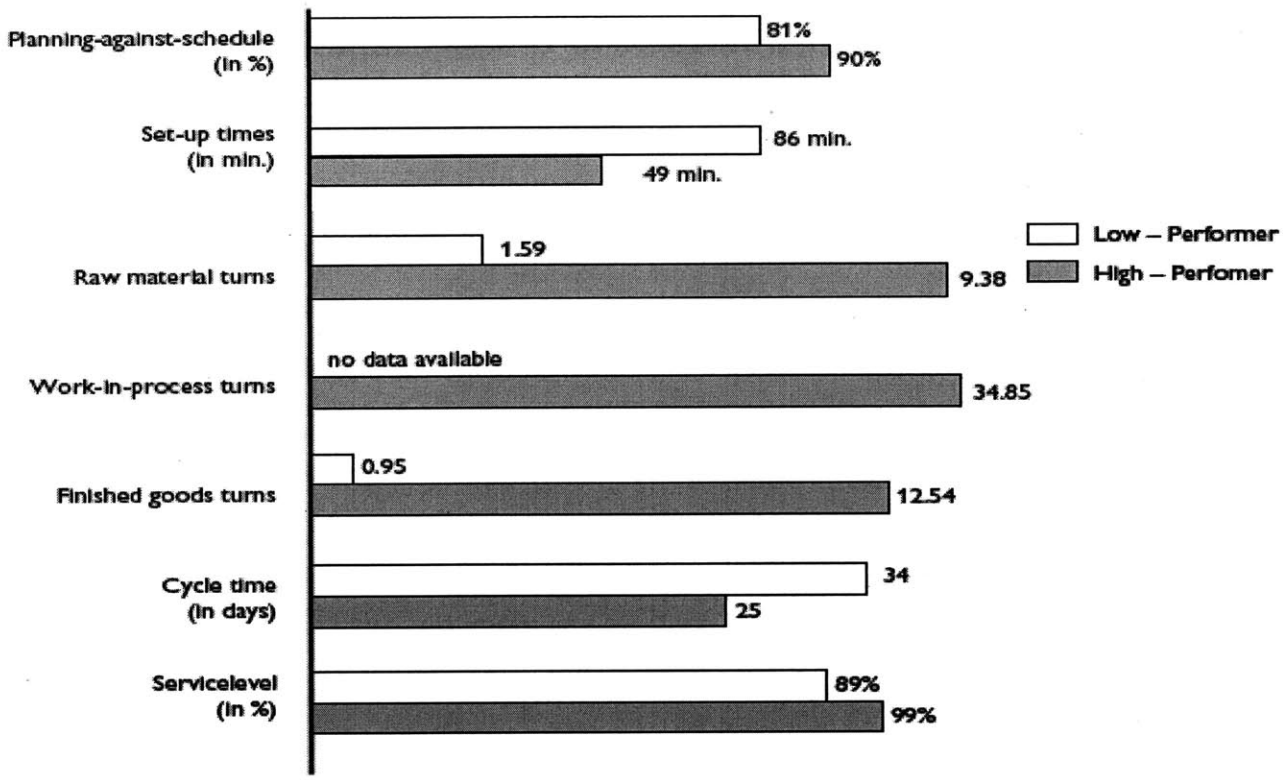


Figure 4 Range of Pharmaceutical Operational Performance (Friedli, 2006)

There are many examples of pharmaceutical and biopharmaceutical companies implementing operational excellence programs. Following the withdrawal of its blockbuster Vioxx, in late 2004, Merck launched the Merck Production System (MPS) as an operational excellence strategy it believes will allow it to become the "most competitive supplier of medicines and vaccines in the world" (Shanley, Merck's Lean Mission, 2006). MPS is based on the lean principles of maximizing customer value through waste elimination. Merck pilot tested its MPS program at its Arecibo, Puerto Rico manufacturing facility. Within 18 months of the program's launch the site had achieved significant results:

- The number of days to perform quality testing was reduced 60%
- Investigation lead time was reduced 70%
- Manufacturing schedule was replaced with a system that reflects the variation in customer demand

These results were achieved through elimination of handoffs, redundant work, and required approvals and by the co-location of employees. Merck has also started an incentive system to reward future improvements (Shanley, Merck's Lean Mission, 2006).

Wyeth and Novartis have also made strides in improving operational improvement. For example Wyeth's Centrum manufacturing process was overhauled in 2006 with the following results:

- Production now paced to meet packaging requirements (the process' customer)
- Pull Systems have been established leading to WIP inventory reduction
- Cycle time has been cut from 33 to 11 days (Thomas, 2006)

Novartis piloted its operational excellence initiative at its Suffern, N.Y. manufacturing plant in November 2002. Through value stream mapping and waste elimination the site was able to reduce cycle time by 70% and spending by 40% (Shanley, Novartis Goes Lean, 2004). The site also reduced the number of key performance indicators (KPI) it was tracking to only a few that allow for transparent performance management. While pharmaceutical companies have begun to implement operational improvement programs, most programs are less than 7 years old. The companies that have taken the initiative have paved the way for how operational excellence can be achieved within the constraints of government regulations (Coffey, 2008).

Amgen faced many challenges in its business in 2007. To address the challenges that Amgen faced in 2007 Operations embarked on an Operational Excellence initiative aimed at reducing the costs of Operations in order to continue investing in its R&D pipeline of future products, a vital activity for a biopharmaceutical company (Villa, 2008). The initial results of the program were a comprehensive restructuring of the Operations division and key decisions to halt investment in capacity expansions in Ireland (Pasanek, 2008). Subsequent goals are to implement a system of manufacturing based on lean thinking. Once the restructuring was completed, Amgen had reduced its workforce by 12-14% (Pasanek, 2008)and closed one of its plants at its Rhode Island site. In addition to this, the Operations Improvement group was created and was comprised of three working groups focused on working on the three aspects of the Operational Excellence framework (Villa, 2008). Operational Excellence is high profile and

has already provided Amgen with significant benefits since its inception. The three components of Operational Excellence are orchestrated to enact this fundamental change in the way of business by ensuring that the internal business controls, work processes, company culture, and project portfolio support each other and Operational Excellence as a whole (Villa, 2008).

AstraZeneca started to work with lean consultants from the car industry to look at their operations including the supply chain. The vice-president of global operations, said: "Pharmaceutical supply chains have been fat and happy. Efficiency was never key. There's a lot we can learn from the lean culture that came from Toyota to remove waste and focus on what the customer wants" (Jack, 2009). In the later part of 2009, in addition to working with lean experts they have brought on full time staff from other fast moving consumer goods industries to maintain the momentum of transforming the culture (Jack, 2009).

IQP and Lean at Novartis Pharma

As previously discussed the global technical operations group of the Pharma division of Novartis has the mission and vision to be the "Toyota of Pharma" and has the support at the highest level of management, including the Head of Global Technical Operations, Tom van Laar. This shift for the group will help them be better situated to address challenges, such as:

- Time to market
- Pricing pressure, generic competition, shortening patent lives
- Increased FDA/EMEA scrutiny
- Increased role of non-physician stakeholders / channel change (direct distribution)

While still taking advantage of opportunities, such as:

- Positive demographic change
- Unmet medical needs
- Growth in biologics
- Growth in emerging markets (van Laar, 2007)

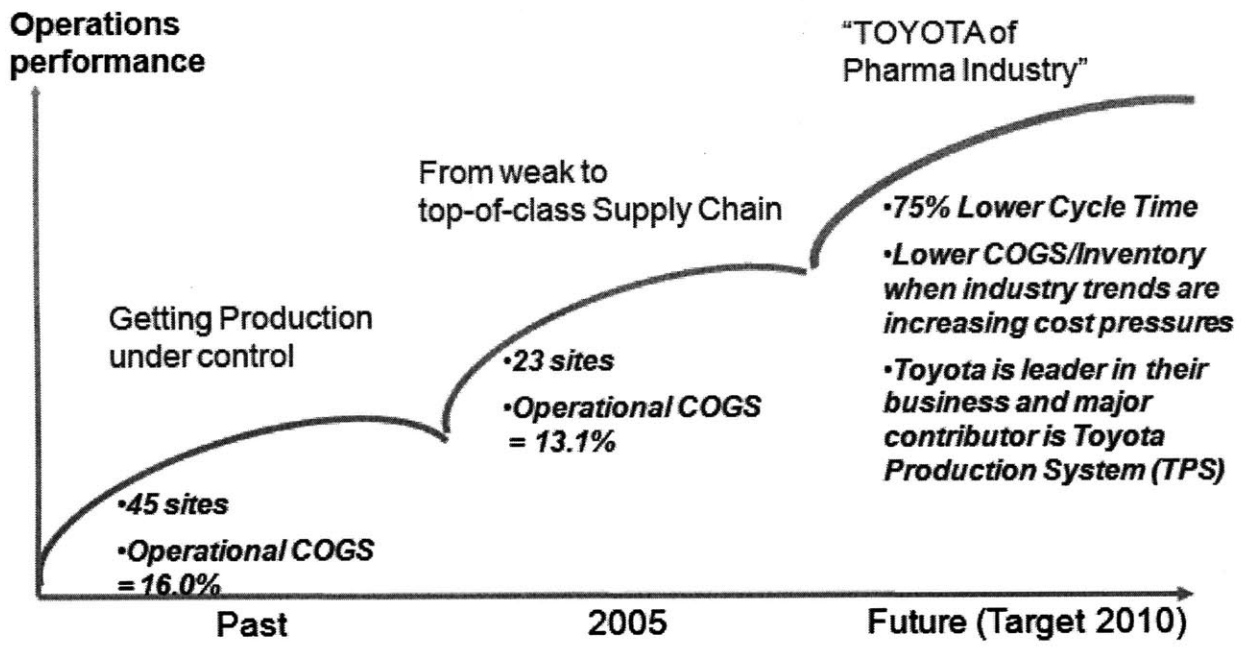


Figure 5 Depiction of the Global TechOps Vision for Novartis (van Laar, 2007)

Chapter 4: Driving Performance through Metrics and Visual Indicators.

Identifying proper metrics

Defining System Performance

While the complexity of the system represented in Figure 6 Typical packaging line layout and process map does not lend itself to formal mathematical modeling; some general relationships can be defined.

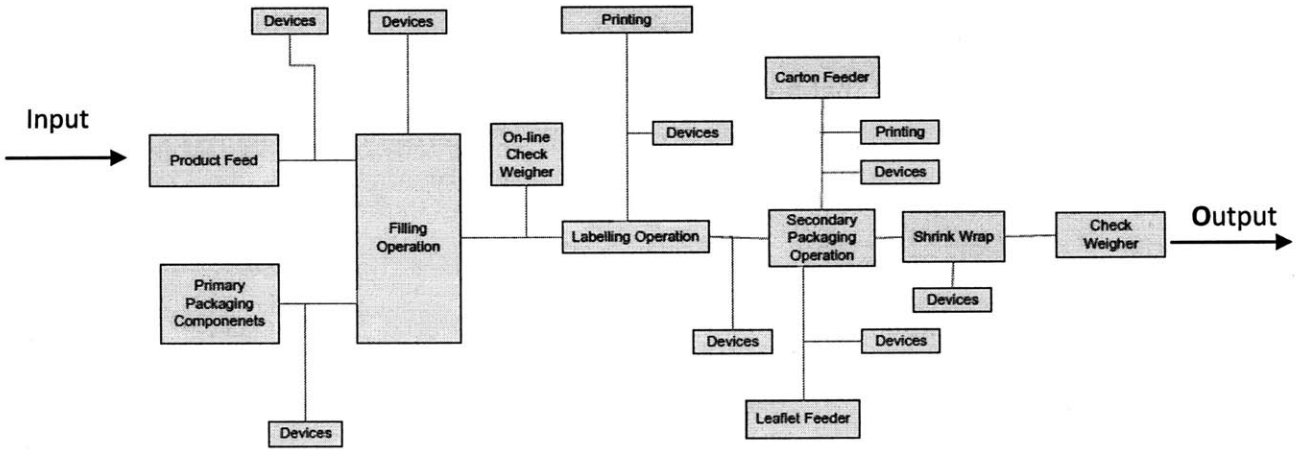


Figure 6 Typical packaging line layout and process map **(Hosseiny)**

Specifically, the performance of the operations can be defined as a function of the inputs and outputs, the design of the network of activities and buffers (design parameters), and the resources employed:

(1) Performance = F (Inputs, Outputs, Design Parameters, Resources) (Couzens, 2006)

It is possible to further decompose the performance function above into more descriptive variables. However, before proceeding with this step, consider the following four process attributes for measuring a company's ability to produce the product: cost, flow time, flexibility, and quality (Anupindi, 2006).

1. Cost: Represents the total cost of the product. The total cost includes direct costs (such as raw materials, utilities, and labor) as well as capital (property and equipment), overhead costs, and money tied up in inventory.
2. Flow time: The flow time is the total time it takes for a company to transform incoming material into finished product.
3. Flexibility: With respect to the company's operations, process flexibility indicates the extent to which the company is capable of meeting customer needs in generating finished products for their customers.
4. Quality: The true quality of a process is fundamentally the product that it produces and if that product performs in the way that they customer expects.

Because this performance expectation around quality is not directly measurable, objective and subjective judgments as well as perception play important roles in the estimation of a product quality. Based on the four important process attributes described above as well as a few generalizations and assumptions, Company performance function defined in (1) can be modified to the following:

(2) Performance = F (Direct Costs, Quality of Output, Quantity of Output, Waste, Flexibility, Flow Time, Inventory, Capital, Overhead Costs) (Couzens, 2006)

If each of the variables in (2) are treated as independent, performance is optimized through minimizing some variables (direct costs, waste, process flow time, inventory levels, money tied up in capital, and overhead costs) while maximizing others (quality of output, quantity of output, and process flexibility). However, the variables in (2) are clearly not independent. For example, the quantity of product produced through operations will be negatively impacted if one of its bottleneck pieces of equipment is missing. Because all the explanatory variables in (2) are interdependent, calculating how to optimize the performance of this complex system is not a straightforward procedure. Going back to the performance relationship defined in (1), optimality conditions, given a fixed set of resources, are obtained through adjusting the design parameters until the following condition is met:

(3) $\frac{d(\text{Performance})}{d(\text{Design Parameters})} = 0$ (Couzens, 2006)

However, because the mathematical modeling relationships in (1) are unknown the optimality condition in (3) is not practically useful. Thus, given the lack of a theoretical or even empirical mathematical model, heuristic methods must be utilized to maximize operational performance. In practice, organizations may attempt to maximize performance using the following rules o f thumb:

- Pursue change initiatives that seek to improve one or more performance variables while leaving the other variables relatively unchanged.
- Scrutinize all change initiatives that promise to positively impact some performance variables but negatively impact others.
- In choosing which change initiatives to pursue, focus resources on those initiatives that are expected to generate the largest performance improvements relative to the money and effort (Couzens, 2006)

Following these rules of thumb is easier said than done. Effectively choosing which change initiatives to pursue in guiding an organization to constantly improve its performance is the essence of good management (Couzens, 2006).

Note that as objectives are developed, and, later, measures, it will be critically important to continually evaluate them in light of changing circumstances or simply for the sake of continuous improvement (Couzens, 2006).

Key performance Indicators

As the name suggests, key performance indicators are a set of high-level metrics used to measure an organization's performance. There are typically no more than a half-dozen "key" metrics for an organization, but they can be influenced by hundreds of lower-level metrics (McCaghren, 2005).

The Balanced Scorecard Framework

In 1992 Robert Kaplan and David Norton proposed the balanced scorecard framework as a way to manage organizations using more than just financial measures (Kaplan, 1996). The management framework suggests first articulating a business strategy and vision, then defining metrics that will measure achievement against that vision from four perspectives: Financial, Customer, Business Process, and Learning and Growth.

Beyond providing accountability and incentive mechanisms for the firm's employees, the Balanced Scorecard gives managers a comprehensive framework that helps translate the Group's mission, vision, and strategy into a coherent set of performance measures that can be easily communicated to employees throughout the organization (Kaplan, 1996). Metrics and performance measurements are critical elements in translating an organization's mission, vision, and strategy into reality. Metrics without strategy is meaningless and strategy without metrics is useless. Ultimately, the firm's group will achieve the highest levels of performance improvement through the design and implementation of a performance measurement system that emphasizes improvements that are of strategic importance (Couzens, 2006).

Performance objectives are frequently developed through the analysis of questions relating to each of the four perspectives:

- Customer: Who are our customers, and how do we add value for them?

- Financial: How do we maintain service levels while adhering to budgetary restraints?
- Internal Processes: Which processes must we excel at in order to continue adding value for customers?
- Employee Learning and Growth: Which organizational infrastructure elements are necessary if we hope to execute our strategy? (Niven, 2006)

Like KPIs, the Balanced Scorecard Framework takes a more enterprise-wide, holistic view to performance metrics. Often the BSC can also be considered a visual display, since there are examples where the BSC is posted in the work group in which the data refers to. That was the case for POCH in which each work area had the PU-wide BSC posted with the "traffic light" scoring for quick snapshot of the PU performance for each metric tracked.

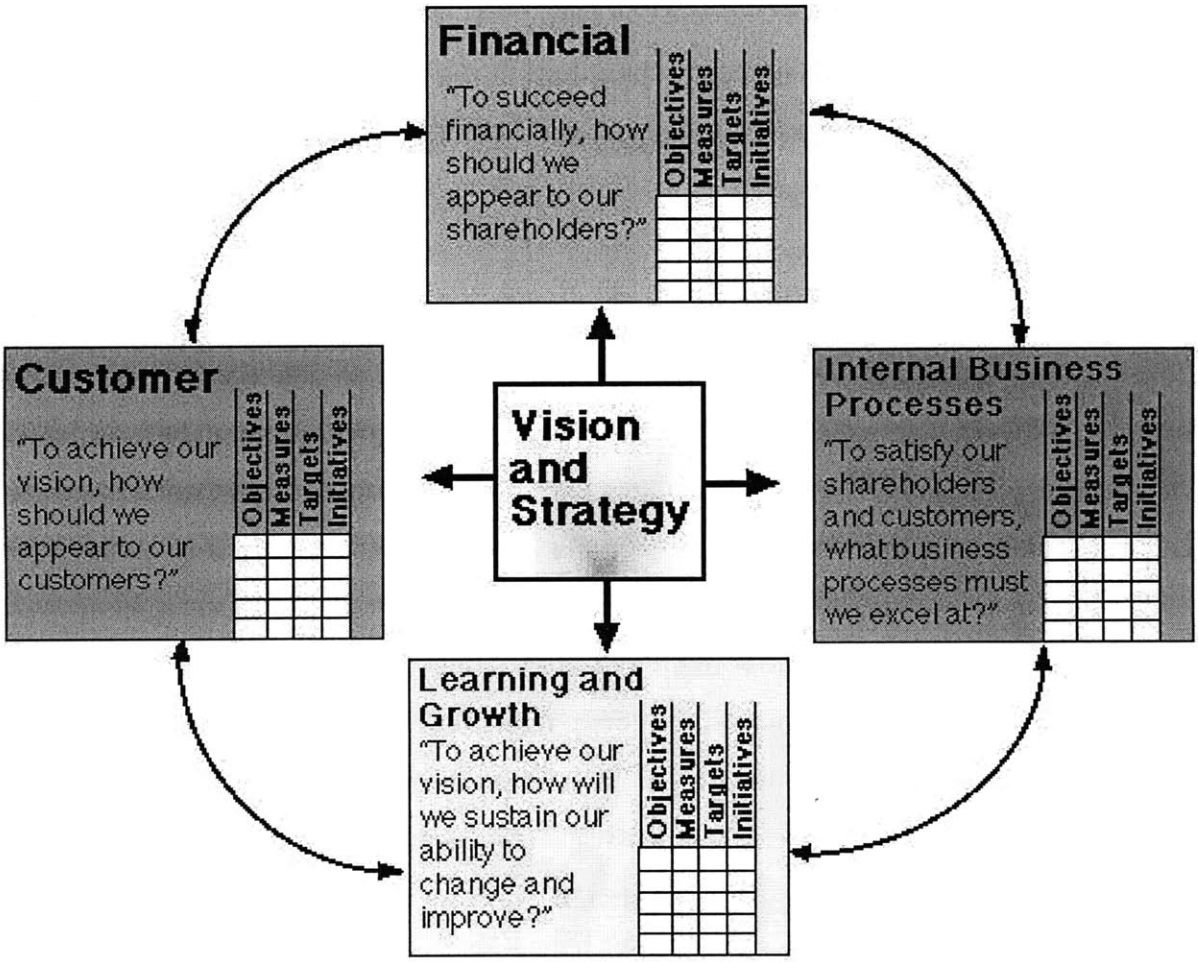


Figure 7 Balanced Scorecard Model (McCaghren, 2005)

SMART framework

Many resources on the design of metrics suggest the SMART acronym as a good framework for evaluating the effectiveness of any metric.

- S = Specific: must be specific and targeted to avoid misinterpretation or dilution.
- M = Measurable: must be able to collect quantifiable, measurable data.
- A = Attainable/Actionable: must be reasonably attainable so that the workforce isn't discouraged. Metrics must also provide an indication for when action is necessary.
- R = Realistic/Relevant: must be cost-effective to capture, and must measure things that are relevant to the business.
- T=Timely: The time-horizon of data capture must match that of the ability to respond. (Trimble)

The last three characteristics are particularly important for the decision-making metrics deployed on a factory floor. The metrics must be relevant and lead to timely actions to be "smart" enough to influence the day-to-day operations (McCaghren, 2005). In addition, the metrics must be able to be influenced by the front line workers and they must be able to have the authority to make those changes.

Lagging vs. Leading indicators

Performance metrics are often classified as either lagging or leading. A lagging indicator is one that is reflective of past performance and is often used to measure an organization's progress against strategic goals. These metrics are often common across organizations and the set is fairly static from year to year, like Gross Margin, EBIT, and Return on Invested Capital (McCaghren, 2005).

Leading indicators, in contrast, attempt to predict a firm's future performance towards strategic goals. These metrics often vary from organization to organization and year to year, because they are closely tied to the strategy the firm employs to reach those goals. Perhaps the most important distinction between the two metrics is that leading indicators can more actively be influenced or controlled. Therefore managers should implement leading indicators on the factory floor where possible because the employees can and will strive to improve them (Seip, 2007).

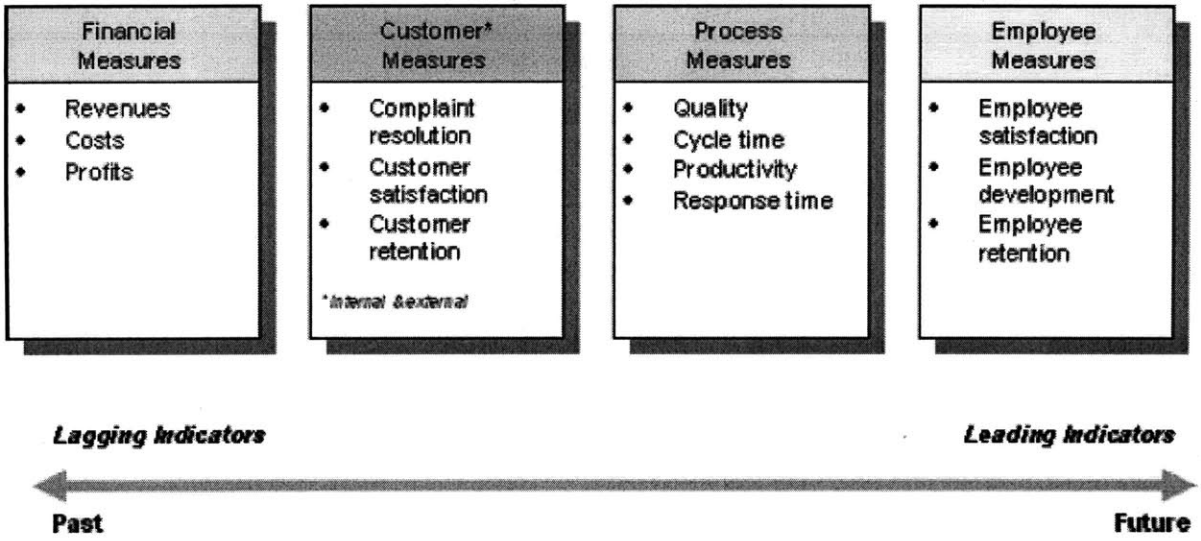


Figure 8 Shows several metrics on the continuum from lagging to leading across different functional areas. (McCaghren, 2005)

The University of California provides the following eleven questions to measure the quality of a metric (Training Resources and Data Exchange (TRADE), 1995):

1. "Is the metric objectively measurable?
2. Does the metric include a clear statement of the end results expected?
3. Does the metric support customer requirements, including compliance issues where appropriate?
4. Does the metric focus on effectiveness and/or efficiency of the system being measured?
5. Does the metric allow for meaningful trend or statistical analysis?
6. Have appropriate industry or other external standards been applied?
7. Does the metric include milestones and/or indicators to express qualitative criteria?
8. Are the metrics challenging but at the same time attainable?
9. Are assumptions and definitions specified for what constitutes satisfactory performance?
10. Have those who are responsible for the performance being measured been fully involved in the development of this metric?
11. Has the metric been mutually agreed upon by you and your customers?"

The University of California also provides a nice classification of performance metrics, as summarized in Figure 9 University of California Performance Measures

Measure of...	Measures...	Expressed as ratio of...
Efficiency	Ability of an organization to perform a task	Actual input/ planned input
Effectiveness	Ability of an organization to plan for output from its processes	Actual output/ planned output
Quality	Whether a unit of work was done correctly. Criteria to define "correctness" are established by the customer(s).	Number of units produced correctly/total number of units produced.
Timeliness	Whether a unit of work was done on time. Criteria to define "on-time" are established by the customer(s).	Number of units produced on time/total number of units produced.
Productivity	The amount of a resource used to produce a unit of work	Outputs/inputs

Figure 9 University of California Performance Measures (Training Resources and Data Exchange (TRADE), 1995)

These attributes, questions, and classifications reinforce the connection between customer expectations and the design of metrics. These questions also highlight the importance of involving those being measured in the design of the metrics.

Khusrow Uzair's SDM thesis at MIT explored the relationships between the seven most popular process improvement programs and the tools and metrics used to implement each program. There are dozens of performance improvement tools that can be utilized in each program, but a smaller set of metrics can be used to evaluate the effectiveness of each tool. Figure 10 - Implementation Tools and Metrics Relationships shows the relationships between the tools, metrics, and improvement programs, and represents the author's suggested toolkit for the most-effective performance measurement metrics (Uzair, 2002). This list also suggests that other management or manufacturing practices often accompany performance measurement programs as tools to help achieve the desired measure. As a company identifies its goals and designs metrics to measure compliance with those goals, it should expect to introduce additional implementation tools to improve the metrics and help realize its goals.

In his thesis "Implementation of a System of Visual Indicators at Intel's D2 Fab," Erik Smith argues that traditional views of manufacturing systems which involve three inputs -material, capital, and labor – are incomplete. The fourth and perhaps most crucial element of a

manufacturing system is information, because it can provide performance indications which inform decision-making on how best to deploy the other three primary inputs. Therefore we will view information as a key asset for a manufacturing facility, and the process of collecting, analyzing, displaying, and acting on information as a core competency for those organizations (Smith, 2003).

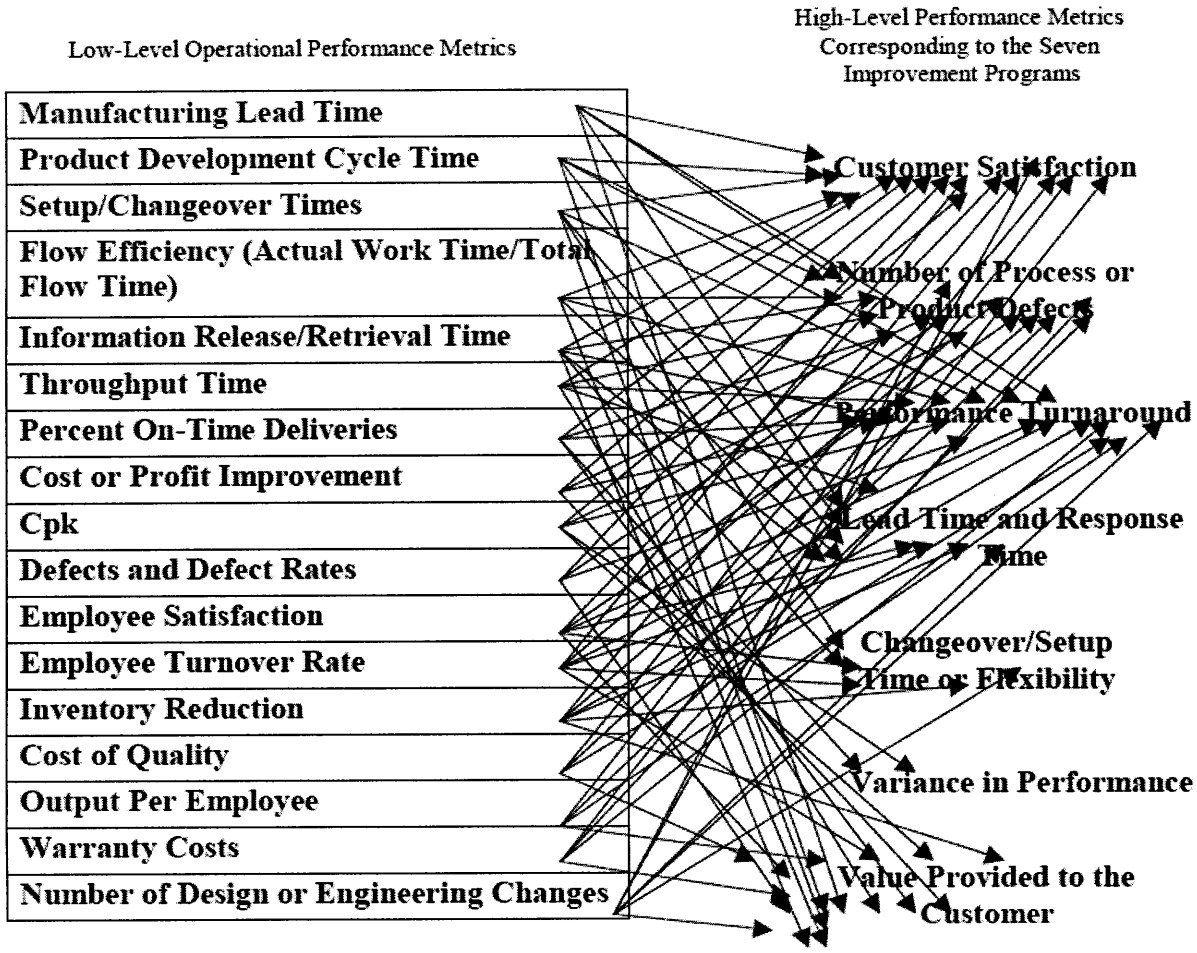


Figure 10 - Implementation Tools and Metrics Relationships (Uzair, 2002)

Data vs. Information

Volumes of data exist in all functional groups in all organizations, yet many managers still make decisions based on intuition. This is because data in its rawest form is difficult to use. To be valuable, that data must be collected, interpreted, and transformed into higher-order information that can then inform decision making. If the costs of collection, interpretation, or

transformation are too high in terms of time of effort, managers will fall back on intuition, experience, or heuristics. Therefore organizations should strive not to be data-rich, but information-rich (McCaghren, 2005).

Timeliness of Information

The clockspeed of information collection and transformation must match that of the decisions which it informs. For instance, if a Statistical Process Control (SPC) chart can only identify excursions several days after they occur, the effort has little or negative value when the probability of an excursion over that period is relatively high. Managers would again rely on their intuition or downstream processes to predict or identify this condition in a more-timely manner. Of course there is always a trade-off. To detect excursions sooner with SPC, there is often a higher cost associated with sampling more frequently and preparing the control charts – which historically has meant manually plotting points by hand and posting a revised chart to the "Quality Wall". Elimination of the marginal cost of preparation by implementing automated charting tools, where data is effortlessly transformed to information and presented in real-time, which is more common in today's manufacturing operations. In an automated setting, efforts can be focused on reducing the cost of sampling to improve the timeliness of the information (McCaghren, 2005).

The Three Dimensions of Information

Transforming data to information is insufficient; organizations should also be concerned with the utility of the information they capture and present. In Neville McCaghren's thesis he theorized information possesses up to three dimensions, where the utility increases with each dimension added.

1D: Information presented in the first dimension is akin to scalars in mathematical terms – they are simply quantities without direction or scale. Metrics in the first-dimension have little value as stand-alone numbers without additional knowledge about the organization or process. Examples include measures like net income or total defects. One's conclusions about a

company reporting net income of $10 million are very different if the organization has 100,000 employees and a market cap of $50 billion, vs. an organization with 100 employees and a $50 million market cap. A report of 50 defects has different meaning if 100 or 100,000 parts were produced.

2D: Like vectors in math, the second dimension adds scale or direction to the data, and is often presented as a ratio. Examples include earnings / share, defects / unit, or yield. By adding a second dimension to the data one can scale the data to benchmark across different product lines or organizations, and the data become insulated against certain variables like volume or time.

3D: The richness of a 2D metric can be enhanced by considering additional variables like time or process station. By plotting earnings / share or defects / unit over time, one can now assess the health of the organization or process. Is it improving? Are there days of the week or quarters in the year that always under-perform? By adding station to the defects / unit metric (now defects / unit / station) one can identify performance differences across stations that might be due to training or tooling issues (McCaghren, 2005).

Role of Visual Indicators

There are many examples in literature and industry of static visual control mechanisms on factory floors and interactive dashboards for executive management. Unfortunately, there are few examples of interactive, dynamic, information-rich dashboards for the factory floor.

Andon Boards

Andon boards, popularized in the Toyota Production System (TPS), are visual control mechanisms that hang on the factory floor. They typically address either current quality issues or daily throughput rates with first-dimension data. Named after the "andon cord" in the TPS system that is pulled when an operator finds a quality problem, a quality-focused andon board lights up to identify the location of the quality problem as shown in Effective andon boards have the following characteristics: immediate process feedback, visibility from all areas of the floor, flexibility to adapt to process changes, and a clear meaning that requires no explanation or interpretation (Spear S. &., 1999). Andon boards are also incorruptible: so long as the power

is on, operators or supervisors cannot ignore them, pad or smooth reported numbers or otherwise alter the reported measures (McCaghren, 2005).

Physical Displays

Not all production control displays are electronic. The Toyota Production System advocates physical storage bins as a way to communicate WIP levels and control production flow. If WIP is accumulating at a particular station, it becomes immediately visible. If the sized storage bin becomes full, run rules dictate that the upstream operation halts production. There is no holy grail for performance metrics; what is most effective for one organization will almost certainly not be optimal for another. The three most important factors to consider when designing metrics are:

- Audience: The metrics for a CEO, plant manager, and operator will all be different. A CEO is concerned with metrics like gross margin, net income, and customer satisfaction. A plant manager might be concerned with metrics that contribute to those global metrics like asset utilization, employee absenteeism, on time delivery, etc. The metrics for an operator should be even more granular: yield at a specific workstation, scrap rates, takt time, etc.
- Decision Making Time Horizon: Similar to the audience, metrics will be designed differently if the decision-making time horizon is minutes versus months. SPC charts on a factory floor are designed to identify out-of-control processes as quickly as possible. Asset utilization metrics, on the other hand, should be designed to dampen noise considerably: one would not decide to divest a plant based on poor utilization numbers for a day.
- Desired Outcome: Metrics don't exist for their own sake: their value is only in the information they convey and the decisions they inform. Each metric should be designed with a purpose: process control, budget planning, service level agreements, etc. (McCaghren, 2005)

A key characteristic of effective performance management programs is that incentives are clearly aligned with the metrics, and the metrics are aligned with the organization's goals. That is, employees are rewarded for efforts that improve the metrics, and dissuaded from actions which negatively impact the metrics, and an improvement in the metrics helps the organization meet its goals. Therefore any efforts to install performance metrics should also be coupled with a clear organizational strategy, and a revamped incentives program (McCaghren, 2005).

Use of metrics within Tech Ops

At POCH, the tool I saw used consistently and reported to the upper management of the site and Novartis, in addition to the shop floor was a monthly Balanced Scorecard. In chapter 5, the metrics used at the POCH site are listed.

Chapter 5: Case Study of the Implementation of select performance metrics

Pilot line selection

Many things went into the pilot line selection. Some of the issues to consider:

- Support and willingness of PU leadership to "host" pilot project
- Improvement performance seen as the most beneficial to the site
- Relatively cohesive and steady operator shop floor team

The biggest factor in selecting the pilot packing line that was chosen was the PU management support. Without that management support, the project would have surely failed or at the best, stalled. Having an enthusiastic leader who believed in the goals of the project helped to bring all others on the team to also buy into the idea. Other pilot lines were considered and preliminary work was done with them, but there were a variety of reasons given by the shop floor workers or why they didn't see value in participation in the visual displays, the conclusion was the leadership of the team that was lacking that ultimately led to the teams being unwilling to participate. Whether it was a lack of feeling empowered to work with me to make their day to day work easier and less frustrating or that the leaders were not completely respected or trusted and therefore were not credible when they supported the idea to the shop floor workers, but in either case they were vocally unsupportive.

The motivation of the project was ultimately to improve performance and empowerment. A line of the solid dose packing area where the site leadership felt was a critical area where they wanted to see improvement were the areas considered as to participations in the pilot study. Several lines within the PU were considered, but ultimately on a recently installed packaging line were selected. The equipment was newer and some of the highest margin products were packaged on this equipment. It was also the equipment that would eventually replace the

older equipment in time. It would make sense to design the system to work on a line that would be around for awhile and present at the site for years to come.

This line and equipment was newer, and therefore, not all shop floor workers were trained on the tools. On the older, established lines, it wasn't unusual to move workers around to cover absences and vacations. The team that was assigned to this recently installed packaging line remained relatively consistent during the ramp up and training phases. It was important to limit the crossover of personnel between the pilot line and non pilot line to be able to get the most accurate comparison of the improvements that could be attributed to the visual management system.

Deconstructing current metrics

The metrics that were currently being used in the solid dose packing lines were:

- Volume produced
- Period Cost Expenses
- Cost per pack
- PMV
- Customer service level
- Back-Orders
- Rejection Factor
- Technical Compliance Factor
- Lost time Accident
- OAE (overall asset effectiveness)
- Though put time
- OTIF (on time in full)

These were presented to the team every month in a balance score card (BSC) format and posted on the shop floor but away from where the workers interacted with the equipment. See Figure 11 Picture of posted metrics on the shop flow. Location POCH, Novartis on a solid dose packing line. for a picture of the posted metrics on the shop floor. In addition, there was some more real-time reporting (updated throughout the shift). The shop floor after each order wrote on a dry erase board the order number and the amount of packs produced under the day and shift that it was completed in. There was a color scheme in place that was supposed to quickly identify if the team is ahead, on, or behind schedule, however, observations indicated that

other colors beside the "on schedule" blue were rarely used. The way this board seemed to be used was each shift team noted how many orders and how big the orders were that the other shift completed in relation to their own. See Figure 12 – Picture of the white board tracking orders and sizes for a solid does packing line at POCH, Novartis for a photo of this board. In addition to the dry erase board, the order was lined out on the schedule that was provided to the floor each twice a week, indicating completeness. This schedule was kept on a printed schedule on a clip board that was maintained by the lead operator of the shift. The yield was also calculated after each order and recorded in the official batch record.

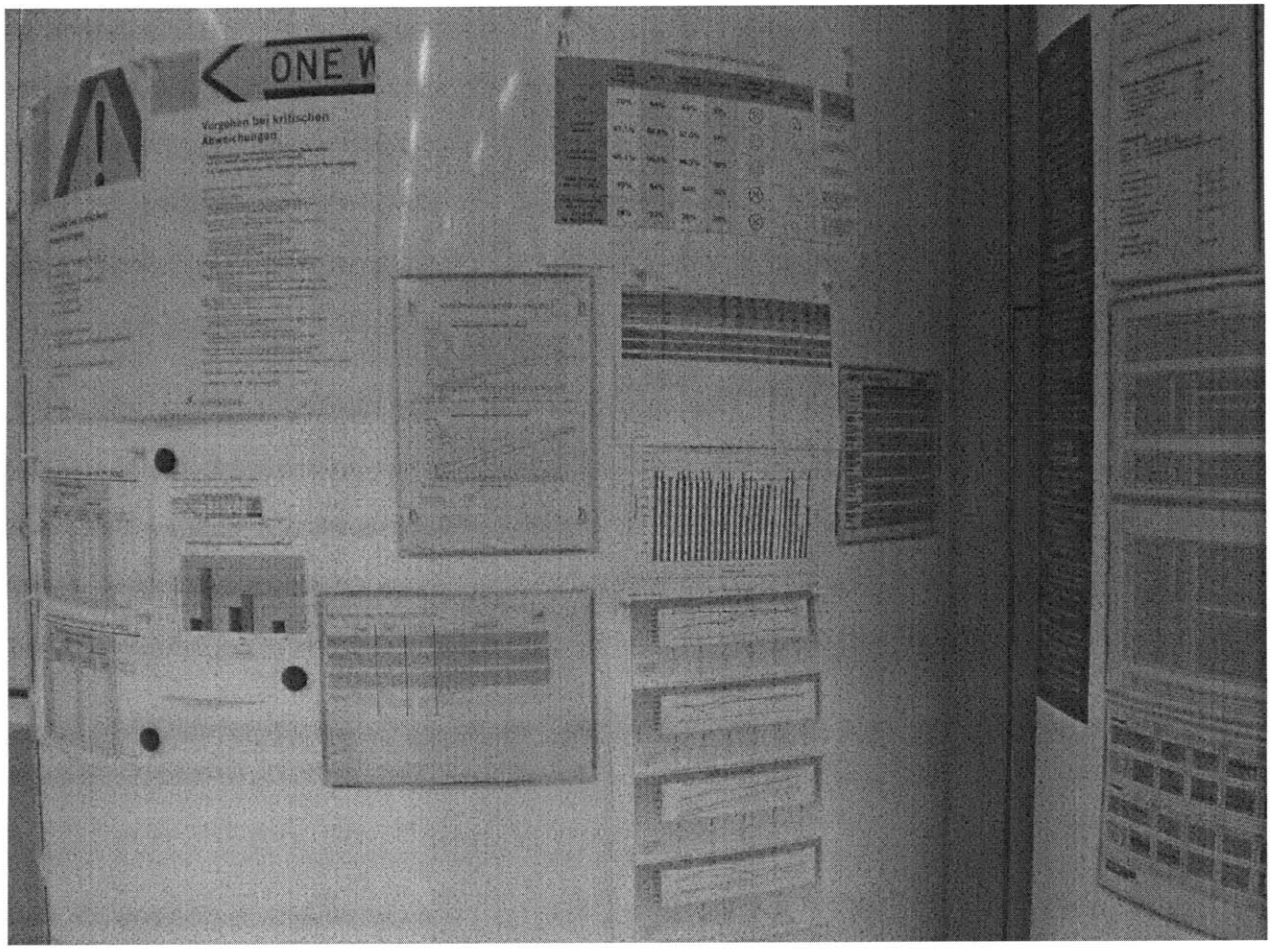


Figure 11 Picture of posted metrics on the shop flow. Location POCH, Novartis on a solid dose packing line.

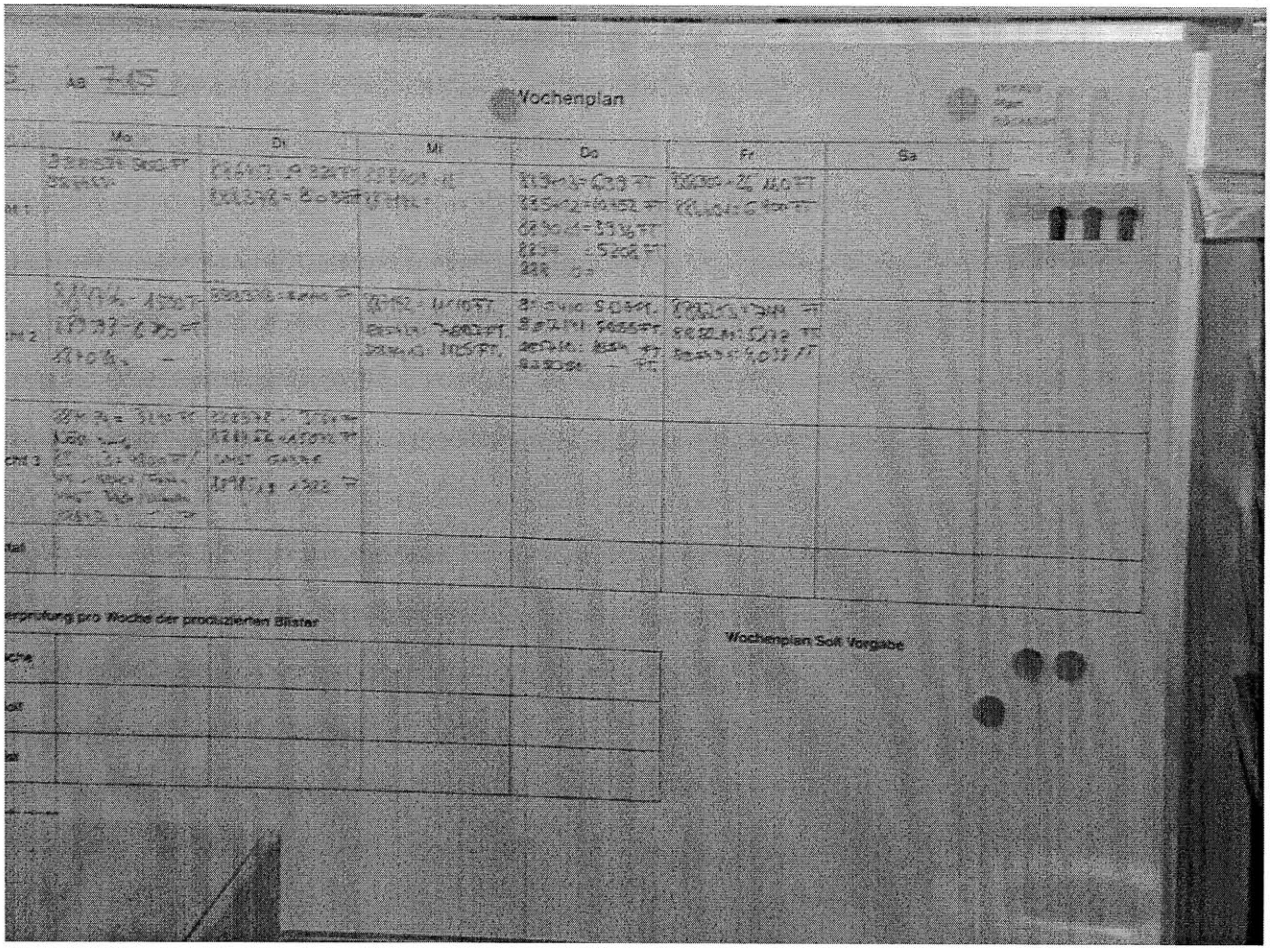


Figure 12 – Picture of the white board tracking orders and sizes for a solid does packing line at POCH, Novartis

Through interviews with the shop floor team, the metric that the team looked at and paid attention to was the OAE. I wanted to understand why the team felt this was the most useful metric to judge performance and how they impacted this metric. The formula for OAE that is used for the equipment was:

OAE = Efficiency X Utilization = Quantity produced / (max. validated line speed * hours available)

Amore useful way to look at it is:

Time account model

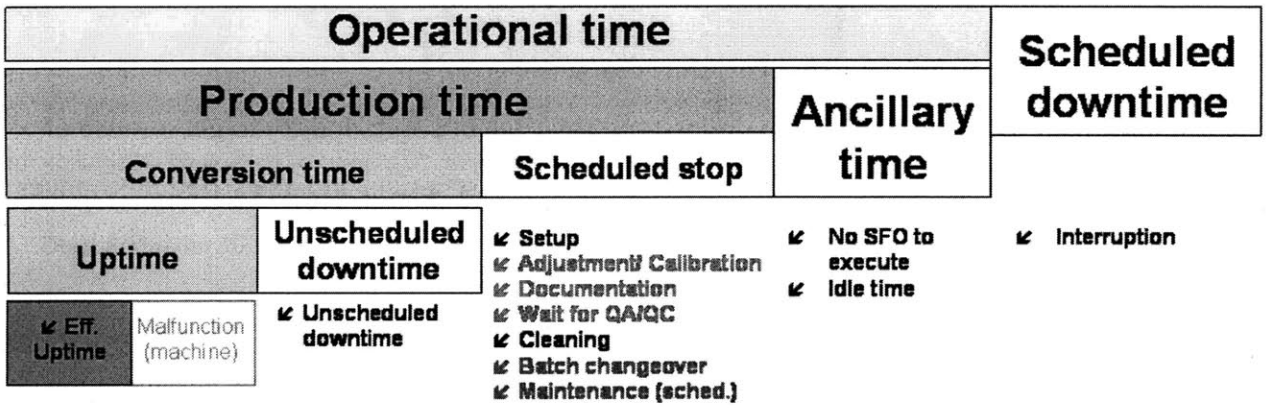


Figure 13 Time Account Model for OAE

A few things were interesting after studying this model. The trend over the past years of the site was to produce smaller and smaller order sizes. This makes a lot of sense for the site and for their customers. Delivering smaller and more frequent orders reduces the overall inventory for Novartis and the customers don't have to hold as much inventory on hand, which improves their satisfaction. However, this has a negative effect of the OAE since smaller order sizes increases the number of orders and each order has a set up time associated with it, taking away from the effective uptime. The shop floor team has no way to influence the size of the orders and thus affect that who component of the OAE calculation. They also cannot affect the scheduled maintenance that is a fact of life with all equipment. The shop team cannot affect the orders that are placed (Ancillary time). If they have no orders, that is out of the control of the team. The order needs to be run at, or below, the maximum validated speed. What this means is the operators cannot just simply turn the machine up to speed up the packaging. So at the end, the two things that the team has control over was:

- How quickly the responded and corrected equipment malfunctions
- How proficient they were in performing the set up and cleaning activities.

As the team thought about the question, "How do you know if it is a good day or bad day?" It became clear that the more experienced employees "just had a sense" based on how many malfunctions they had to respond to and if the set up and cleanings went smoothly. But for the

newer employees, there was no real indication other than how many orders they produced that shift. And unless those employees sought out and understood how to read and interpret the complicated schedule, they would have no sense if they were behind schedule.

Through observing several shift changes, shift changes involved every employee meeting individually with their counter part to understand the previous shift and try to get a sense of what is to come, if they knew it themselves. However, the schedule and any schedule changes that might have occurred during the previous shift would only get talked about with the lead operator turn over, not with the whole team.

After interviews with all the key stake holders, the most important goal was to complete the orders on time for their customers, OTIF. At the end, you don't sell OAE, you sell completed packaged drugs in accordance with the order the customer placed. The packaging was the last step in the value chain. Therefore, they often felt the pressure of the customer deadline, even though they had no say in the order falling behind schedule in each of the previous steps for whatever reason. This resulted in the schedule being modified within the week and sometimes even within the day.

The schedule and the team's ability to execute the schedule that they were provided by the planning group seemed to be the key to the success of the packaging line. Even with the importance of the shift's schedule, it was not communicated to the whole shift team. The project developed into having the schedule become visualized and the goals for the shift to become clear to the lead operator and then to the whole team.

Development of the shift scheduling tool

The goal was to develop a tool that would address the concerns of the shift team and have the following characteristics:

- Useful information that is needed to make decisions about the production
- Real Time information, or as close as possible
- Located at the point where the work was being done

An iterative approach would allow the tool to be adjusted as needed before a lot of time and resources were spent on developing something that wasn't useful to the workers who were going to be using the tool.

Iteration 1

The lead operator translated the planning schedule into an hour by hour expectation of what should be done each hour of the shift. This was accomplished by using a simple template on a sheet of paper that was kept on a clipboard next to the master schedule. The dry erase board continued to be used in the same manner. There were a few requirements expressed as the first iteration was developed. It was clear that the lead operator was busy at the beginning of each shift, so any additional tasks that were placed on them should be quick and not detract from the other required tasks, such as keeping the official batch records up to date. The feedback from this first basic form and process was that it took less than 5 minutes to complete at the beginning of shift and it was helpful in improving the communication between the operators and the maintenance specialists. The operators were able to show the maintenance specialists when they could expect the change over between orders and what kind of cleaning it would be. In addition, the whole team knew how many orders they were expected to complete that shift and how big the orders were.

Iteration 2

The initial feedback was very promising and encouraging, but to realize the full vision of a visual shop floor, the scheduling tool needed to move from the desk to a large board in view of everyone who could benefit from this information. The logical next step was to translate the schedule to a large poster sized schedule. With this new format, we needed a way to make it reusable. The PU had several extra magnetic dry erase boards. Magnets were used to schedule both the orders and the set up and cleaning times that were required for the shift. The vision was to eventually get away from recording the number of packs produced and get the focus to compliance to schedule. The idea was to get this tool to be close to real time as possible so the team could adjust mid shift if possible to get back on schedule if they fell behind. If a team was falling behind schedule the only two things they could do to get back on schedule was to prepare and execute the steps of setting up and cleaning the machines

between orders in less time than scheduled or to limit the time the machine was not producing due to malfunction. In other words, having a very quick response time to the error and having the skilled personnel available to correct the issue. The magnets seemed like they would be a perfect solution to the real time component of the scheduling tool. At the end of each order, the operator would move the magnet that represented the order down to the corresponding shift row that represented events completed. The same process would happen at the end of the scheduled set up and cleaning activities. The result was that at any point during the day, anyone who came onto the shop floor could see if the team was ahead or behind of schedule at a glance by comparing the current time and the position of the magnets on the board at that time. If the magnets prior to the current time were moved down to the completed section, they were on or ahead of schedule, if they were still waiting to be completed, they were behind and questions could be asked as to the cause and offer to help correct. Depending on how many events were left to be completed, someone would have a sense of how much the team is behind, and vice versa for being ahead of schedule. Figure 14 shows a picture of the shift scheduling tool posted in the work area, adjacent to the place where the work is being done with the magnets representing the orders and set up and cleaning periods.

It was important to the teams that they get "credit" for larger orders and longer machine change over. To give the team that sense of how much work was involved in the event, there were two different lengths to represent orders and change overs. The shorter magnet represented small orders and routine set up and cleaning activities, while the longer magnets represented larger orders and involved tool cleaning. In addition, three colors were used for scheduled orders so each shift could have a distinctive color that represented the orders that were scheduled on their shift. This would allow the next shift to "get credit" for an order that was scheduled on one shift, but because that shift was behind didn't get completed until the following shift. If that was the situation one shift would have a magnet that was the color of the previous shift and then the rest of the completed orders that were scheduled for that shift would be placed in the completed row in that shift's color.

Even though this visually expressed the goals and accomplishments of each shift team, at this point this did not replace the board where they reported out how many packs were completed by shift for the week. Since in this iteration everything was only for a 24 hour period, the performance for the week was difficult to assess.

This version with the magnets still fit with the criteria of not taking too much of the lead operator's time at the beginning of shift since the magnets were quick to simply place onto the board as they translated the schedule from the planning department to the planning board.

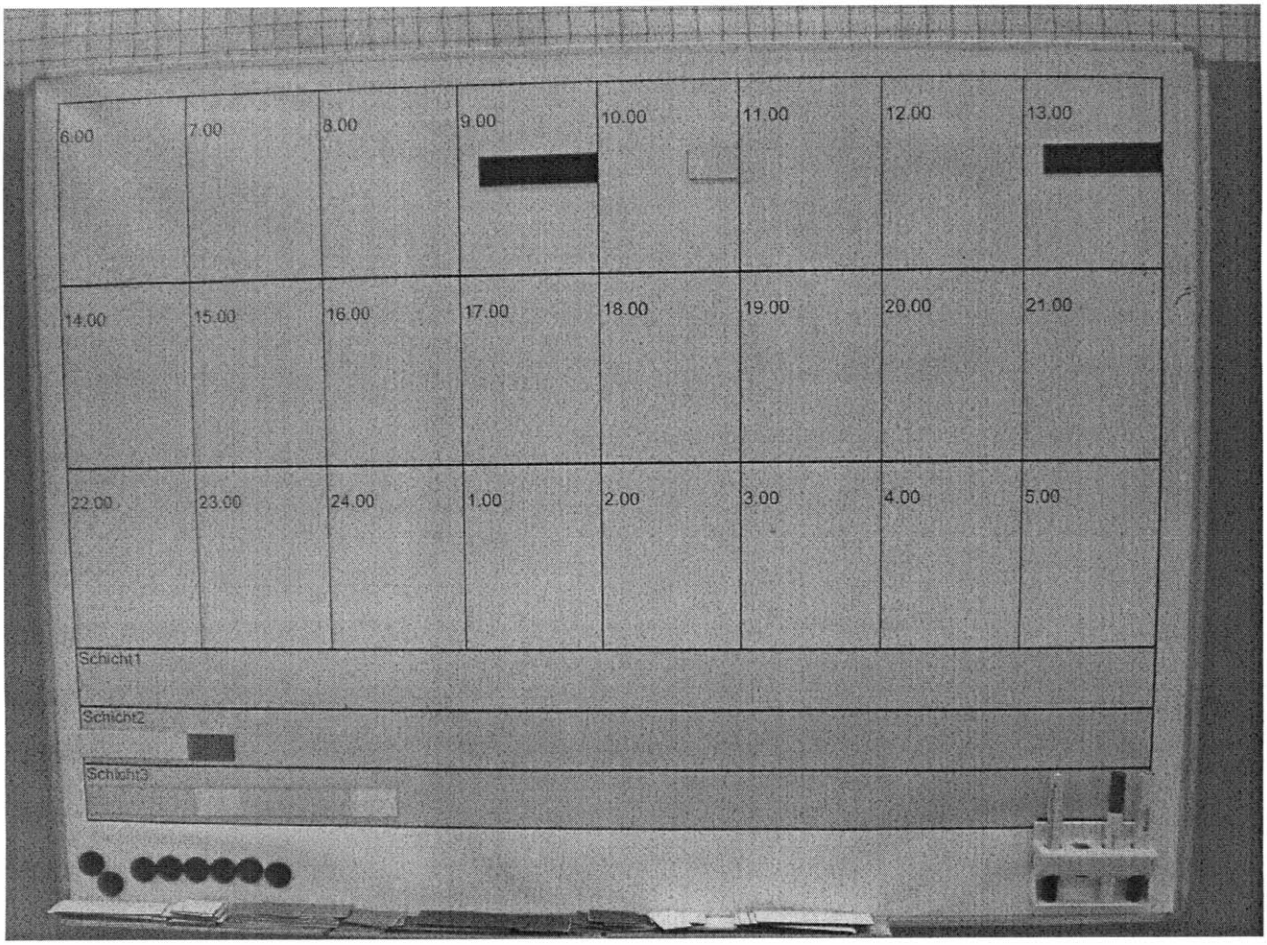


Figure 14 Picture of the shift scheduling too that resulted from the second iteration. Note: the white magnets represented equipment change over and set up. The colored magnets represented packaging orders.

Third iteration

The third iteration's goal was to get the weeks performance visualized in addition to the daily schedule. Feedback was positive for the scheduling board, so no changes were needed to this aspect. Again, flexibility and ease of use were important criteria for the weekly performance aspect of visualizing performance. The dry erase board that was currently being used to track the number of packs completed was repurposed to track how many orders each shift produced against the overall target that was given by the planning department. The way this would work was the lead operator at the end of the day (third shift) would translate that day's completed orders onto the weekly tracking board before "wiping" the shift scheduling tool clean. The magnets were put directly on the weekly tracking board. Again, this was a quick and easy way to see if a team was completing the orders that were scheduled on their shift, doing more than was scheduled on their shift, or less that the next shift had to make up for. See figure 15 for a photograph of the weekly board in practice. It is then that the first shift could use the magnets to translate that day's schedule onto the shift scheduling tool and take note of the previous day's achievements on the weekly performance tracker.

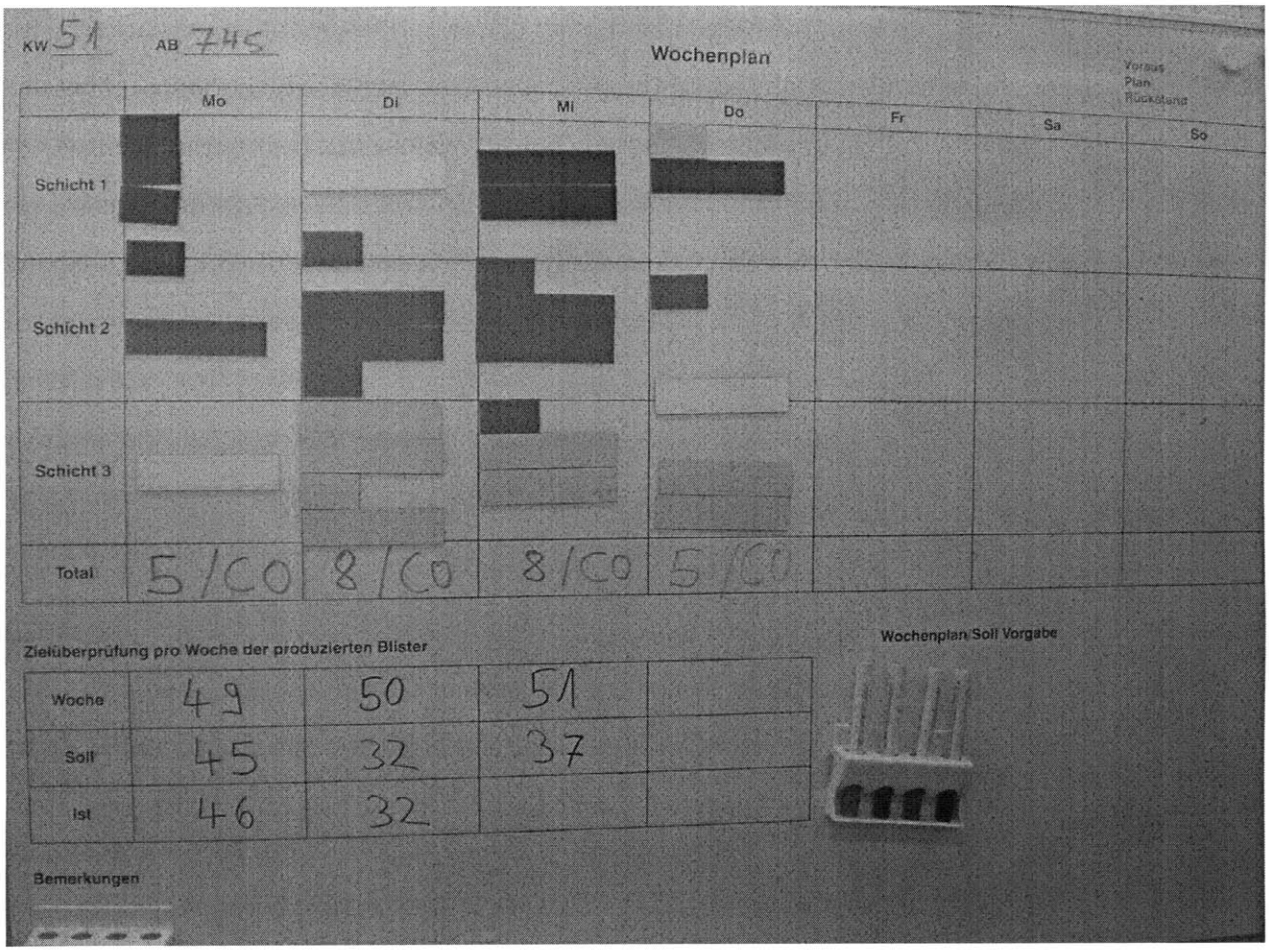


Figure 15 Photo of the weekly shift performance board. Location is solid dose packing line POCH, Novartis.

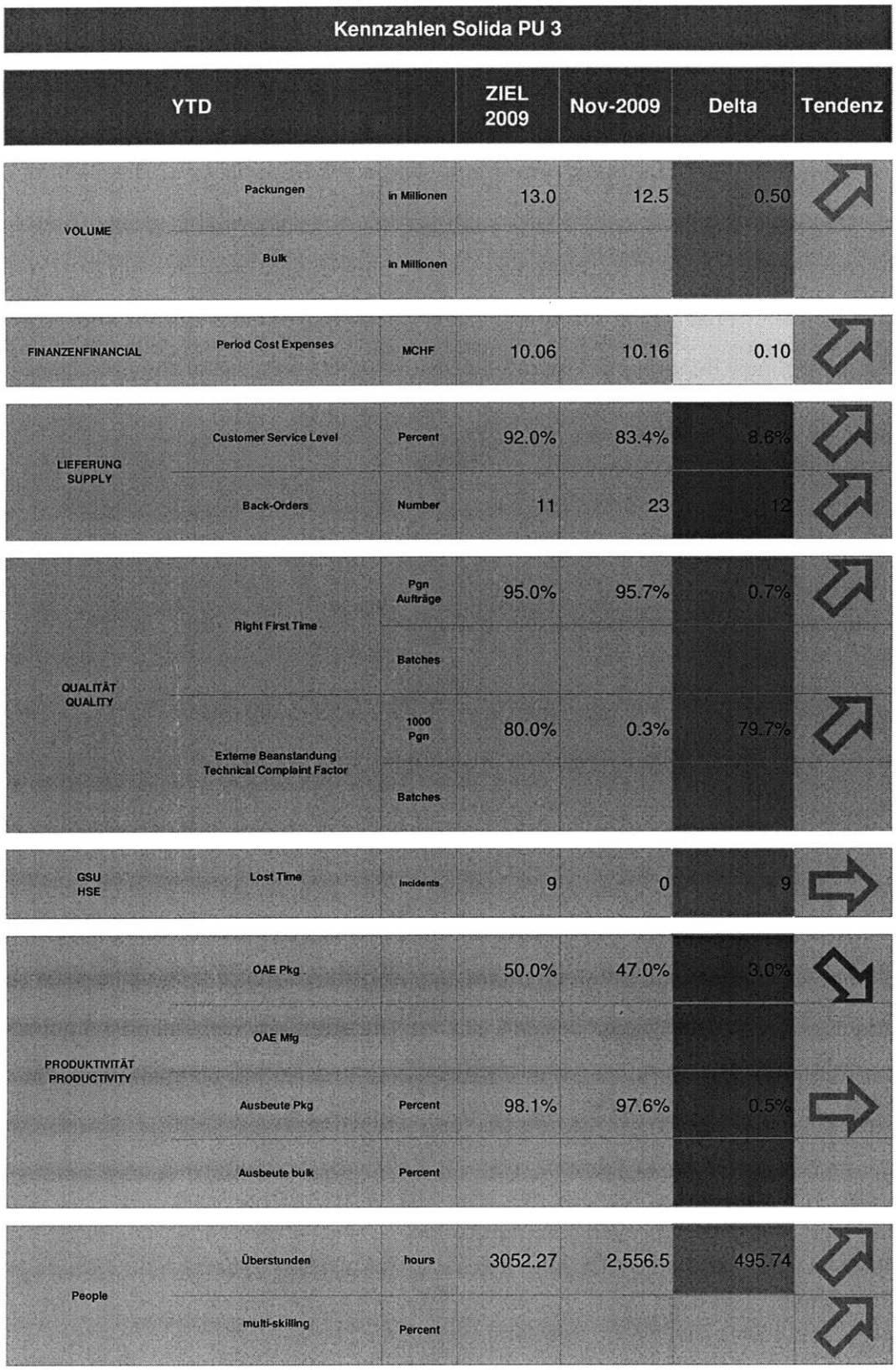
Operational team ownership

The input and direction that the operational team provided was critical to the success of the implementation of the visualization tool. If the teams didn't feel involved or heard as the needs and desires were expressed, the tool could have been discarded and the success certainly in jeopardy. This project was not supposed to be for a 6 month period of time, but instead leave in place a tool that is adaptable and useful for years to come. With a few key members of the team moving on within the Novartis organization, and with the conclusion of this internship, it was important to impart a sense of ownership over the tool in the short period of time. Without people dedicated to its ongoing use, there was a risk of the tool being discontinued from use. However, if the team has fully bought into the value it has been shown to provide there may be more iterations of the tool, but in general, it will be seen as valuable and continue to be used.

Ownership was established from the beginning though conversations about what is important to the shop floor and in conversations about the purpose of the project. By not only telling the teams that a useful tool to help improve performance was my goal, but by listening to what they wanted and showing them that their wishes and concerns were being addressed as the tool was evolving helped them believe that, in fact, they had control over the final product and their voices were heard and valued.

Standardizing reporting

In addition to the visual shift scheduling tools, a new revised BSC was developed for each PU to be posted and displayed in the work areas. Most of the original metrics were left alone, but a few more were added that would be particularly interesting to the front line workforce. Some of the metrics added for the PU levels were first time right under the quality section, and multi-skilling under the people section. Multi skilling is a measure of how much cross training is taking place and the flexibility of the work force to pick up alternate jobs. The updated BSC for one of the PU s is shown in Figure 16 Updated BSC for one of the PU s at POCH, Novartis



Kennzahlen Solida PU 3						
YTD			ZIEL 2009	Nov-2009	Delta	Tendenz
VOLUME	Packungen	in Millionen	13.0	12.5	0.50	
	Bulk	in Millionen				
FINANZENFINANCIAL	Period Cost Expenses	MCHF	10.06	10.16	0.10	
LIEFERUNG SUPPLY	Customer Service Level	Percent	92.0%	83.4%	8.6%	
	Back-Orders	Number	11	23	12	
QUALITÄT QUALITY	Right First Time	Pgn Aufträge	95.0%	95.7%	0.7%	
		Batches				
	Externe Beanstandung Technical Complaint Factor	1000 Pgn	80.0%	0.3%	79.7%	
		Batches				
GSU HSE	Lost Time	Incidents	9	0	9	
PRODUKTIVITÄT PRODUCTIVITY	OAE Pkg		50.0%	47.0%	3.0%	
	OAE Mfg					
	Ausbeute Pkg	Percent	98.1%	97.6%	0.5%	
	Ausbeute bulk	Percent				
People	Überstunden	hours	3052.27	2,556.5	495.74	
	multi-skilling	Percent				

Figure 16 Updated BSC for one of the PU s at POCH, Novartis

Performance Improvements

In order to determine if the implementation of the shift scheduling tool was effective the time it took to turn over the equipment between orders and campaigns was analyzed. The cleaning required between campaigns is more extensive since this when the line switches drug product completely, whereas change over within the same campaign are usually less since it is the same drug product, just a different packaging size of the blister packs and/or different box and pamphlets which are country dependant. As stated previously, this was one of the primary ways that the team could get back on schedule, crisp execution of the set up and cleaning activities. The resulting improvements were

- 27.95% reduction in the amount of time that it took to switch the line between products.
- 5.94% reduction in the time it took to set up the machine between orders in the campaign.

These results were from the pilot packaging line. The baseline was for all orders that were filled on the line from the time it was installed (early 2009) until the first iteration of the shift scheduling template was started in July 2009. The improvement was measured with orders that were completed through the end of December 2009.

In addition to these tangible results, a survey was conducted to determine the overall ownership and empowerment that was felt by the team as a result of the project. The results are given in Figure 17 Survey results by position and question. The questions were all on a 5 point scale. There was no significance in the amount of time the respondent has been employed at Novartis or in their role on the team. Some notable survey responses were:

- Previous metrics are comfortable and perceived useful to the shop floor.
- Shift scheduling tool has improved communication.
- As compared to the first half of the year, it is easier for all roles to determine if the team is ahead or behind schedule.
- The team wants to keep using the developed scheduling tool.

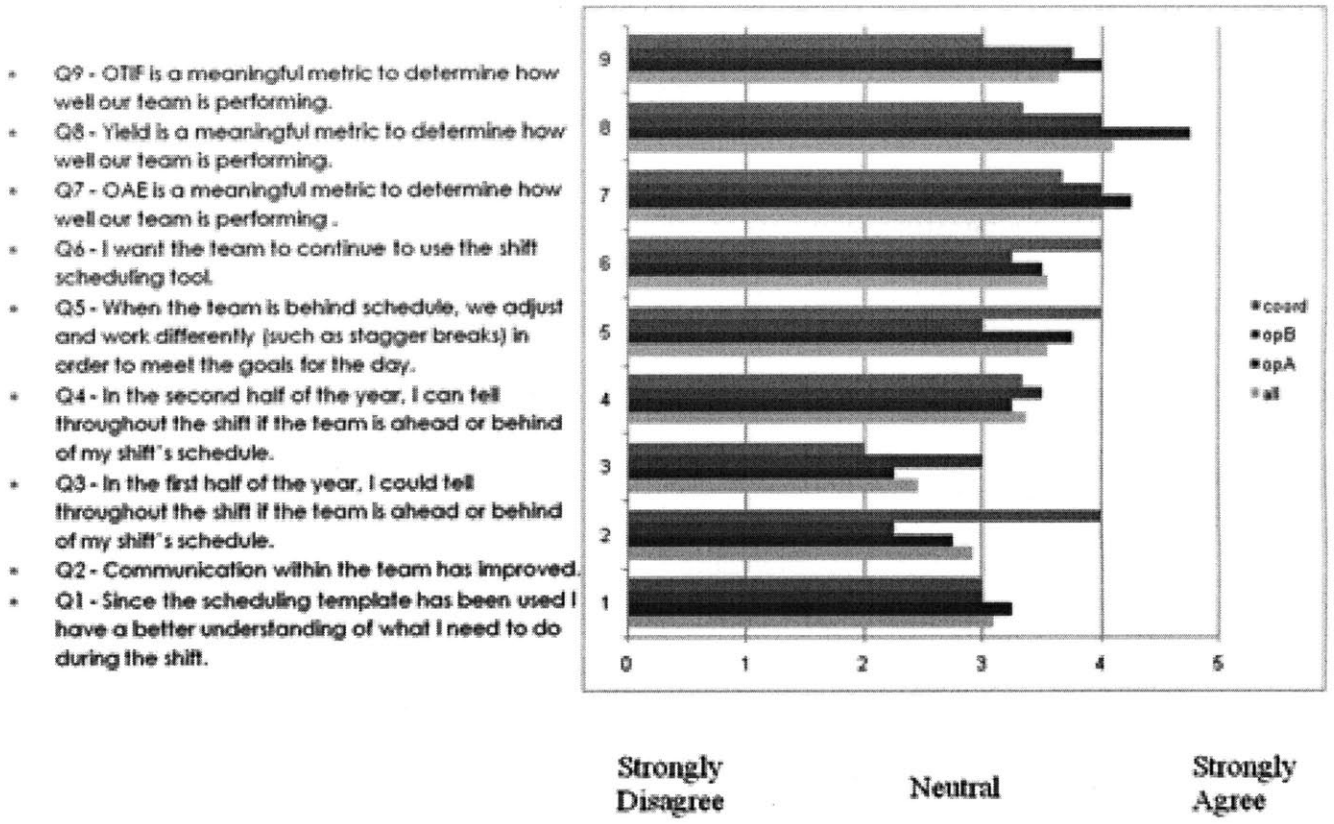


Figure 17 Survey results by position and question

Recommendations and Conclusions

It seems clear that the shop floor wants to continue to use the shift scheduling tool. I would recommend that they do and continue to encourage the team to make adjustments to the tool as they see fit. In addition, I would recommend that the success that was seen on the solid dose packaging line be shared with the other solid dose packing lines at POCH. Through some best practice sharing forum, I also recommend that the template and shop floor workers acceptance of the tool make it possible to expand the use to other solid dose packing lines throughout the Novartis technical operations network.

The template was purposefully made generic and easily adaptable. I recommend the a pilot line be formed in another process step within the pilot line PU to see if similar results could be realized in another step in the manufacturing process. Through observations and interviews, not having a visualized schedule or daily/shift goals was a common problem throughout POCH.

More generally conclusions were:

- Change, especially cultural, is difficult and takes considerable time and effort.
- Even when changes are implemented slowly with small iterations, it might not be well received.
- Without a strong culture of continuous improvement, teams may not perceive that there are things that can be improved.
- Behaviors will change if the team can all understand what is expected of them.
- Visual metrics improve communication.

Future Work

In the future, work with the scheduling team would be helpful. A disconnection was observed between changes, especially to a published production plan, to the schedule from the planning department and the resulting impact on shop floor performance was significant. This impact could be studied including the root causes of changes in publish plans to determine what changes were just too costly to make.

In the short time the compression tools were observed, it was noted that the flow of information from shop floor worker noting issues to the equipment performance and to the managements and/or engineers who could ultimately correct those issues was lacking. There were systems in place to report issues, but it did not seem like there was a systematic way that that information was retrieved, reviewed, and solved. Benchmarking this process throughout the technical operations network and sharing best processes would be a great start to developing a well defined process, ensuring ownership was defined along the way. Being able to "close the loop" could go very far in root cause analysis, in addition to increasing empowerment, at POCH and eventually throughout the Novartis network.

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