Optimization of SKU Creation Process and Adherence Improvement through use of Workflow Management

by

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Submitted to the MIT Sloan School of Management and the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degrees of
Master of Business Administration
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Abstract

Over the past several years and into the foreseeable future, Amgen has been experiencing substantial SKU/DFU proliferation. Formerly, Amgen focused primarily on the North American and other developed markets (low to medium mix, high to medium volumes). However more recently, expansion into "emerging markets" has been a focus (high mix, low volumes). Consequently, the complexity of Amgen's product portfolio has substantially increased.

Most of the international expansion efforts take place at the Breda packaging facility in the Netherlands (ABR). Here the International Operations team manages SKU launches, SKU refreshes (life cycle management) and SKU rationalization for European, Australian and Emerging Markets. Currently the International Operations Leads manually manage product launches using a combination of Microsoft Excel, and Microsoft Project, along with various other tools and databases. All tools and processes used are manual or semi-manual, labor intensive and prone to error.

The goal of this project was to begin streamlining these processes through the implementation of a Workflow Management Tool. Specifically, a proof of concept for the planning portion of the SKU creation process was the focus.

The work studied here resulted in four outputs:

1. Detailed process map for the planning phase of the SKU creation process
2. URS document for Block 1 of workflow tool and draft documents for Block 2 and Block 3
3. Draft Commit-to-Launch process and associated checklist
4. Near and longer term plan for workflow tool implementation

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Chapter 1: Introduction

1.1. Amgen background

Amgen discovers, develops, and delivers innovative human therapeutics. It is the world's largest biopharmaceutical company, employees approximately 17,000 people worldwide and is headquartered in Thousand Oaks, California. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing novel medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses[i]. Amgen pioneered the development of novel products based on advances in recombinant DNA and molecular biology, and launched the biotechnology industry's first blockbuster medicines[ii]. Amgen has 10 principal products; Aranesp®, Enbrel®, EPOGEN®, Neulasta®, NUEPOGEN®, Nplate®, Prolia®, Sensipar®, Vectibix®, and XGEVA®. Key financial highlights from 2011 include total revenue of $15.6 billion, product sales of $15.3 billion with an R&D expense of $3.2 billion[iii].

Amgen Breda, the company's European distribution center, is located in The Netherlands between the ports of Rotterdam and Antwerp and close to airports in The Netherlands, Belgium, and Germany. The site houses commercial operations that assemble devices and label, package, and distribute product to Europe, North Africa, and the Middle East[iv].

1.2. Motivation

Over the past several years and into the foreseeable future, Amgen has been experiencing substantial Stock Keeping Unit (SKU)/Demand Forecasting Unit (DFU) proliferation. Formerly, Amgen focused primarily on the North American and other developed markets (low mix, high volumes). However more recently, expansion into "emerging markets" has been a focus (high mix, low volumes). This market segmentation is most notable when looking at revenue versus

product mix. The North American market is responsible for approximately 80% of company total sales revenue and 75% of total pack sales. However the North American market is only responsible for 10% of Amgen's total SKU's. Contrasting this, the international market is responsible for 20% of company revenue and 25% of total pack sales, but contributes 90% of the company's total SKU count. Torres, Khanderia and Smith explain in detail the impact of this SKU proliferation and suggest potential ways of handling these different markets through Supply Chain Segmentation[v]

This increase in SKU's has been in response to company initiatives to grow internationally. As the North American market has matured, the company has been forced to rely on international markets to increase company revenues. Consequently, the complexity of Amgen's product portfolio has substantially increased as Amgen has expanded abroad. Over a period of eighteen months, Amgen will launch 128 new product/country combinations. Figure 1. 1 **Error! Reference source not found.**below is a snapshot of Amgen's North American and International Markets.

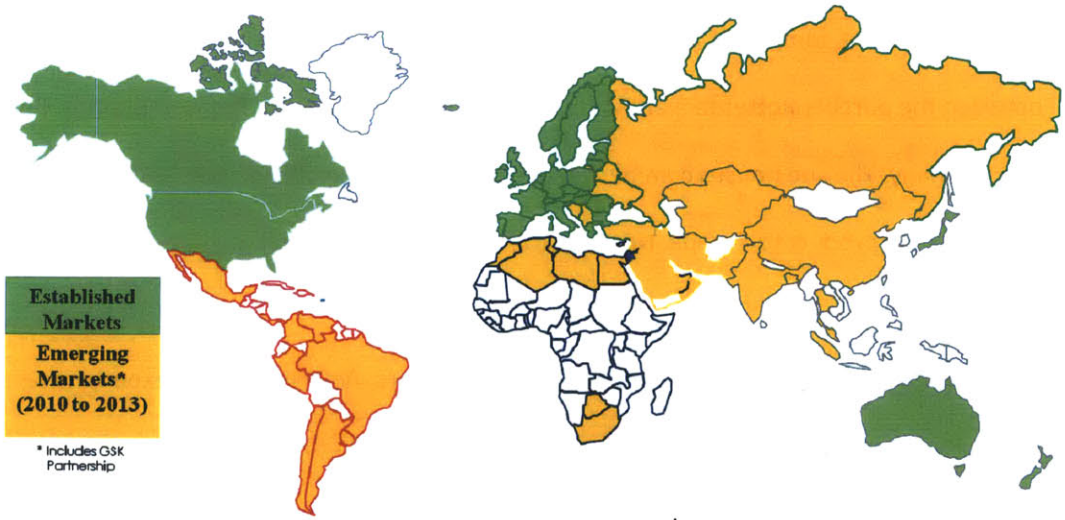


Figure 1. 1: Amgen's Market Mix[vi]

Most of the international expansion efforts take place at the Breda packaging facility in the Netherlands (ABR). Here the International Operations team manages SKU launches, SKU

refreshes (life cycle management) and SKU rationalization for European, Australian and Emerging Markets. Currently the International Operations Leads manually manage product launches using a combination of Microsoft Excel, Microsoft Project, along with various other tools and databases. All tools and processes used are manual or semi-manual, labor intensive and prone to error. The legacy of these methodologies can be partially attributed to the former focus on low mix/high volume markets. When focusing on a market segment that has fewer SKUs, this methodology was adequate. However, as international market expansion has continued, these old methodologies have increasingly become burdensome and time consuming. Figure 1. 2 depicts the SKU growth from 2010 forecasted into 2013.

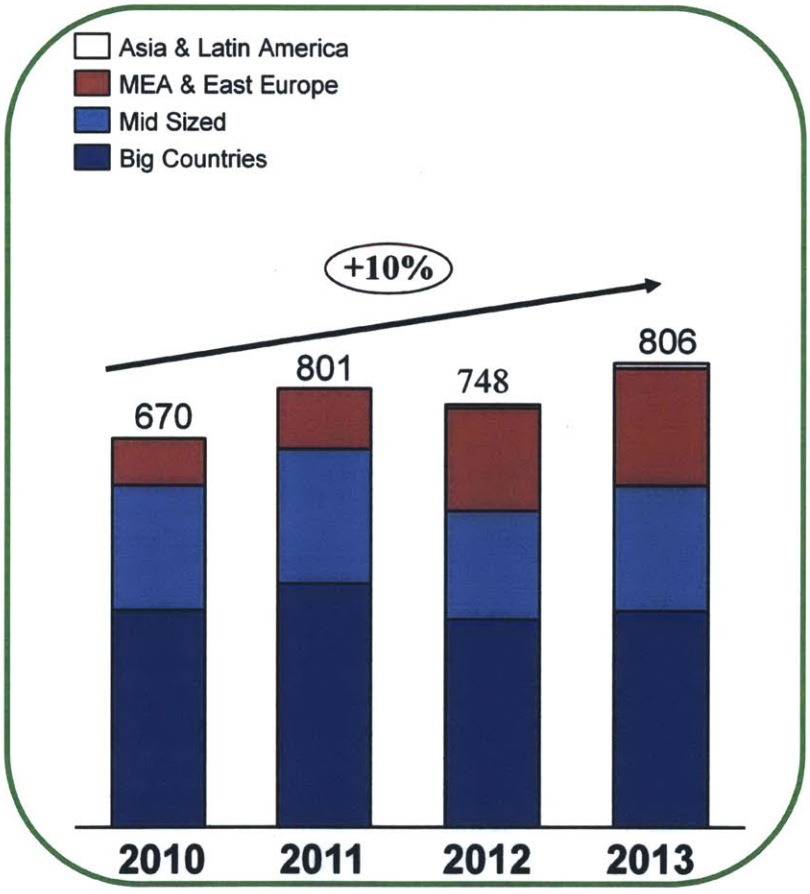


Figure 1. 2: Forecasted SKU Growth

The goal of this internship is to streamline the launch processes through the implementation of a Workflow Management Tool. Such a tool will help drive process discipline, identify glitches and process disconnects, provide line of sight visibility, reference single sources of truth and help reduce workload. Specifically, a proof of concept for the SKU creation process has been developed and implementation initiated. A series of steps were executed to define a User Requirements Document. Additionally, a repeatable process has been developed for expanding this Workflow Management Tool into adjacent sub-processes.

In short, Amgen's success in new markets is creating additional complexity in its operations. To address this complexity, process standardization is being implemented in many departments. To help drive this process standardization in International Operations, a workflow management tool is being developed and implemented.

In this document, the implementation of aforementioned workflow will be discussed. First, project rationalization will be developed. With background information in place and a hypothesis to test, the project methodology will then be introduced. The implementation (or going-forward) plan will be presented followed by the development of a repeatable process for implementing a workflow management tool. Finally, a discussion of the results and project wrap-up will close this document.

1.3. Problem statement

The initial problem statement for this internship was to determine how best to implement a workflow management tool for Amgen's International Operations Team. However, as the project unfolded, it became clear that the scope of the original problem statement was much larger than anticipated, and was much more complicated than just implementing a workflow tool. Therefore over time a more specific problem statement evolved: How to implement a workflow tool in phases over a 12 to 18 month period, which piece of the SKU creation process to begin with and how best to define the process step for the workflow tool in the chosen phase of the project.

Effectively the original problem statement was decomposed into multiple ones. This internship ended up focusing on only a portion of the original problem statement.

1.4. Hypothesis

Two hypotheses are presented here. The first is specifically addressed in this document: The SKU creation process is not adequately documented and subject matter experts do not understand how their tasks/roles impact others. The second hypothesis could not be addressed in the time permitted. Instead it is presented here to help establish the foundation of future work: A workflow management tool will increase process visibility, reduce the amount of time it takes to create a new SKU and help drive the continuous improvement cycle.

1.5. Scope adjustment

During the course of the internship, two events happened that changed the scope of the project. First, it was discovered that the current process documentation was inadequate to support the development of a workflow tool. Specifically, the process as documented did not reflect the manner in which work was completed on a daily basis. Second, the original organization split into multiple entities. This meant that the SKU Creation process, which originally had been contained within one organization, now stretched across multiple. The process can be split into three sections; "Strategy," "Planning" and "Execution." The new Regional Organizations now own the "Strategy" and "Planning" portions of the process and the Site Based Organization (ABR) owns "Execution."

To address these items, a Value Stream Mapping exercise was added to the scope of the project to capture adequate process definition to support development of the workflow tool. Furthermore, with the split in the organization, it was decided that the proof-of-concept should focus on the "Planning" portion of the SKU creation process. Finally, as an outcome of the VSM exercise, a new Commit-to-Launch (CtL) process was proposed. Part of this process was the creation of a CtL checklist – this checklist was added to the scope of the workflow tool project.

1.6. Actions taken overview

Early on, significant time was spent learning and attempting to understand the processes as documented. Later a project team was formed and VSM exercises were conducted. During the VSM exercise, adequate detail was captured to document the "Planning" portion of the process. Multiple projects were initiated based on the outcome of the VSM, and as previously mentioned; the creation of a CtL checklist was added to the scope of the project. Using the results of the VSM, a detailed process map was developed. Building on this, the User Requirements Specification (URS) and CtL checklist were drafted. The URS was reviewed internally by Amgen personnel and externally by the service provider (McErnest). Furthermore, a quote from the service provider for the workflow tool has been received and the procurement process has been initiated. The CtL checklist is currently being piloted within emerging markets with full implementation anticipated in the first quarter of 2012.

This internship resulted in four project outputs:

1. Detailed process map for the planning phase of the SKU creation process
2. URS document for Block 1 of workflow tool and draft documents for Block 2 and Block 3
3. Draft Commit-to-Launch process and associated checklist
4. Near and longer term plan for workflow tool implementation

Chapter 2 of this document presents project rationalization. Then in Chapter 3, project methodology is discussed. With that as a basis, the specific deliverables are discussed in Chapter 4. In Chapter 5, a repeatable process is suggested for workflow tool implementation. Finally, in Chapter 6, we summarize the project and propose future areas to focus additional effort.

Chapter 2: Project Rationalization

2.1. A dollar today equals a lot of dollars tomorrow

Generally speaking, a product launched into a market follows a well behaved profile throughout its lifecycle. In the beginning, sometime after development and regulatory approval, the product has no sales (because it has not been launched yet). Once country specific approval has been received and the commercialization process is complete, a product is then launched into that country and sales gradually increase over time for that country specific Demand Forecast Unit (DFU). Sales growth continues for the DFU, but eventually hits a plateau. Sales will then remain at this plateau level until patent protection runs out or some other product for the ailment enters the market place. At this point, if the DFU was left alone, it would follow some "natural" path of sales decrease. However, DFUs are managed at this point in their lifecycles, and are obsoleted in a manner that best fits the specific situation. Figure 2. 1 below is a general representation of the typical DFU Product Lifecycle.

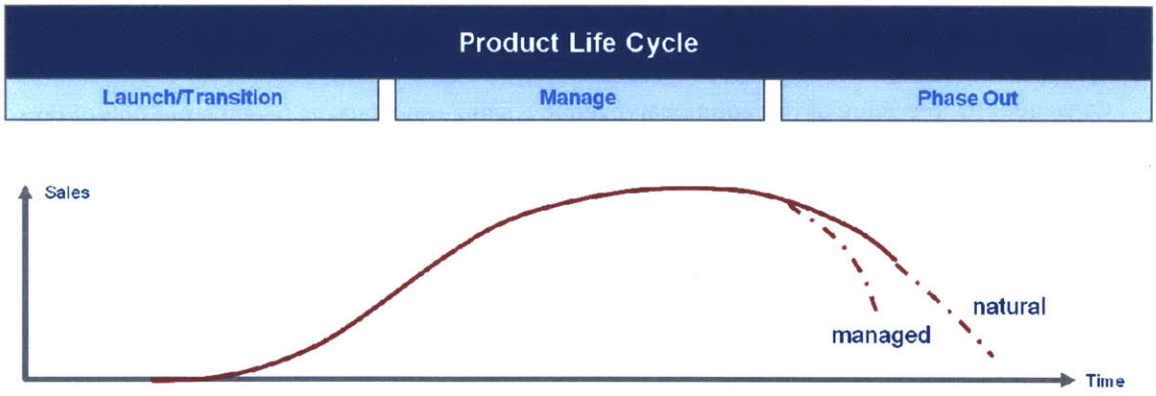


Figure 2. 1: Demand Forecast Unit Product Lifecycle

Under these circumstances, it is of paramount importance to launch a product into a market as soon as possible. Once patent protection is lost, product can quickly lose up to 90% of its sales revenue[vii]. By delaying the launch of a country specific DFU, the company stands to lose a substantial amount of revenue over the life of a product. Additionally, if the company could launch the product earlier, it would stand to generate additional revenue over the life of the

product. By moving the launch date forward by some arbitrary unit of time, the updated product lifecycle profile would look like that seen in Figure 2. 2.

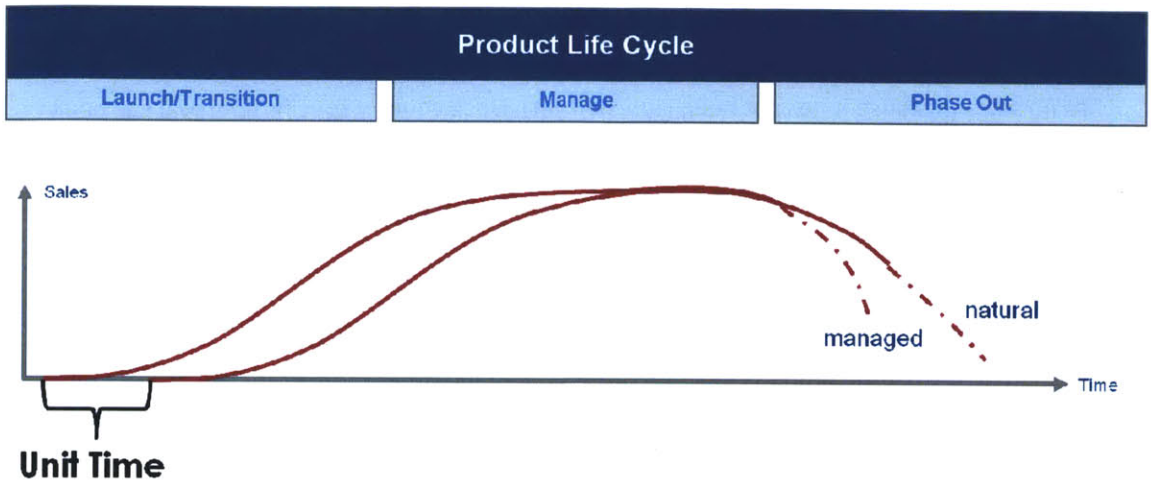


Figure 2. 2: Shifted DFU Product Lifecycle

Therefore, the total additional revenue for a product DFU would be equal to the area between these two product lifecycle curves (this ignores the time value of money). This can be further simplified by realizing that the total area between these two curves is equal to the unit of time multiplied by the revenue per unit of time in the plateau phase of a DFU's lifecycle. Consequently, the value of this additional revenue is simply equal to the revenue per unit of time at the plateau period times the unit of time. Figure 2. 3 illustrates this.

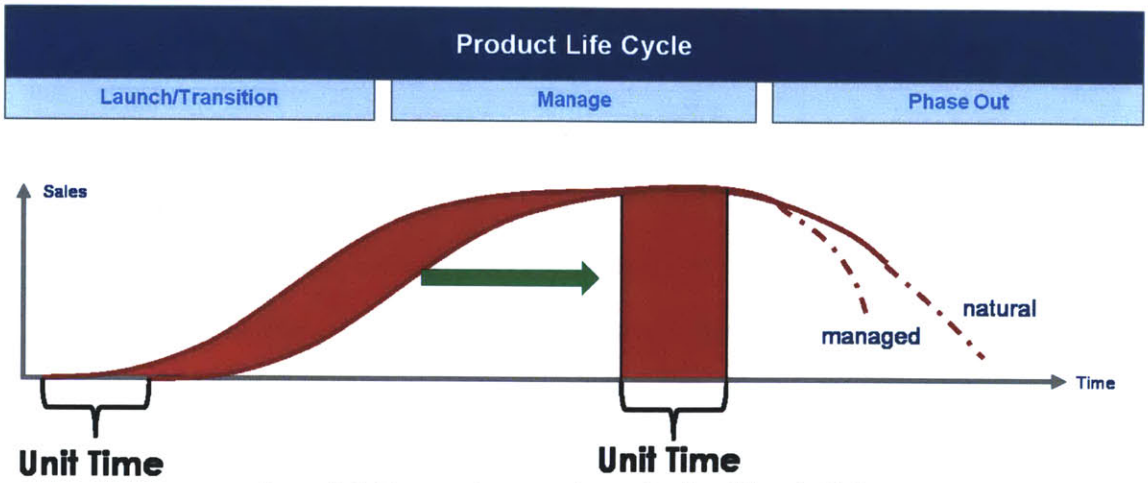


Figure 2. 3: Revenue Increase due to Product Lifecycle Shift

2.2. Failed attempt to use product launch delays as rationalization

In an effort to rationalize the implementation of a work flow management tool and the potential value it could bring to the company, a very labor intensive review of product launches was initiated. In this review, product launch archives were scrubbed to find which products were launched late and how late they were launched. The original idea was to use financial data from sales in conjunction with launch timeliness to quantify the impact of product delays. However this logic was flawed.

The biggest issue with this logic has to do with the framework in which it is set. A vast majority (estimated at greater than ninety percent) of these project launch delays are actually due to the commercialization process. What happens is the commercialization group targets a particular date to launch new DFUs into their markets. The international operations (IO) group is then responsible for executing product launches according to this target date. However, as the date approaches, delays in launch process steps outside the control of IO can/do happen. Examples of this include delays in receiving marketing authorization or country specific pricing agreements. Therefore the commercialization group will change the target launch date, and IO adjusts the plan accordingly.

One conversation between a vice president and a senior manager characterizes this situation very well. When the vice president inquired if all product launches were per plan for the year, the senior manager responded, *"All launches are per plan, but sometimes the plan changes."*

Since the proposed workflow tool will be used by IO to manage product launches and the aforementioned product launch delays are due to process steps outside of IO's realm of

influence, the original argument rationalizing the product (namely, the introduction of the workflow tool will increase product lifetime revenue) is not valid.

2.3. Use of the current product portfolio as an example of financial benefit

A second quantitative attempt was made to rationalize the implementation of the workflow management tool. This time, the current product portfolio was used as an example to determine the total increase to annual revenue assuming a decrease in the product launch time; and hence an increase in total product lifecycle sales. Here a one month improvement to product launch time is used as an example.

In this analysis, the time value of money was once again ignored (cash flows were not discounted). Furthermore, it was assumed that the example product portfolio had a life of ten years. In this analysis, two extreme values were determined for one month's revenue; a minimum and maximum value. The minimum value was found by looking at the most recent month's sales. This is an acceptable minimum value because each product in the portfolio is at various stages in its lifecycle. Some will be in the launch phase, some will be in the plateau stage, and some will be approaching obsolescence. Therefore this value is reasonably considered acceptable as a minimum. The maximum was found by taking the max monthly sales of each DFU within the available data. This is considered a maximum because all DFUs experience an oversell at some point. In addition to this, country specific products occasionally get replaced; i.e., the DFUs get swapped out. Therefore, some "double-dipping" undoubtedly happened while undergoing this analysis; i.e., two maximums were counted in the total for a country/product/dosage combination.

The results of this analysis were quite profound. The range of values determined for the increased revenue over the life of the current product portfolio was 285 to 564 million dollars. Conservatively this represents 300 million dollars of revenue over the life of the current portfolio.

Once again, assuming a ten year life of a product portfolio, a one month reduction in the product launch process would represent a 30 million dollar increase in annual revenue. Just a one day improvement in the product launch process for every product currently in the portfolio would represent one million additional dollars in annual revenue.

To illustrate this methodology, a simple example is given. In Table 2. 1 below, an imitation product portfolio is given with six months of financial data. To determine the minimum value for each product, the most recent month's financial data is captured (highlighted in yellow). To determine the max value, the maximum month's revenue over the life of the portfolio (here, only six months are represented) is captured (highlighted in green). By summing the min and max values, you get a range of revenues over the life of the product portfolio that could be realized if a one month improvement in the SKU creation process was realized $5000 to $7700 here. Therefore a conservative value for the total potential revenue realized in this example would be $5,000 (or the summation of the minimum values) over the life of the product portfolio.

Table 2. 1: Revenue Increase Example

Monthly Sales								
Product	**Jan**	**Feb**	**March**	**April**	**May**	**June**	**Min**	**Max**
A	$1,000	$900	$1,000	$2,000	$600	$1,000	$1,000	$2,000
B	$0	$0	$0	$0	$100	$300	$300	$300
C	$400	$300	$200	$100	$0	$0	$0	$400
D	$700	$700	$600	$700	$700	$700	$700	$700
E	$100	$0	$0	$0	$0	$0	$0	$100
F	$200	$200	$100	$300	$400	$100	$100	$400
G	$2,000	$1,700	$2,300	$3,000	$1,000	$2,100	$2,100	$3,000
H	$300	$300	$300	$200	$200	$300	$300	$300
I	$0	$0	$0	$0	$200	$500	$500	$500
Total							$5,000	$7,700

However, once again, the initial logic was flawed. Although this analysis is believed to be correct, the tool that is to be implemented will be an operations tool. Generally speaking, IO launches products on time. However, target launch dates are assigned by the commercialization

organization. Therefore any resulting efficiencies gained from this tool would result in the IO launch process beginning later and still launching on time. Therefore the incremental value of the tool would have to be quantified on a cost savings basis; increasing the bottom line, not the top.

Although the value of reducing the overall time required for the commercialization process is substantial, it falls outside of the scope of this project. Therefore this analysis with its initially flawed logic is mentioned here to highlight potential areas for future improvement and increased revenues.

2.4. Risk reduction and process adherence

After two failed attempts to quantitatively justify the project, qualitative rationalization has been completed as a justification to implement the workflow management tool. As previously mentioned, literature sources quote substantial time savings in the execution (or launching) of projects[viii]. One article by Reijers and Poelmans is of particular interest, because 25 different workflow tools implemented into 13 different companies are studied. Generally speaking, implementation of these workflow tools was viewed as positive with some examples showing reduced process times by up to 50%[ix]. This time savings itself translates to a cost savings and hence an increase in net earnings. Unfortunately, the company does not do activity based time accounting, so it is impossible to accurately forecast the savings associated with a reduction in product launch times. Nevertheless, a cost reduction in DFU launch time will translate directly to a reduction in cost.

Further rationalization includes the need to develop and adhere to standard processes. It is well documented in manufacturing environments that as you consistently repeat a standard process, there is substantial learning and a reduction in the amount of time it takes to complete the process. T.P. Wright introduced the concept to the aerospace industry in 1936[x]. Since then,

learning curves have been applied to all types of work from simple tasks to complex jobs with process time reductions of up to 96%[xi]

Although process documentation exist that defines processes exist at Amgen, it is but one way to "get the job done." In fact, each employee had a different way to complete their work. Although similar themes existed, no one followed the standard. Part of this is believed to be due to the confusing nature of the process documentation. Furthermore, as you gain experience in a position, the ability to skip steps that might not seem necessary is developed. Therefore the thought is that by putting a workflow tool in place based off a standard process, you force people to adhere to it. This in turn will drive long term learning, process efficiencies and reduces the risks associated with multiple working methods.

Eventual automation of the workflow tool also adds value. As the phased implementation goes forward, the workflow tool will be "plugged into" existing systems such as SAP. By automating the tool in such a fashion, you will create an environment in which a single source of truth exists. Multiple documents managing the status of a project will no longer exist and employee workload is reduced due to the removal of error prone manual micromanaging. Line of sight visibility also becomes a possibility. By integrating simple visibility displays and dashboards, one can instantly identify where delays in a project are occurring and focus on them. Furthermore, process steps prone to delay can be identified for process improvement activity.

Finally, senior leadership recognizes the need to adhere to standard procedures. In two separate instances, different vice presidents made statements directly to this point. The first said, *"We need to do things systematically, methodologically and consistently... this will allow you to focus on quality, which will drive cost down."* The second said, *"To get better we need to be a little more consistent in how we get things done."* Both of these statements support the

implementation of a workflow management tool. This tool will help standardize work, drive adherence to processes and ultimately drive the continuous improvement cycle.

In the next chapter, we shall discuss methodology and how the project was executed.

Chapter 3: Methodology

3.1. Familiarization

The first several weeks of this project were spent understanding the problem statement and the organization it was imbedded in. During the first week, substantial time was spent understanding ABR Readiness and phase 1 of the project. Two days were spent with the former project owner reviewing process documentation and training material that had been developed. With this as a knowledge base, I began job shadowing the International Operations Leads (IOLs). The goal was to gain a deeper understanding of their day to day activities. This was especially important since the tool to be implemented was meant to streamline their work and drive process adherence into their work statement.

In this same timeframe, a series of meetings were established with key stakeholders. These meetings involved personnel from a wide range of support organizations including: Information Systems, Supply Chain, Planning, Product Development, Finance, Customer Service, Human Resources, Regulatory, Quality, Project Management, International Commercialization, Production and many more. The goal of these meetings was to widen the breath of background knowledge of the organization for the project and to a certain extent, gain their buy in for the workflow tool project. Some of these meetings served as a "rubber stamp" of support by the less impacted organizations. Other meetings were more involved, discussing the details of local supply chain strategy. In one meeting, the details of a previous initiative and reasons for its failure were discussed. Finally, these meetings served as a basis for the creation of a steering team. All of this input was drastically important as these stakeholders were either responsible for running a particular organization or the SME's directly responsible for completing process steps during the creation of a new SKU.

3.2. Study design

Very early in the project, a study design structure was instituted. The project was broken up into three stages: Understanding the problem, rationalizing the project & creating a plan, and

executing & implementing. Understanding the problem largely focused on the familiarization piece of the project. Rationalization and creating a plan naturally came next and looked at the potential value of implementing a workflow tool and how to go about it. Executing and implementing focused on getting the project done.

At the beginning, anticipated steps for each stage of the project were listed. At each stage, the expected outcome and anticipated required resources were listed. As one academic professor commonly mentioned in class, this created the opportunity to be surprised and increased the learning potential. After each stage of the project was completed, the actual outcome was compared to the expected outcome and forthcoming stages were updated accordingly to incorporate this new knowledge. Figure 3. 1 below summarizes this study design.

	Understand the Problem	Rationalize the Project and Create a Plan	Execute and Implement
Steps	Introductory meetings Job Shadowing Process Reviews Supplier meeting	SKU launch timeliness review DFU financial data review Process Gap Analysis Coordinate Project Team	Create Project Team; Plan & Conduct VSM Develop user requirements Create detailed implementation plan Implement Proof of Concept (if possible)
Expected Outcome	Thorough understanding of problem statement and ability to develop plan	Project rationalization complete based on product launch timeliness and financial data	Well defined processes to write user requirements document ; phased implementation plan in place
Actual Outcome	Good understanding of project except for IS; initial difficulty establishing relationship WF Tool should be implemented in phases instead of all at once	Rationalization shifted to risk reduction vs. incremental launch improvements or launch delays Recent events need to be captured and included – VSM activities added to plan to capture high level process	TBD
Required Resources	Meetings with a multitude of Amgen personnel, supplier and Information Systems	Launch (IO archives) & DFU financial (finance dept) data International Operations	PM&BO to coordinate VSM activity, various personnel to support VSM and IS to assist with user requirements doc

Figure 3. 1: Study Design

3.3. Supplier meeting

After approximately six weeks of familiarization (and other activities) a meeting was held with the previously identified preferred supplier. This particular supplier was a small Business Process Management Consulting firm specializing in workflow management systems (McErnest) and had been selected prior to the project to implement the proposed workflow management tool.

During this meeting, tool details were discussed and definition requirements reviewed. The most important point to come out of the meeting was the need to implement the workflow tool in phases. Up until this point, the scope of the project had seemed overwhelming. During this meeting, it became apparent that the project needed to be broken up into phases, and the initial implementation of the workflow tool should be with a small piece of the overarching process with a limited number of organizations involved. The aforementioned study design was updated to incorporate this information and the next stage of the project initiated.

3.4. Quantitative and qualitative rocess review

Early on in the familiarization process, it became evident that although the SKU creation process was documented, it did not necessarily capture the way work was done. Qualitatively, the processes did not reflect the manner in which work was executed. Each IOL had substantial Subject Mater Expert (SME) expertise and accordingly had a personally customized way of executing the creation of an SKU. Therefore, the process as documented was but one way of getting the work done.

Although this individualism was observed early in the familiarization process, it was more difficult to quantify or capture in a manner that could be easily communicated (beyond the vague statement that "employees don't follow standard work"). Eventually a methodology to quantify this individualism was identified. During phase 1 of ABR Readiness, a process step checklist had been developed. This checklist included 167 required steps to create a new SKU. Using this checklist as a baseline, each IOL was asked to bucket each step into one of three categories: A high level milestone, tracked at the highest level within the organization for each SKU created, an IOL level task tracked and completed by an International Operations Lead, or a Subject Matter Expert (SME) level task that needed to be completed at the SME level, but not necessarily tracked at the IOL level.

After two IOLs reviewed this checklist and provided their input, only 30 of the 167 required steps were commonly bucketed. In other words, 137 of the 167 steps were grouped into conflicting categories; meaning that the IOLs did not agree on who was responsible for each step and its importance within the SKU creation process. This review provided a quantifiable basis for further process development. Therefore the aforementioned study design was updated and a Value Stream Mapping (VSM) exercise for the targeted portion of the SKU creation process was added to the project plan.

3.5. VSM planning

Initially there was substantial resistance to conducting a VSM exercise. Various stakeholders felt that if a VSM was conducted, it would mean all the previous work that had been completed to document and standardize their processes would be scrapped, effectively throwing away a year of work. The aforementioned methodology to quantify the process documentation deficiencies provided initial leverage to gain support for the VSM exercise. Furthermore, to gain buy-in, the VSM was sold as a process validation exercise. We would validate the existing process as opposed to recreating what had been previously completed. Spinning the proposed VSM in this manner helped to gain support at the working level within the organization. Finally, a steering team was created to oversee the project at the site leadership level. Included among this team was the site leader, Director of Quality, Director of International Supply Chain, and Director of Information Systems. This steering team was instrumental in removing roadblocks during the entire project and securing resources for the VSM.

With the necessary support in place, planning for the VSM began. The author's past experience conducting Value Stream Mapping suggested that the exercise would take up to two weeks in duration. This experience came from the aerospace industry, executing what was referred to as a "Visual" VSM. A good description of the value stream methodology can be found in *Learning to See* by Mike Rother and John Shook[xii].

It quickly became apparent that the organization did not have the necessary resources to support a very extensive VSM. Therefore an abbreviated methodology specifically tailored to this company was used, and a three day exercise was scheduled. Details of the methodology will be discussed below.

With the VSM scheduled, SME's across the entire Value Stream were identified for participation. The steering team was utilized to secure the necessary personnel for the exercise and when necessary, find suitable alternatives. Once personnel were identified for the VSM, one-on-one meetings were conducted to rapidly bring people up to speed on the project. A project team was created based on this group of personnel and weekly status meetings were held. Finally, the Business Process Management office was brought in to provide oversight for the project and visibility across the entire site.

3.6. Business unit reorganization

While planning for the VSM was underway, a business unit reorganization that affected the project was instituted. Figure 3. 2 below illustrates the organizational split. The singular organization was split into multiple ones; effectively separating the supply and demand portions of the business for international markets. The product demand portion of the business was reorganized into geographically based regions; each region became an independent organization led by a director who reported up to a vice president at the corporate level. The product supply piece now became the sole responsibility of the original site and reported to a different vice president at the corporate level. This split in the organization modified the focus of the project.

Figure 3. 3 is a depiction of the lifecycle of an SKU. The SKU is created during the launch phase of the product life cycle. Sales grow over time until the SKU eventually plateau's during the life cycle management phase. Toward the end of the product life cycle, the SKU experiences declining sales (for whatever reason) and is eventually obsoleted.

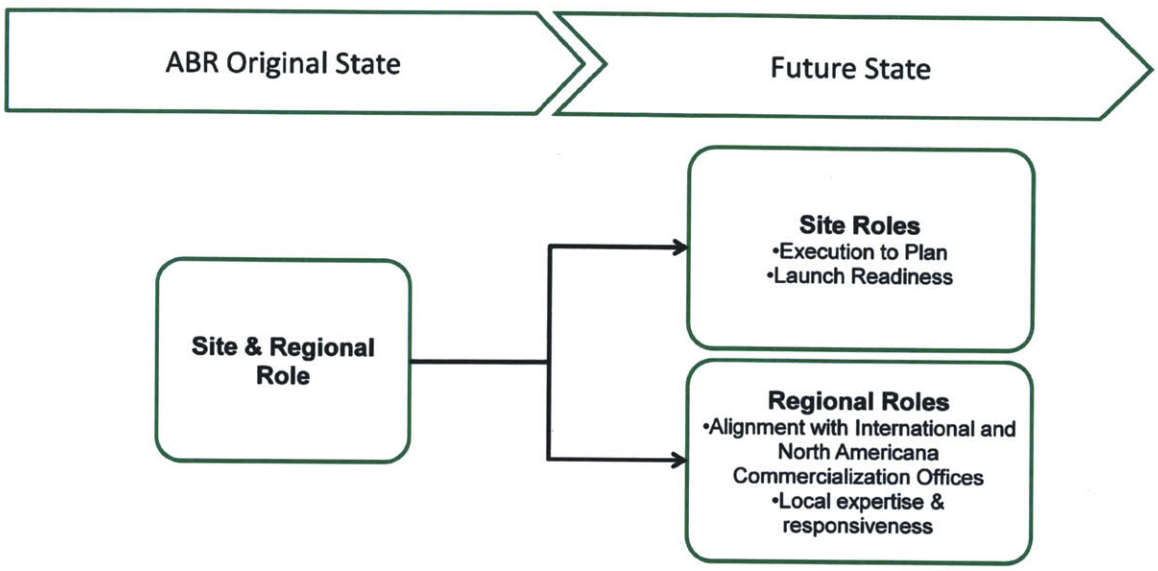


Figure 3. 2: Business Reorganization

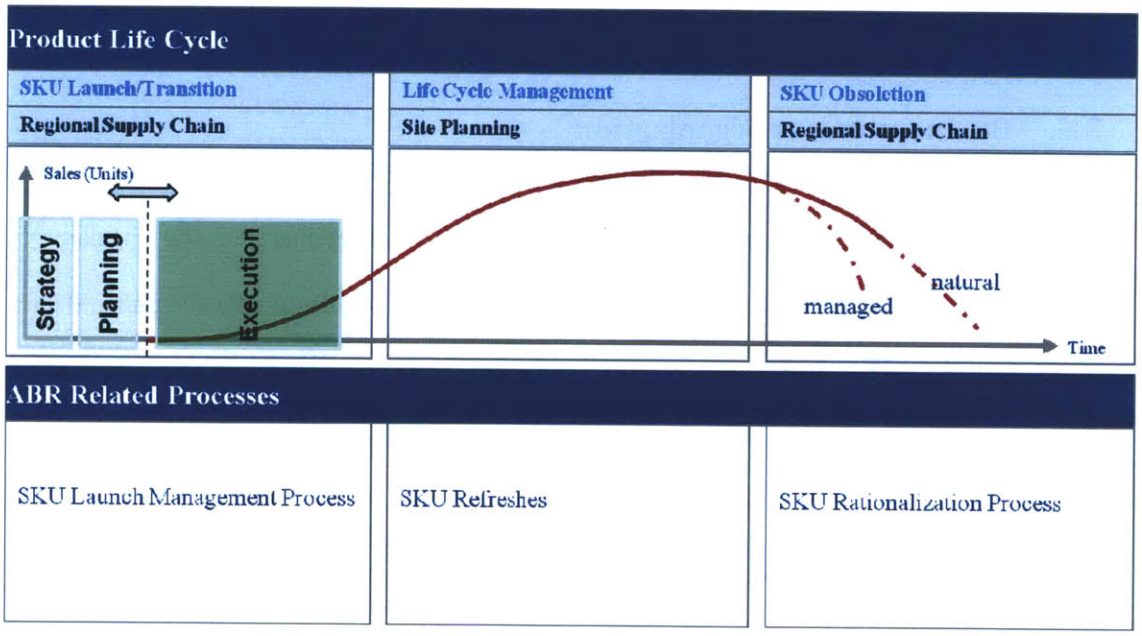


Figure 3. 3: Stock Keeping Unit Lifecycle

The goal of the internship was to create a proof-of-concept for the SKU creation (or launch) process. The creation process can be broken down into three phases; "strategy", "planning" and "execution." In the original organization, all three phases of the SKU creation process where contained within a singular business unit. However, with the change in the organizational structure, the strategy and planning portions of the process now reside with the regional units

and the execution piece with the site. Furthermore, with the organizational split, this project migrated with the team that formed Region 1. Therefore, the potential scope for the proof-of-concept was naturally limited to the strategy and planning portions of the SKU creation process. Eventually it was decided to focus on the "planning" portion of the SKU creation process during the VSM. The reasoning was twofold. First, the "strategy" phase was viewed as a mature process. Second, it was believed that the workflow tool would have a greater impact if used during the "planning" phase of the process.

3.7. VSM execution

A three day mapping exercise was conducted. The first day focused on the current state process. As previously mentioned, the as-documented process was used as a baseline. Figure 3.4 is a high level view of the original process.

Figure 3.4: Original Process Mapping

Large banner style copies of this map were printed out, and the team modified the as-documented process to reflect how work was actually completed. At the end of the morning session on day 1, the picture in Figure 3. 5 was taken. In short, the process was not accurately captured in Agmen's documentation. .

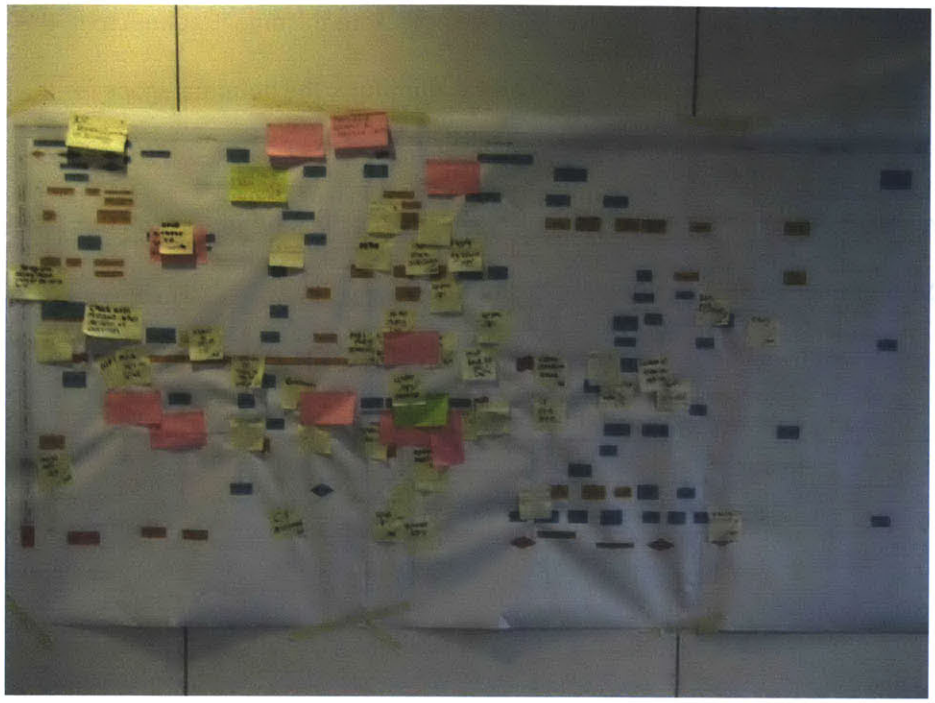


Figure 3. 5: Modified Process Map

With this as a backdrop, it was decided to start the afternoon session of day 1 with a fresh piece of butcher paper to document the high level current state process. Figure 3.6 is the result of the afternoon session on day 1.

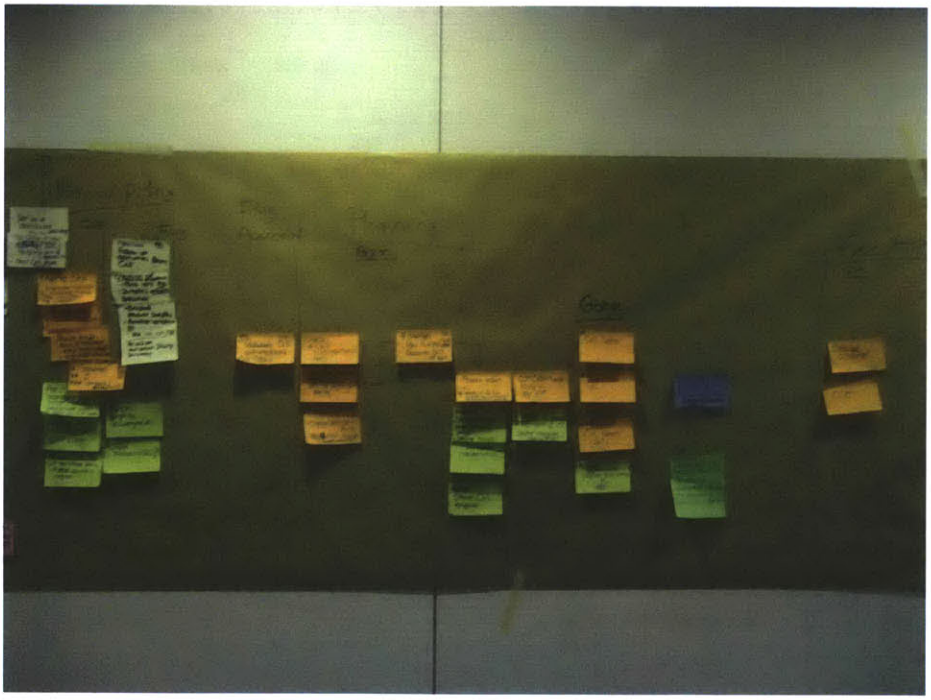


Figure 3.6: High Level Current State Mapping

On day 2, the team started by identifying potential improvement opportunities, commonly referred to as Kaizan's. These Kaizan's were then ranked in order of importance and ability to be executed in short order. Note that only changes that could be implemented in short order (less than a month) were considered in order to enable the original project to still be completed within the given time frame. With these Kaizan's in mind, the afternoon session of day 2 was utilized to create a high level future state. Figure 3.7 is a picture of the final high level future state.

Figure 3.7: Final High Level Process Mapping

The morning session of day 3 was utilized to further develop the future state map – to identify all the detailed process steps imbedded in the higher level map. The final detailed mapping can be seen in Figure 3.8. The afternoon session of day 3 was used to develop solutions to the identified Kaizan's and/or create their associated action plans. Finally, a report out to the leadership team was conducted.

Most of these Kaizan's and their associated action plans fall outside of the scope of this project, except to note that they were completed. One of the Kaizan's was added to the scope of this project: the development of a Commit-to-Launch (CtL) checklist. This task was taken on by the

author, because it was believed to be an intermediate step to the creation of the workflow tool. This topic will be covered in more detail in the next chapter. Another interesting improvement idea was the introduction of a complexity rating system for the SKU creation process. Each proposed SKU would be rated from one to three stars based on its complexity. The star rating in turn would dictate the level of governance required during the process highlighted below. Additionally, the star rating would be utilized for capacity planning. Higher rated stars required more time and resources, so only a certain number and combination of projects could be handled at a time.

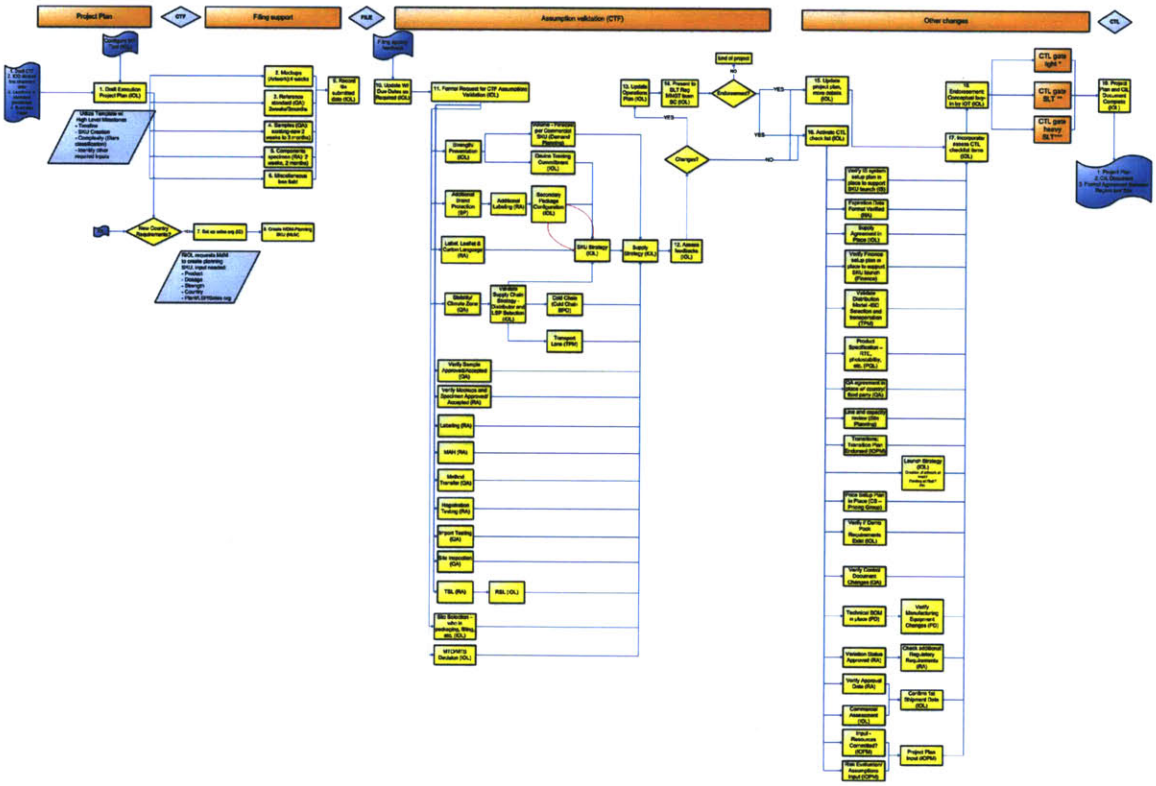


Figure 3.8: Detailed Process Map

Next we will present specific project outputs that resulted from the work conducted on this internship.

Chapter 4: Output

4.1. Overview

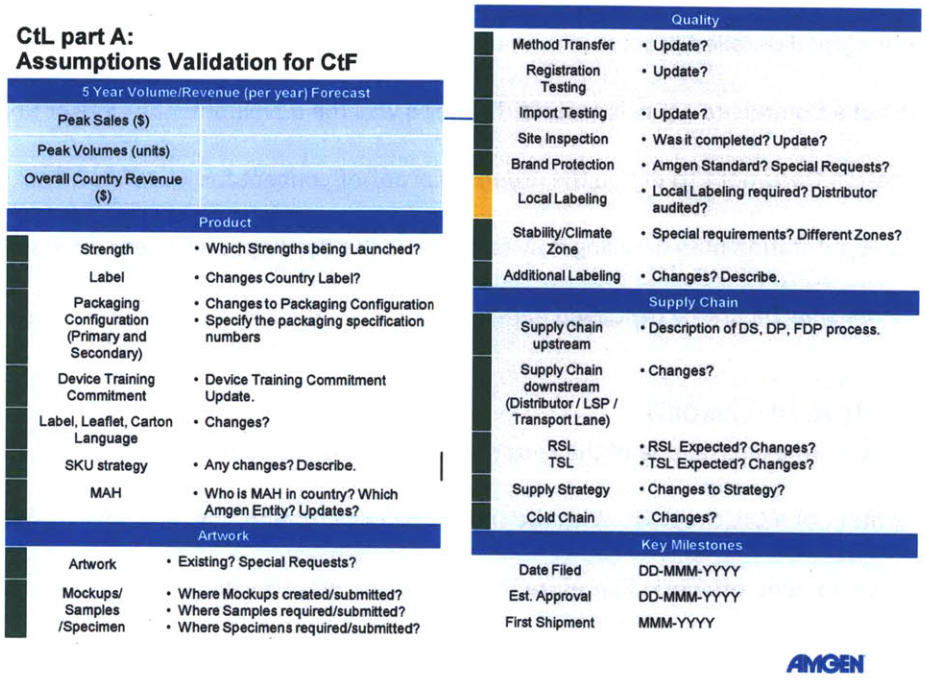
During the course of this project, there were four primary outputs. The first is the aforementioned detailed process map that was a result of the VSM exercise. The second was the creation of a Commit-to-Launch process. The third was the development of a User Requirements Specification Document to define the proposed proof-of-concept for a workflow tool. The fourth is an implementation plan detailing how to continue the development of the workflow tool. The latter three shall be briefly described here.

4.2. Commit-to-Launch

During the VSM exercise, one of the Kaizan's added to the scope of this project was the development of a CtL checklist. With the split in the organization, the new entities needed a formal way to hand off work. Therefore the CtL process was conceived. This process consists of two primary components: the CtL checklist and a formal agreement between a region and the site to commit to an SKU launch.

The formal agreement is very straightforward, and therefore will not be discussed any further other than to note that it is part of the process. The CtL checklist on the other hand substantially overlapped with the development of the detailed process map. In short, the CtL checklist is simply that – a checklist. It consists of two parts; Part A and Part B. Part A validates the assumptions from the Strategy phase of the SKU creation process. Part B deals with the process steps associated with the Planning phase. Each checklist item has a red/yellow/green checkbox to indicate the status of each step. Red indicates that the checklist item is behind schedule with no go-forward plan. Yellow indicates that the checklist item is behind schedule, but has a go-forward plan. Green indicates that the checklist item is on schedule with no issues. Each checklist item also has a small text field to enter task specific information that is important. Figure 4.1 and Figure 4.2 are representative examples of part A and B of the CtL checklist. In these, all checklist

items are green, except for local labeling, which is yellow and indicates it is behind schedule, but has a go-forward plan.



CtL part A:
Assumptions Validation for CtF

5 Year Volume/Revenue (per year) Forecast	
Peak Sales ($)	
Peak Volumes (units)	
Overall Country Revenue ($)	

Product	
Strength	• Which Strengths being Launched?
Label	• Changes Country Label?
Packaging Configuration (Primary and Secondary)	• Changes to Packaging Configuration • Specify the packaging specification numbers
Device Training Commitment	• Device Training Commitment Update.
Label, Leaflet, Carton Language	• Changes?
SKU strategy	• Any changes? Describe.
MAH	• Who is MAH in country? Which Amgen Entity? Updates?

Artwork	
Artwork	• Existing? Special Requests?
Mockups/ Samples /Specimen	• Where Mockups created/submitted? • Where Samples required/submitted? • Where Specimens required/submitted?

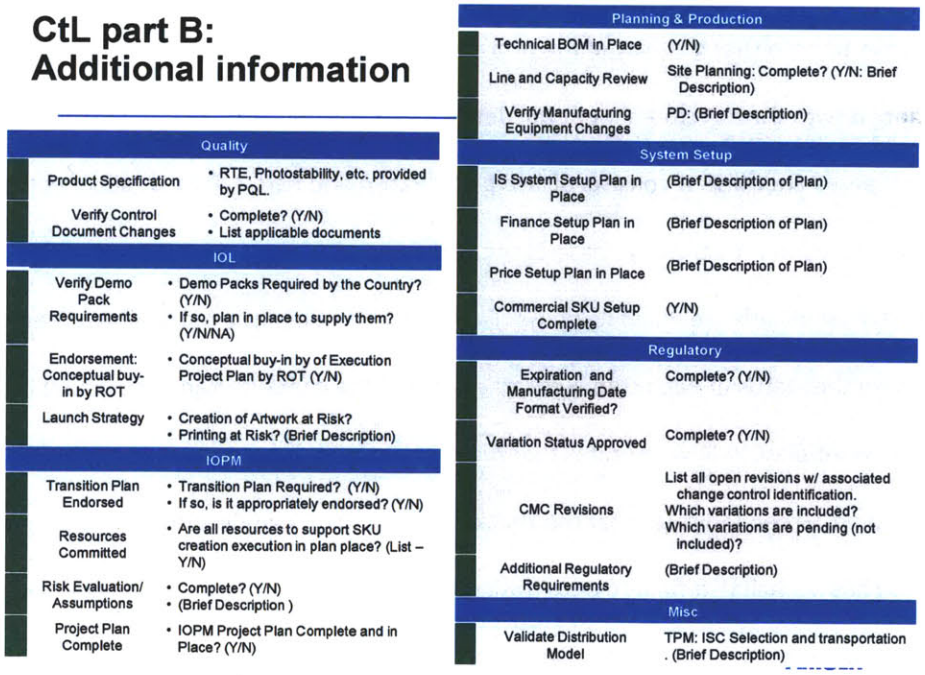
Quality	
Method Transfer	• Update?
Registration Testing	• Update?
Import Testing	• Update?
Site Inspection	• Was it completed? Update?
Brand Protection	• Amgen Standard? Special Requests?
Local Labeling	• Local Labeling required? Distributor audited?
Stability/Climate Zone	• Special requirements? Different Zones?
Additional Labeling	• Changes? Describe.

Supply Chain	
Supply Chain upstream	• Description of DS, DP, FDP process.
Supply Chain downstream (Distributor / LSP / Transport Lane)	• Changes?
RSL TSL	• RSL Expected? Changes? • TSL Expected? Changes?
Supply Strategy	• Changes to Strategy?
Cold Chain	• Changes?

Key Milestones	
Date Filed	DD-MMM-YYYY
Est. Approval	DD-MMM-YYYY
First Shipment	MMM-YYYY

AMGEN

Figure 4.1: Commit-to-Launch Checklist Part A



CtL part B:
Additional information

Quality	
Product Specification	• RTE, Photostability, etc. provided by PQL.
Verify Control Document Changes	• Complete? (Y/N) • List applicable documents

IOL	
Verify Demo Pack Requirements	• Demo Packs Required by the Country? (Y/N) • If so, plan in place to supply them? (Y/N/NA)
Endorsement: Conceptual buy-in by ROT	• Conceptual buy-in by of Execution Project Plan by ROT (Y/N)
Launch Strategy	• Creation of Artwork at Risk? • Printing at Risk? (Brief Description)

IOPM	
Transition Plan Endorsed	• Transition Plan Required? (Y/N) • If so, is it appropriately endorsed? (Y/N)
Resources Committed	• Are all resources to support SKU creation execution in plan place? (List – Y/N)
Risk Evaluation/ Assumptions	• Complete? (Y/N) • (Brief Description)
Project Plan Complete	• IOPM Project Plan Complete and in Place? (Y/N)

Planning & Production	
Technical BOM in Place	(Y/N)
Line and Capacity Review	Site Planning: Complete? (Y/N: Brief Description)
Verify Manufacturing Equipment Changes	PD: (Brief Description)

System Setup	
IS System Setup Plan in Place	(Brief Description of Plan)
Finance Setup Plan in Place	(Brief Description of Plan)
Price Setup Plan in Place	(Brief Description of Plan)
Commercial SKU Setup Complete	(Y/N)

Regulatory	
Expiration and Manufacturing Date Format Verified?	Complete? (Y/N)
Variation Status Approved	Complete? (Y/N)
CMC Revisions	List all open revisions w/ associated change control identification. Which variations are included? Which variations are pending (not included)?
Additional Regulatory Requirements	(Brief Description)

Misc	
Validate Distribution Model	TPM: ISC Selection and transportation . (Brief Description)

Figure 4.2: Commit-to-Launch Checklist Part B

4.3. User requirements specification

The URS document serves as a foundation to bring together multi disciplinary system requirements into a single document to support system design, construction, commissioning, qualification, validation and ongoing operation/maintenance. A User Requirement is a condition that must be satisfied in order for a system to meet its intended purpose from the perspectives of all stakeholders. In short, it defines the requirements of the workflow tool. Three of these documents were created; the first was submitted to the service provider (McErnest) and the other two were drafts created for use during future development.

Based on the URS submited to McErnest, multiple mockups of the proposed workflow tool were created. Figure 4.3 and Figure 4.4 and two examples. Furthermore, a quote was received from the service provider and a purchase order initiated.

Figure 4.3: Workflow Tool Interface Example 1

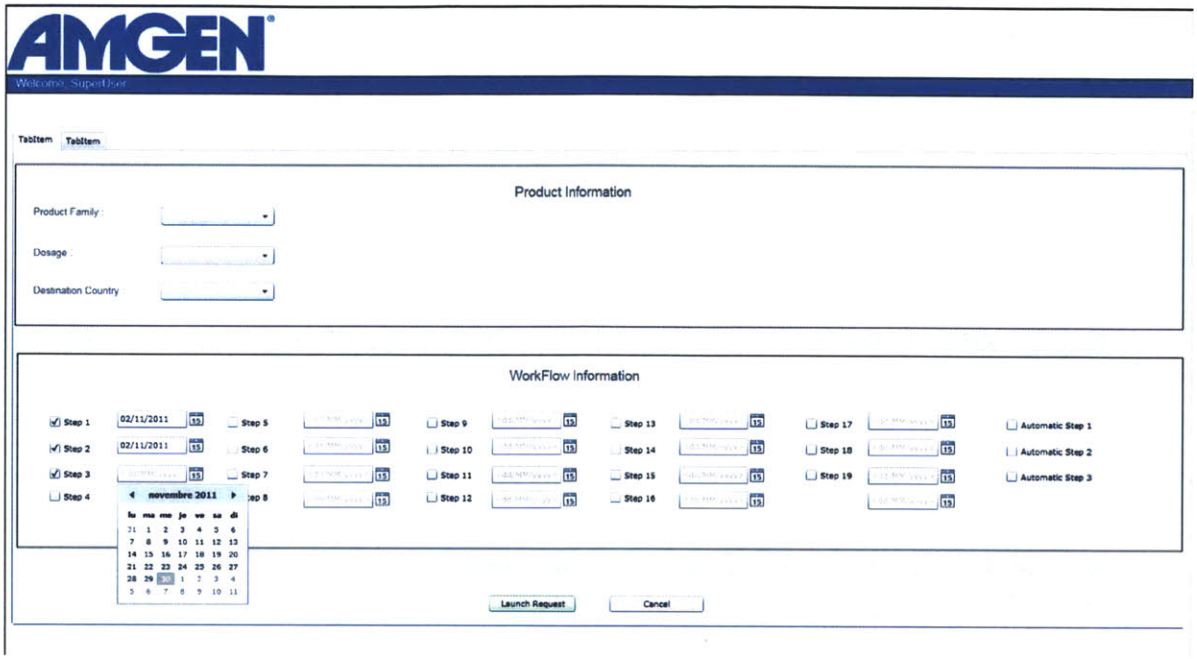


Figure 4.4: Workflow Tool Interface Example 2

4.4. Implementation plan

Finally, an implementation plan was created to propose a timeline on how the workflow tool should be put into place. Figure 4.5 captures the implementation plan for Block I. Figure 4.6 is the longer range, broader scope implementation plan for the entire (currently proposed) workflow tool.

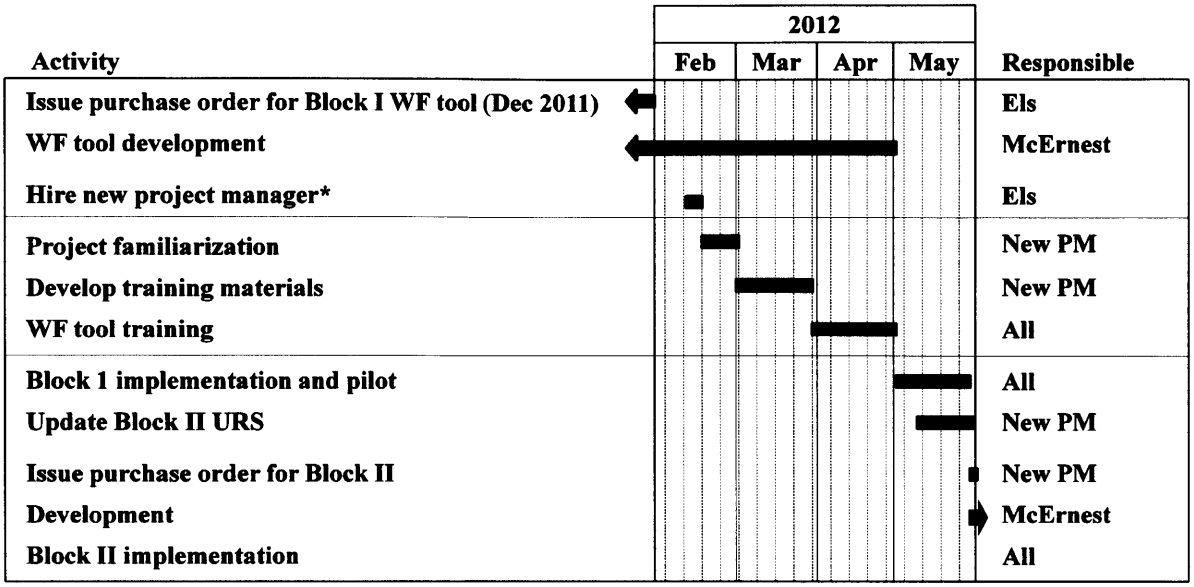


Figure 4.5: Block 1 Implementation Plan

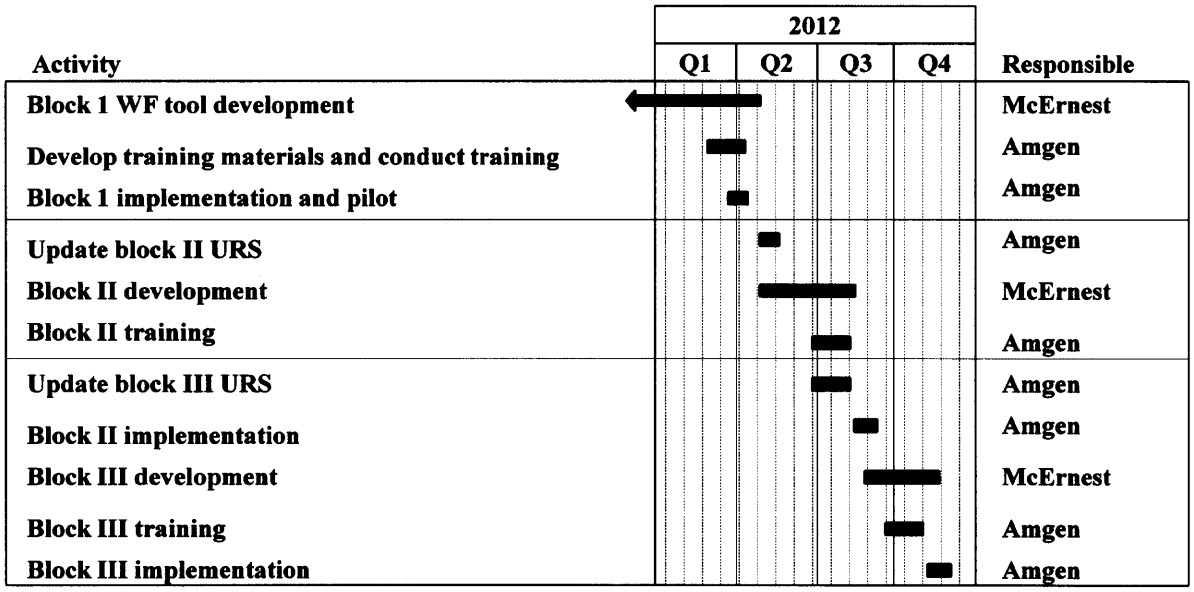


Figure 4.6: High Level Implementation Plan

Note: this implementation plan was/is highly dependent on hiring a replacement Project Manager to continue the work that the author began. Any delay in hiring a replacement will result in a slide to this proposed schedule.

In the next section, we explore indirect project deliverables and develop a repeatable process for workflow tool implementation.

Chapter 5: Repeatable Process for Workflow Tool Implementation

5.1. Indirect project deliverables

The deliverable for this project was to create a URS document defining a workflow tool for the SKU creation process. In order to achieve this goal, several sub-deliverables were added to the scope of this project. As described in the previous chapters, all of these agreed to deliverables were completed. Namely:

1. Detailed process map for the planning phase of the SKU creation process
2. URS document for Block 1 of workflow tool and draft documents for Block 2 and Block 3
3. Draft Commit-to-Launch process and associated checklist
4. Near and longer term plan for workflow tool implementation

In addition to these identified project deliverables, there are some indirect benefits to the organization; two of these shall be discussed here. The first is the creation of a process for implementing a workflow tool which can be used in the future to expand its functionality. The second, longer term benefit is the new ability to drive the continuous improvement cycle through the use of the workflow tool.

5.2. Workflow tool implementation process

Although a study design framework was used in completing this project, no specific process for implementing a workflow tool was followed. During the familiarization process of this project, significant time was spent trying to find a guide on how to implement a workflow tool – unfortunately nothing was found and the "process" for implementation turned out to be one of discovery. Some helpful hints did come from *Project Portfolio Management.*

Using the ad-hoc path followed to complete this project as a basis, the following process is proposed for continued implementation of the current workflow tool (or implementation of a new workflow tool in a different organization):

1. Project Familiarization (6 – 8 weeks)
    a. Spend the first two weeks familiarizing oneself with the organization and the process that is to be implemented in a workflow tool. If a specific process has yet to be identified for workflow tool implementation, allow an additional 2 weeks for selection. Note: this step is not necessary if the project manager is familiar with the organization and process in question.
    b. During the following four weeks, in addition to the familiarization process, establish a steering committee and project team. Note: this step is not necessary if an active project team and steering committee are in place – no need in reinventing the wheel.
        i. The project team should be a representative mix of all roles that the workflow tool will interface with.
            1. Hold weekly or bi-biweekly project team meetings.
        ii. The steering committee should consist of a team of senior leaders that can remove any unexpected road blocks and enable the project team to be successful.
            1. Hold monthly steering committee team meetings.
2. VSM and preparation (5 weeks)
    a. Once project and steering teams are in place, begin preparation for a VSM for the targeted process (4 weeks).
        i. Secure VSM facilitator(s).
        ii. Create VSM A3.
            1. Note: An A3 is a one-page problem solving approach used to get to the root cause of an issue[xiii]
        iii. Secure room, audio visual and any other required facilities resources.
        iv. Select target VSM date.

1. Note: date must be far enough out to give adequate time for preparation activities; four weeks should be an absolute minimum.

v. Secure VSM participants.

1. Utilize steering team as necessary.

vi. For VSM participants, who are not part of the project team, hold one-on-one meetings for project familiarization.

vii. Conduct any necessary training prior to VSM exercise.

1. Project team meetings are a good venue for this.

b. Last minute VSM preparation (2 days)

i. Ideally nothing comes up, but in reality, prepare for something unexpected to happen last minute before your VSM activity.

c. Conduct VSM (3 days)

i. *Learning to See*[xiv] is a good resource for those with no prior VSM experience. Otherwise, utilize your facilitator.

ii. Only select Kaizen's for implementation that fit within your workflow tool implementation time frame (i.e., don't base your future state for implementation on a Kaizen that will take a year to implement, if you plan to have the workflow tool in place six months from now).

3. Create detailed process mapping based on the results of the VSM (2 weeks)

a. This will direct input to the URS document for the workflow tool.

4. Create/update URS document (4 weeks)

a. Create document (2 weeks).

b. Internal review (1 week).

c. Service provider review (1 week).

5. Workflow tool development by service provider (4 months)

a. Respond to any information request by service provider.

b. Develop training materials (1 month).

c. Train workflow tool users (1 month).

6. Workflow tool pilot and implementation (6 weeks).

7. Update this process based on best practice (1 – 2 days)

Note: Steps 5 and 6 were not completed during this project and are listed here as process implementation suggestions.

5.3. Continuous improvement cycle

As mentioned at the beginning of this document, the goal of this internship was to streamline the launch processes through the implementation of a Workflow Management Tool. In the near term, the value of this project comes in the form of process standardization. Through the use of the VSM methodology, inconsistencies and process disconnects were identified. Furthermore, as the tool is implemented, it will help to drive process discipline as line of sight visibility is created and all stakeholders begin to follow the standard process.

Longer term, the real value of this project will come from a reduction in workload. Although this reduction in workload will not be immediate, the workflow tool helps to create a framework for continuous improvement. Initially, workload will go up a little as personnel learn and adapt to this new tool. However, as employees gain experience with the workflow tool, this will help drive process adherence. As process adherence increases, right first time will also improve. With improved process visibility, the ability to identify areas for future process improvement will increase. And as these areas of improvement are acted upon and implemented within the workflow tool, the continuous improvement cycle will begin all over again. Figure 5.1 is a simple depiction of this continuous improvement cycle.

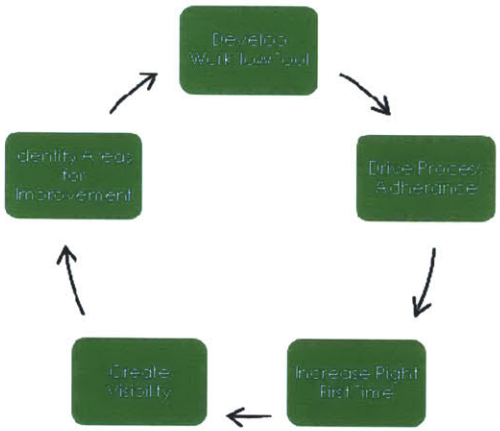


Figure 5.1: The Continuous Improvement Cycle

In short, there are more benefits to implementing the workflow management tool than those that are immediately obvious. Although process standardization and improvement is the near term focus, the real value of this project comes from the longer term indirect benefits; namely, the introduction of a tool that creates a framework for the continuous improvement cycle.

Chapter 6: Conclusion

6.1. Summary

The original motivation for this research project was the growth of Amgen's product offerings and the increased system complexity associated with a larger number of SKU's. However, during the internship it was hypothesized that the SKU creation process was not adequately documented and subject matter experts did not understand how their tasks/roles impacted others. Through a systematic approach, namely Value Stream Mapping, we proved that the process was not correctly documented and that numerous stakeholders did not understand how their work impacted others within the organization. Although senior product managers understand what work needed to be completed and when it needed to be finished, SMEs did not. Furthermore, manually managing the SKU creation process was quite cumbersome.

Once our first hypothesis was proven, the project then shifted into completing the originally (along with a few new ones) defined deliverables. The project resulted in four primary outputs:

1. Detailed process map for the planning phase of the SKU creation process
2. URS document for Block 1 of workflow tool and draft documents for Block 2 and Block 3
3. Draft Commit-to-Launch process and associated checklist
4. Near and longer term plan for workflow tool implementation

6.2. Next steps

Going forward, several tasks need to be completed for the project to be a success. First, it is the author's belief that a Business Process Owner needs to be in put place for the SKU creation (and other ABR Readiness) process(es). Currently, BPO's are normal employees who dedicate their "spare" time to managing and updating processes. This is not effective; the BPO should be a full-time position in which the individual's sole task is managing business processes.

Second, the aforementioned CtL process should be fully implemented as soon as possible. With the creation of multiple new organizations, there needs to be a smooth hand off process for the SKU creation process – the CtL provides this.

Next, and most critical to this project, is the implementation of the workflow tool proof-of-concept in May. Several tasks need to be addressed for the implementation to be successful. First, a new Project Manager needs to be identified (and potentially hired). Once they are adequately familiarized with the project, they will need to work with the service provider and develop training materials for Amgen personnel and instruct them on how to use it. As soon as the proof of concept is available, it will need to be tested and piloted. After validation is complete, the PoC will then be ready for implementation.

Finally, it is suggested that once Block I implementation has been completed, the PM follow the process defined in chapter 5 for Block II (As seen in Figure 6. 1 below) and so forth.

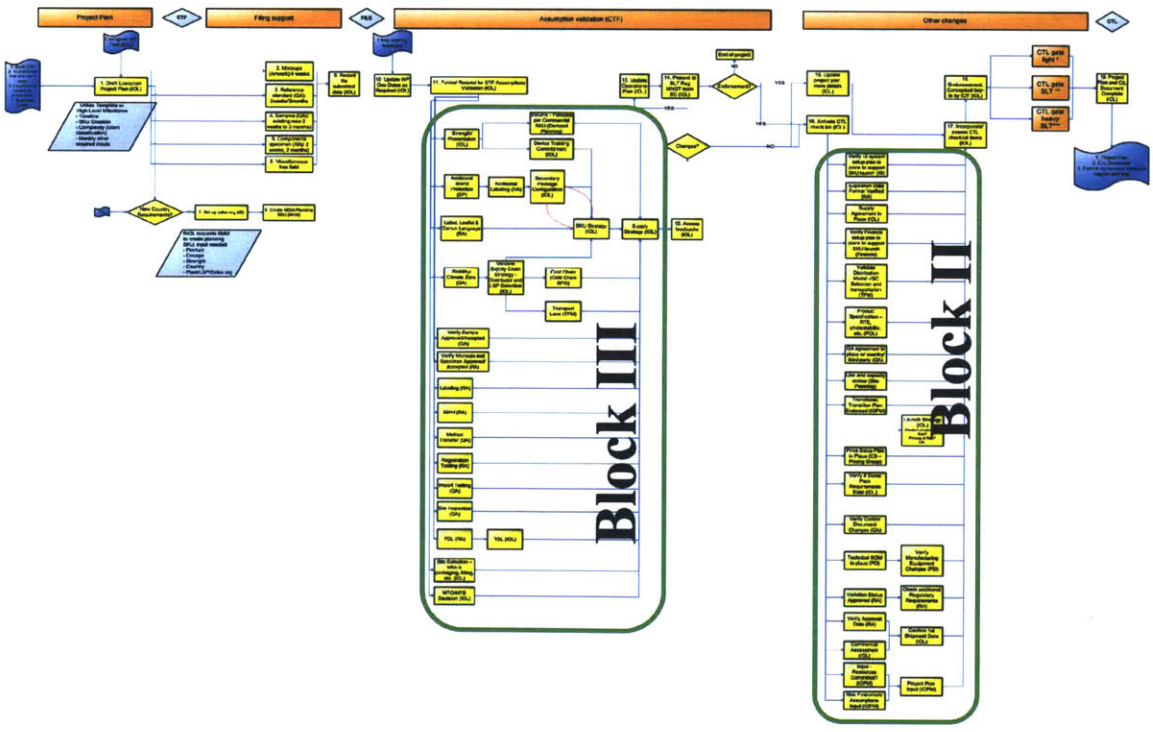


Figure 6. 1: Block II and Block III

6.3. Future work/internship ideas

Further in the future, Amgen could benefit from conducting other internships at their international packaging facility. Two hypotheses were presented here; however, the second could not be proven in the given time. A follow on project to this one could continue the development of the workflow tool and expand it into the surrounding processes. Even further into the future, Amgen could sponsor a project that would incorporate this type of tool at the global level. This internship's goal would be to create process methodology standardization and to drive the continuous improvement cycle at a global level.

Finally an equally interesting topic that would make an excellent project is an analysis on how Amgen determines their finished drug product inventory levels. Currently, Amgen only takes the fixed cost of production into account when determining optimal production runs. By neglecting holding cost, they are generating sub-optimal inventory levels. Therefore, the proposed project would be to evaluate all inventory levels at the ABR site and do an EOQ analysis on the manufacturing lot size planning process.

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