Understanding the Dynamics of Organizational and Process Complexity: A Case Study in the Pharmaceutical Industry

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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

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Abstract

This thesis aims to show that with proper resource management, cross-functional communication, and organizational structure manufacturing and supply chain organizations can minimize the adverse impacts of organizational and process complexity and grow for the future. To do this we study at the pharmaceutical industry and Novartis Pharma Technical Operations ("TechOps"). We conduct employee interviews, benchmark across global industries, case study two representative products, and turn to the field of system dynamics to map the relationships over time. This paper will prove that the generic dynamic model of production and supply issues presented can be directly applied to the situation at TechOps and other large manufacturing companies. We will use this and our knowledge of future changes to determine the best next steps for organizational improvements.

As the pharmaceutical industry evolves, TechOps has an increasing need to be more agile and flexible to the changing market environments. The Vision 2015 for TechOps is to look beyond manufacturing alone to become a world-class supply organization. In other words, TechOps not only needs to have the technical expertise they have built through their functional divisions, but also brand ownership and global optimization of product production. Through our research, we see that TechOps will not be able to achieve this goal if they do not reverse the adverse impacts of their complex supply chain through better end-to-end visibility and organizational enhancements. However, moving directly into an organization structure that is based solely on product lines would not fit strategically and culturally with the organization. Furthermore, since TechOps has always been divided along manufacturing functions, there are few resources that have the experience and insight across the various operations; TechOps needs to build these capabilities into their organization over time.

Therefore, we recommend that TechOps explore the enhancement of the **Supply Chain Brand Lead** role into an established owner of the end-to-end supply process for identified products, look into establishing a **Manufacturing Services and Technology** (MS&T) group that will own technical process changes among the functions and revise the **Key Performance Indicators** (KPIs) to optimize performance end-to-end, be brand focused, expose complexity and trigger proactive responses. All of these changes should be facilitated by additional communication tools and incentives.

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Table of Contents

Table of Figures

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1 Chapter 1: Introduction

Today pharmaceuticals are manufactured using batch processing methods, and, as a result, typical manufacturing departments of pharmaceutical companies are organized around these batch process steps, focusing on building technical expertise and optimizing individual functions. Novartis Pharma Technical Operations (TechOps) is no exception. TechOps operational functions have deep technical knowledge of their respective processes (such as chemical production, cell culture, and galenic production, etc), and this division of labor has worked to grow their business to where it is today. However, the pharmaceutical industry is a complex industry facing significant changes and challenges we will continue to see for years to come. For example, the FDA and regulatory bodies are imposing higher safety regulations, companies are partnering with universities (like Novartis and MIT) to pioneer new manufacturing techniques, and the biotech is growing more than ever before.

Supply issues in the pharmaceutical industry can range in severity from being short a single batch of drug substance (DS) to delivery failures a life-saving drug. The problems can stem from any number of root causes: backorders at a supplier, information discrepancies in the IT systems or incompatibility of a production change with a given machine. At a global level, executives want to see customer services levels meeting and exceeding their already high targets, which means controlling the enterprise effects of supply issues. To do this, the pharmaceutical manufacturing and supply chain organizations need a clear picture of what is happening end-to-end in their division.

For a functionally organized, global company, how can the organization change to reduce the costs of complexity and create sustainable end-to-end visibility? The research this paper presents is a result of a six-month engagement at Novartis Pharma global corporate headquarters in Basel, Switzerland from June – Dec 2011, and aims to answer this question. The answer, we will see, comes from setting the right incentives that encourage collaboration, communication and product ownership. The main focus of the paper is a systems dynamics model that shows the high level relationship among organizational structure of a global manufacturing group, processes, and communication and how these relationships can affect production and supply issues and issue resolution. This model and supplementary studies are used to help Novartis Pharma plan future organizational changes, and these techniques can be applied to a wide range of companies and industries.

1.1 Thesis Motivation

As studied in depth by Stephen A. Wilson and Andrei Perumal in their book *Waging War on Complexity Costs: Reshape Your Cost Structure, Free Up Cash Flows and Boost Productivity by Attacking Process, Product and Organizational Complexity* (2010), truly global companies deal with a variety of complexity issues that compound each other. Including:

- Organizational complexities as functional entities, number of resources, and systems grow and diversify
- Process complexities from producing products in decentralized, world-wide manufacturing and supply chains
- Product complexities as they cater to multi-cultural markets and growing customizations.

The interaction of these complexities and the costs associated with them can have a great affect on the health of an organization, especially one going through an industry transformation, like the pharmaceutical industry is. Because of these changes, companies need better control over their complexities in order to be flexible to these changing markets. Thus, to understand how strengthen TechOps, we need to first understand how the business is organized today and where they want to be in the future, investigate the effect of complexity and communication on the organization, and recognize how these complexities will affect future changes.

Communication effectiveness — the ability to share information in a manner that is useful — is a key component to the success of any organization. MIT Professor Thomas Allen proves that the physical location of people within a research and development (R&D) group has a profound effect on communication and innovation in his book *Managing the Flow of Technology* (1984). Using similar techniques our research aims to understand how global manufacturing and supply chains organizations are also affected by their physical locations, and how this ultimately plays a role in perpetuating supply issues.

Additionally how information is used and shared within available IT systems is an important component of effective communication. However, as studies were done on communication, and information flow, it became apparent the sheer complexity of the organization and its processes also played a role in the number of supply issues the company faces.

The motivation of this thesis is to understand if and how the communication and information flows are affected by the global organizational structure and vice versa. Then we use this information to define a method by which to organize the manufacturing and supply chain divisions for better informed decision making by creating better visibility in the end-to-end processes of its major products.

1.1 Problem Statement

To study the dynamic relationships in a real-world setting we look at Novartis Pharma Technical Operations. Novartis Pharma ("Pharma"). It is a perfect example of a global company with complex supply chains and manufacturing processes dealing with low end-to-end visibility. TechOps is looking to modify their global organization in such a way that give them a full picture of the health of the supply chain without losing any of technical capabilities. However, it is difficult to understand exactly what to change and how. In investigating a method of how to strengthen the Global TechOps organization that fulfills their goal of being world class supply organization, disparities in communication become apparent, and the undesirable side effects of organizational and process complexity surface.

What are the management implications of these adverse side effects? How can we change the organization to combat these issues from a global level that fits with the strategy and culture of the company? How can we find a good balance between brand ownership and functional expertise within the TechOps organization?

1.2 Hypothesis and Approach

As we investigate the effect of complexity and communication on an organization, we turn to the field of system dynamics to map the relationships of these factors to the issues companies see at a global level. This paper will prove that the generic model of production and supply issues presented can be directly applied to the situation at Novartis will help determine the best next steps for organizational

improvement. The model requires the organization to be both organizationally and systematically complex. Thus we will prove that Novartis's organization displays many of the characteristics of a complex organization. We will first look at the current state of the organization and understand TechOps future vision through its major initiatives. Then, through product case studies, we will show complexities in the production processes. Through a communication study of the global operational organization, we will show concretely the lack of cross-functional communication with the current organizational structure. We can apply the model to see how compounding complexities of the organization and processed over time can directly impact production and supply, justifying the need for global organizational improvements.

This paper will recommend that in order to raise the end-to-end visibility and move toward an organizational structure that is aligned with their future goals, TechOps will need to increase their communication effectiveness, reduce its organizational and process complexities through better resource and project management and build additional incentives into the roles and responsibilities into the global team. Additionally, we see that making gradual changes to the organizational structure will help solve short term problems caused by these complexities while planning for long term industry changes.

1.3 Thesis Outline

Chapter 1 introduces the thesis topic. It over-views of thesis motivation, problem statement and hypothesis and previews of the subsequent chapters.

Chapter 2 covers the major literature theoretical concepts written about organizational behavior, organizational structure and their relationship with communication and information flow. It introduces Systems Dynamics modeling, and how this can be used to demonstrate behaviors over time. It details the background and definitions of Organizational and Process Complexity and their effects on the company. It talks about the Allen curve and studies regarding physical space and communication frequency. These three concepts will be brought together to show how decisions about the future organization will be make at Novartis and how these techniques can be applied to other companies.

Chapter 3 explains the applicable the model and the necessary inputs. It shows what generally happens with unaligned issue resolution systems and how fire-fighting propagates in a complex system.

Chapter 4 introduces the case study of Novartis and gives an overview of the pharmaceutical industry and Novartis Pharma.

Chapter 5 delves deeper into the TechOps organization to show the major initiatives that are driving the desire for organizational change.

Chapter 6 case studies two of Pharma's products. Product 1 is a small molecule drug with high growth projections. Product 2 is a large molecule drug slated to go to market for multiple indications. Case studying these drugs gives us insight in the vast process complexities TechOps is facing.

Chapter 7 explains the communications study conducted by the author over a 1 month period in October 2011 at global TechOps. Using techniques developed at the MIT International Institute of the Management of Technology, we see from the short study the communication patterns and frequency among the participants and can derive what factors play the largest role in communication effectiveness.

The study not only further verifies how the dynamic model fits TechOps current situation; it also helps shape the recommended next steps.

Chapter 8 shows how we use the study results and the model analysis to come to some consensus about the changes needed in at Novartis, and how to use these results to create a program roadmap. It also gives a detailed 3-lens analysis on what strategic, political, and cultural considerations need to be taken into account on the final recommendation. It explains the larger applications of the model and major conclusions. Additionally this chapter gives suggestions for follow-up studies and further research.

2 Chapter 2: Literature Review

This chapter will give an overview of research conducted in organizational behavior, system dynamics, complexity reduction, project management and business dynamics aided in the generation of the model design. We will define organizational and process complexity and their interactions. We will look at communication studies designed by the MIT International Institute of the Management of Technology and use the distribution of communication probability among the departments also affects the severity of production and supply issues.

2.1 System Dynamics Modeling

Systems Dynamics is the study of the behavior of complex systems over time. As explained by its creator, Jay W. Forrester (Forrester, 1961) "[System dynamics] is an approach that should help in important management problems... The goal should be to find management policies and organizational structures that lead to greater success." (Sterman, 2000). We will be using system dynamics modeling to help us determine the appropriate actions to take in the Novartis case study.

Dynamic models are represented by causal loop and stock and flow diagrams. The causal loops show the feedback relationship of the variables in the system. Stocks and flows "characterize the state of the system" (Sterman, 2000). The stocks are accumulations in the system, and flows are the rate of either built up (inflow) or reduction of stock (outflow). Mathematically, stocks are integral of the difference between the inflow and the outflow plus the initial value of the stock.

We will use research of Jay W. Forrester, John Sterman and Nelson Repenning to make some assumptions in our model. In particular, we will assume that the production change dynamics behave in a similar way product development dynamics when it comes to fire fighting as presented in the paper "Understanding fire fighting in new product development" by Nelson Repenning; illustrated in **Figure 1** below. (Repenning, 2001)

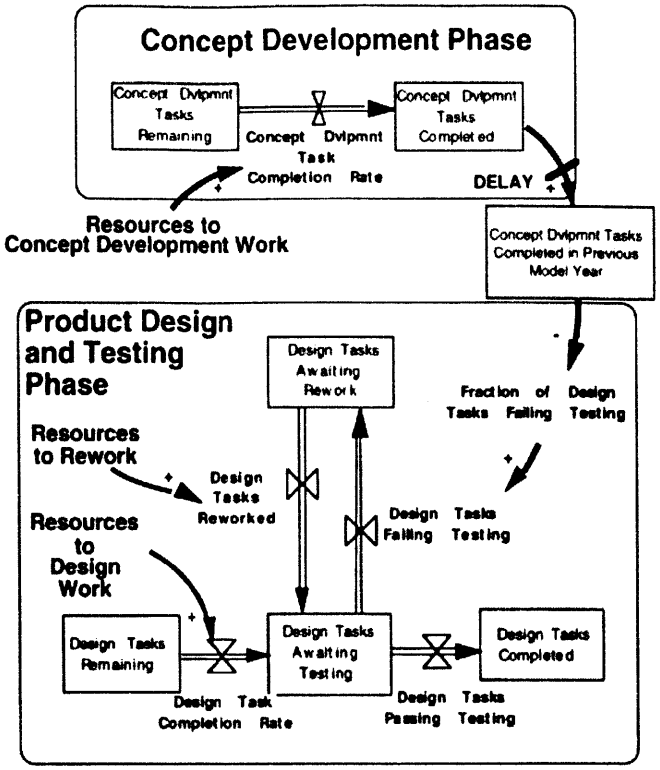

Figure 1: Fire-Fighting Dynamic Diagram

We will also use similar relationships among suppliers, manufacturers and distributors as described in *Business Dynamics* models (Sterman, 2000)

2.2 Organizational Design

Organizational Structure is the arrangement of authority, communication and financials within an organization. In a research paper presented at the International Requirements Engineering Conference in 2011 "The organizational structure is meant to determine not only the division of labor and modes of operation to achieve a work outcome but also the ways in which information between organizational roles should flow" (Marczak & Damian, 2011).

Organizational Design is the management of the interaction of the elements of the organizational structure, and has been studied extensively by Professor Jay R. Galbraith of the European Institute for Advanced Studies. To help build the model, we took into Galbraith's information processing view of organizational design. Galbraith claims organizations are designed around information needs and uncertainties in the task they need to perform. There are 5 strategies by which they organize themselves (see **Figure 2**). Organizations either reduce the need of information processing through 1. Additional resource management and 2.Creating output oriented groups. In the case of TechOps, this would be a focus on product line, rather than operational functions. Additionally, organizations increase their capacity to process information by 3.implementing vertical information systems with standard language

and formalized decision-making language and 4.by creating lateral relationships. In other words, they "create joint decision processes which cut across lines of authority" and moves decision making authority down the hierarchy. Galbraith points out that while lateral relationships tend to happen spontaneously, multi-national companies must design it into the organization through integrating roles, managerial linking, liaisons, task forces, and direct contact (p. 33). The final strategy is to reduce the overall uncertainty in the organizations environment (rather than react to uncertainty) (Galbraith, 1974). By looking at organization and process complexities presented in the **Section 2.3** and interpreting the output of the model, we can find the optimal combination of these strategies for TechOps.

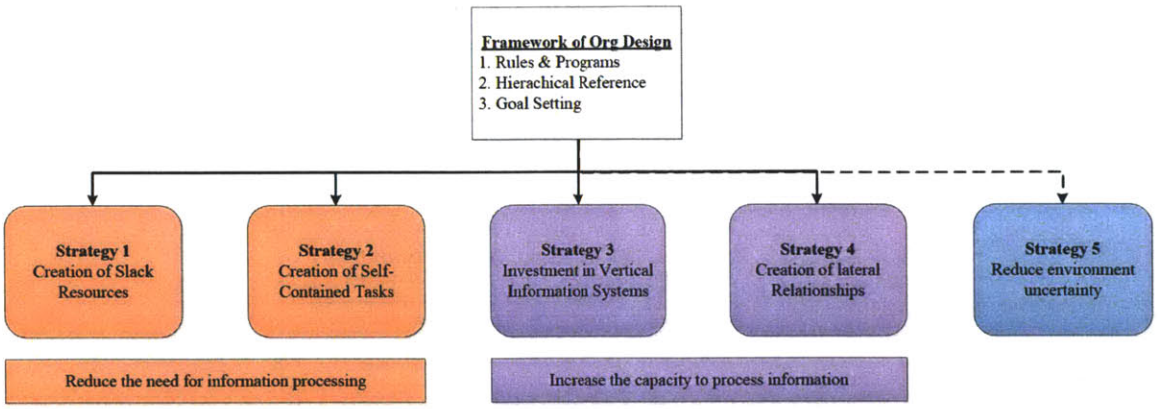

Figure 2: Organizational Design Strategies

Adapted from Figure 1, pg 30 (Galbraith, 1974)

2.3 Defining Complexity and the Organizational/Process Complexity Face

Complexity in business processes has been defined many literature and academic articles give a fairly comprehensive list of definitions of systems complexity and consolidate the definition into two components: detailed and dynamic complexity (Bozarth, Warsing, Flynn, & Flynn, 2009). The definitions of detailed and dynamic complexity are supported by Sterman (Sterman, 2000). Detail complexity is " the distinct number of components or parts that make up a system", and dynamic complexity as "the unpredictability of a system's response to a given set of inputs, driven in part by the interconnectedness of the many parts that make up the system." Bozarth, Warsing, Flynn, & Flynn (2009) in their thesis and supplementary literature prove that complexity in the supply chain leads to higher manufacturing costs and impacts scheduling optimization. Additional they show the adverse impact of complexity on customer service and plant competitive performance. We will use these assumptions and similar techniques to infer the process complexity effect included in the systems dynamics model.

In their book *Waging War on Complexity Costs*(2010), Wilson & Perumal talk about three types of business complexities that effect the productivity, cash flows and cost structure: Product, Process and Organizational complexity. **Figures 3** and **4** show how these dimensions interact with each other. Essentially what these figures represent is the geometric relationship between their complexities. Thus

explaining that looking at process changes without understanding how they affect the organization will be ineffective. As we will see in the Novartis example, not all complexity dimensions are taken into account when making decisions. For example, while there was a large effort to reduce inventory, production and customer processes were not updated in such a way that accounted for the lower inventory values. However, by becoming aware of the adverse effects of these complexities, companies can not only gain competitive advantages, they can make their processes and product sustainable and flexible to future changes.

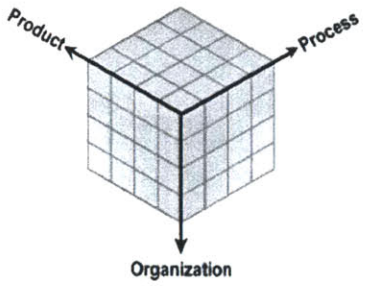

Figure 3: Complexity Cube
(Wilson & Perumal, 2010) **Figure 3**

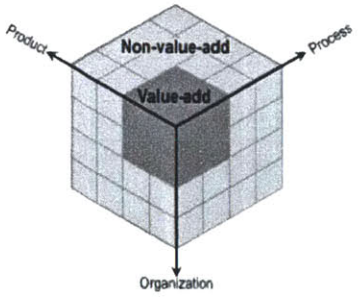

Figure 4: Complexity Cube VA & NVA
(Wilson & Perumal, 2010) **Figure 4**

This paper will use focus on the Organizational/Process complexity face. We will look at the interactions of the many departments and process within TechOps, and try to understand how to make changes that will reduce the impact of these complexities in the long term.

Looking specifically at organizational complexity in literature, we come across several definitions. The *International Encyclopedia of Business and Management* (Dooley, 2002), defines organizational complexity as "the amount of differentiation that exists within different elements constituting the organization." They then breakdown this definition into: amount of professional specialization (i.e. number of different roles needed) and level of qualifications and the amount of variety in the core

processes and technologies. In the pharmaceutical industry, we see a high level of specialization, qualification and variety: there are many different roles needed to produce and sell products from scientists and lab technicians to regulatory liaisons to finance and strategy professionals. Even manufacturing floor operators require higher education degrees and extensive training, and operations in multiple countries, multiple suppliers, brands, and customers. Ultimately, organizational complexity is a function of the processes of the company and the products provided. Thus, as defined by Wilson & Perumal (2010), "organizational complexity is the number of facilities, assets, functional entities, organizationally units, systems, etc. involved in executing the processes of a company." We can look at organizational complexity and process complexity separately as examples of detailed complexity and their interaction on the Organizational/Process Face as the dynamic component.

The literature emphasizes that companies need to focus on reducing is not just complexity itself, but the undesirable impact of that complexity (such as increased costs). Bozarth, Warsing, Flynn, and Flynn (2009) also explain that the goal in not to eliminate all complexities in the system, but to "understand the potential performance impacts of these choices, and, where necessary, take actions to offset or accommodate the higher levels of complexity that strategic imperatives might entail." This paper will only be looking at the supply and production issues from a higher level (not detailed perspective), as Wilson & Perumal suggest to do.

As the nature of the pharmaceutical industry has an unwavering amount of process complexity built in when taking account development and manufacturing regulations, and varying country sales requirements. While complexities can lead to some competitive advantages, mismanaging these complexities will create a rigid compartmentalized organization, which can eventually lead to diminishing profits. For the both the organization and process face, it proves very difficult of assign a specific dollar-value to each component of complexity, therefore we want to break the work down into value-add or non-value add components. We then look for a way to reduce the non-value added tasks and the costs of the non-value added tasks.

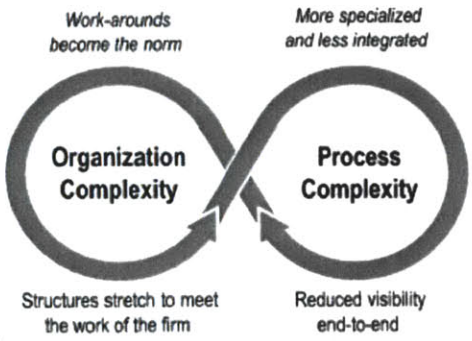

Figure 5: Organization-Process Complexity Relationship
(Wilson & Perumal, 2010) **Figure 10**

Delving deeper in the interactions between organizational and process complexities, Wilson & Permumal suggest that several patterns immerge as a result of their relationship:

1. Exceptions become the rule
2. Linkages across the company become masked

3. Long project lead times with low resource productivity

In dealing with #1, we will also take into account studies done by Repenning (2001) on the phenomena of "fire fighting" (assigning limited resources to solve unanticipated, urgent problems; we will refer to the team of people assigned to this "fight fires" as a "Tiger Teams" which is the common language at Novartis). Repenning shows that not only is fire-fighting self reinforcing, but that complex product development systems (ones with multiple parallel projects and product launches) are particularly susceptible to this dynamic. In our model, we apply this same dynamic to the product change request (CR) process. We will use the Wilson & Permumal research to make assumptions on the mathematical relationships between change and issue resolution lead times, and effect of deteriorating end-to-end links. We also use the results of the communications study to show the lack of end-to-end communication, which is discussed in the next section.

2.4 Communication Studies

A major aspect to the interaction of organization and process is communication. One way to specifically measure how the departments are linked to each other within a company is to study communication patterns across departments and physical distances between resources. Professor Thomas J. Allen, the Howard W. Johnson Professor of the MIT Sloan School of Management, has conducted many studies with engineers and researchers though MIT's International Institute of the Management of Technology. In Prof. Allen's first book, *Managing the Flow of Technology* (1984), he proved that the frequency of communication among engineers and researchers drops exponentially as the distance between them increases (called the Allen curve after its discoverer). In addition, Professor Allen expended his study to look at how pairs of engineers interact if they are working on similar projects or report to the same department, and discovered that while there is a slight uplift in frequency of communication, the general shape stays the same for resources sharing department and projects (See **Figure 5**)

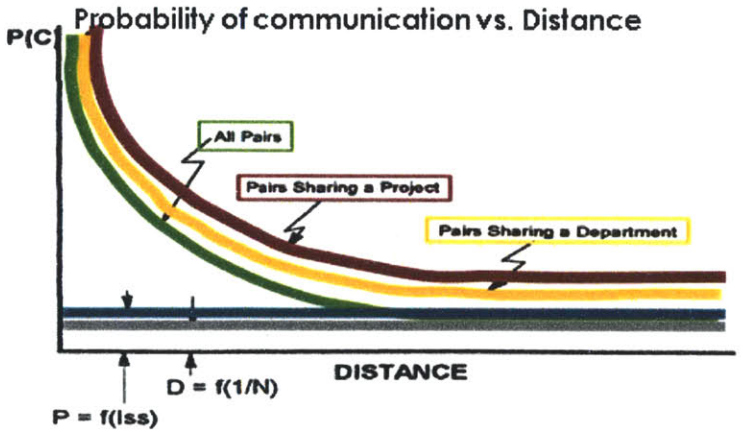

Figure 6: Allen Curve
(Allen, 1997)**Figure 8**

What does the curve look like in an operational organization, where meeting schedules, production plans and business tasks drive the daily communication, not innovations? One of the hypotheses of this thesis

is that it would look very similar to the Allen curve. However, what we found was that based on incentives and roles and responsibilities of the global TechOps resources the department has a greater impact on the frequency of communication than distance. Additionally, if we look into the compounding complexities of the Organization/Process face and build the communication pattern information flow into a dynamic model, we see the direct impact of these variables on how quickly a company can resolve production issues and supply issues. And we see this happening in TechOps.

2.5 Summary

In this chapter we discussed assumptions brought together by the research that will be included in the systems dynamics model. We then reviewed the literature of organizational structure and design theory, and defined dynamic and detail complexity, organizational complexity, and process complexity. We talked about communication and the Allen curve, and how similar techniques will be used to gather information on the communication patterns of the Novartis Pharma global operations group. In the following chapters we will explore application of these theories in the case study of Novartis Pharma Technical Operations.

3 Chapter 3: Systems Dynamics Modeling

This chapter will explain the generic model created from theory and research. The model will show the dynamics between production changes, production issues, supply issue build-up, which ultimately affects customer service levels. This chapter will explain the base model, the stocks, flow, and auxiliary variables that make up the model. It then adds the effect of organizational and process complexity and communication factors. The goal of the model is to communicate the proliferation of Tiger Teams and thus the need for organizational change to executives, and can be adapted to many companies and industries. In later chapters we case study Novartis as an example of how the model can be applied in the real world. Because this model was developed for global teams, the "production issues" and "supply issues" we discuss are in a very generic sense of the term. The issues encountered vary greatly in severity, cost, and fundamental root cause. However, what the dynamic model does show there is a positive outcome of reducing organizational and process complexity and facilitating effective communication.

3.1 Base Model – Production and Supply Issues

The initial model (**Figure 7**) shows how the productions changes beget production issues, production issues turn into supply issues, and supply issues can affect customer service levels. Given the nature of the pharmaceutical industry and the Novartis change process, time is measured in months.

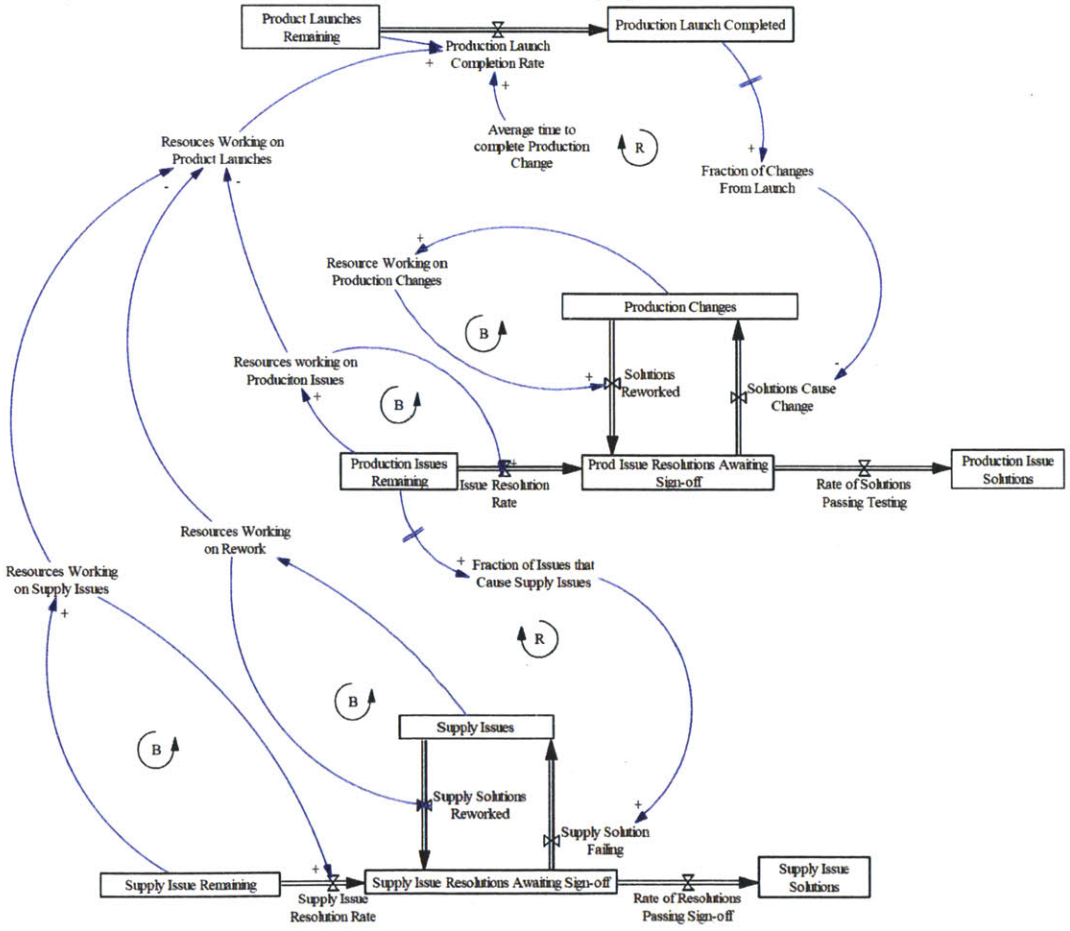

Figure 7: Issue Dynamics - Base Model

3.1.1 Product Launches

In the model, resources are assigned to production launches. New product launches can be brand new products with first time introductions to the market or (in many of Novartis's cases) the launching of new SKUs or variation within an existing product family. The stock of *Product Launches Remaining* is drained by the flow of *Product Launch Completion Rate*. When those tasks are completed, they accumulate in the stock of *Product Launched Completed*. However, there is some probability, P_I, that the production change was not compatible with other processes, and thus causes downstream or upstream production issues. Additionally, not all suggested changes are implemented by the go-live date, and thus turn into change requests (CRs) slated to be implemented after launch.

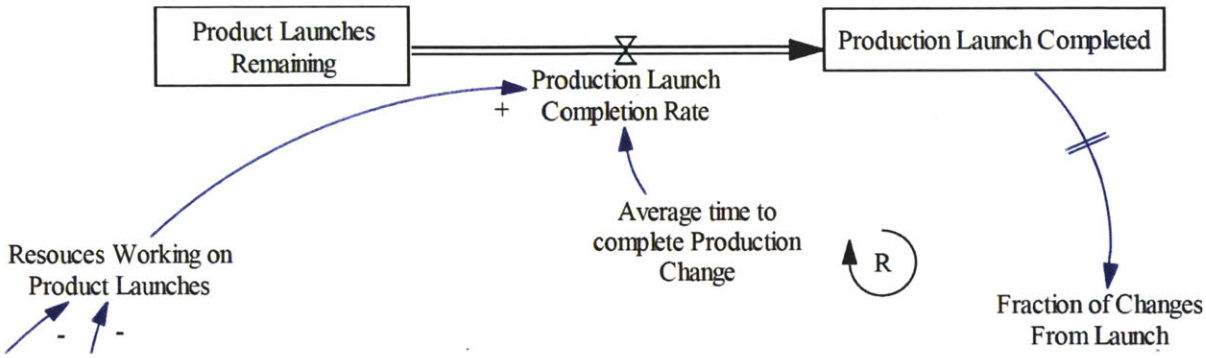

Figure 8: Product Launches

3.1.2 Production Issues

Production Changes include planned production change-overs and official change requests. Planned change-overs occur in multiproduct and multi SKU production lines. Since TechOps is manufacturing 12,000+ SKUs, changeovers happen quite frequently. As we will see in detail in the product case studies in **Chapter 6**, even BPO plants which have much lower volume and number of products than ChemOps and PharmOps plants, have several change-overs per year. Production change requests (CRs) can come from a variety of sources. They can be technology issues that were not implemented before the launch of the product, preventative upgrades to equipment, or process changes that only affect the non-manufacturing steps as part of a Lean transformation. All production change requests in TechOps are inputted into an information system and reviewed by a cross-functional governing body. Despite the governing board, ownership of the change request system itself and the changes in general is not consistent across sites, and how a change will affect either an upstream or downstream process is rarely known due to complexities in the system. Therefore, we see fallout of production changes that cause production issues. We will see how the risk of organizational complexity applies to Novartis in **Section 5.2**. The CRs in the model are assumed to be approved already.

In this part of the model (**Figure 9**) shows after a time delay, there is probability of P_I that requirements were not implemented before the product launch, and therefore production changes are needed after the fact; these take the form of CRs. Production changes that are not completed in a timely manner will cause production issues, which, in turn require additional resources. The outset of the model simulation, all

production issues reside in the stock of *Production Issues Remaining*. As resources are applied resolve issues, the tasks are executed and then accumulate in the stock of *Production Solutions Awaiting Sign-off*. As they are reviewed and approved by the stakeholders, they flow to the stock of *Production Issue Solutions*. The solution may in fact require an additional production change, accumulating in the stock *Production Changes*. QA and, testing is incorporated into the model as an "uncapacitated delay", meaning it takes time, but consumes no additional resources (Repenning, 2001).

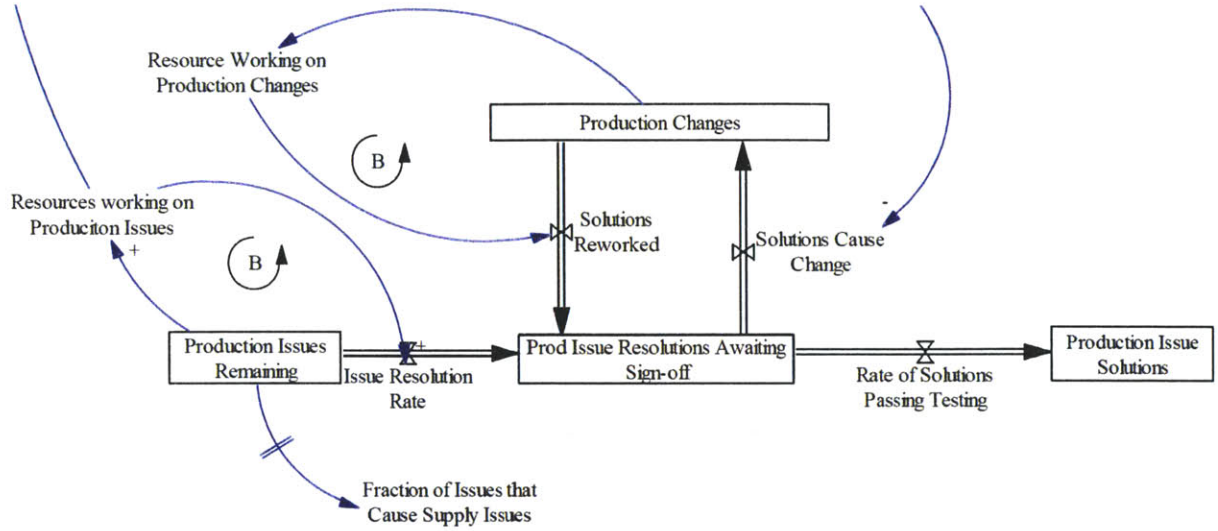

Figure 9: Production Issues Base Model

As change-overs happen more frequently, the system is prone to errors as planning and scheduling become more complicated.. CRs are proactive measures to prevent production issues; however the high priority changes usually result from a process that was not implemented before product launch. Production changes go through a rigorous approval and testing process, but there can be fall out of additional issues for several reasons that all loop back to complexity causes or lack of proper information and communication; including:

- Unexpected consequences
- Preventative measure was not prioritized properly
- Changes not communicated effectively to downstream parties
- Lack the sophistication in proactive tracking to see that the change may cause an issue before it is too late

Section 3.2 shows when production process becomes more complicated and complex, and change approval more decentralized, the P_I grows.

3.1.3 Supply Issues

Supply issues refer to inventory levels beginning lower than the designated safety stock amount. Supply issues can be caused by growing production issues, late order changes, or simply by the inventory management systems not being up to date. Supply issues will cause customer service issues if the inventory is so low that orders cannot be delivered on time and in full. Novartis, like most

pharmaceutical companies strive to maintain high (above 99%) customer service level (CSL). Recently, the CSL for some non-life saving drugs dropped to well below Novartis standards.

The model (**Figure 10**) is very similar to the Production Issue portion presented in the previous section. There is probability of P_S that a production issue will cause a supply issue if it goes untreated or uncommunicatied. There are also supply issues that are not caused directly by production issues but are internal to the complexities of the supply chain process. Thus from the outset of the simulation, supply issues reside in the stock of *Supply Issues Remaining*. As resources are applied to resolve issues, the tasks are executed and then accumulate in the stock of *Supply Issues Awaiting Sign-off*. As they are reviewed by the stakeholders, they flow to the stock of *Supply Issue Solutions*.

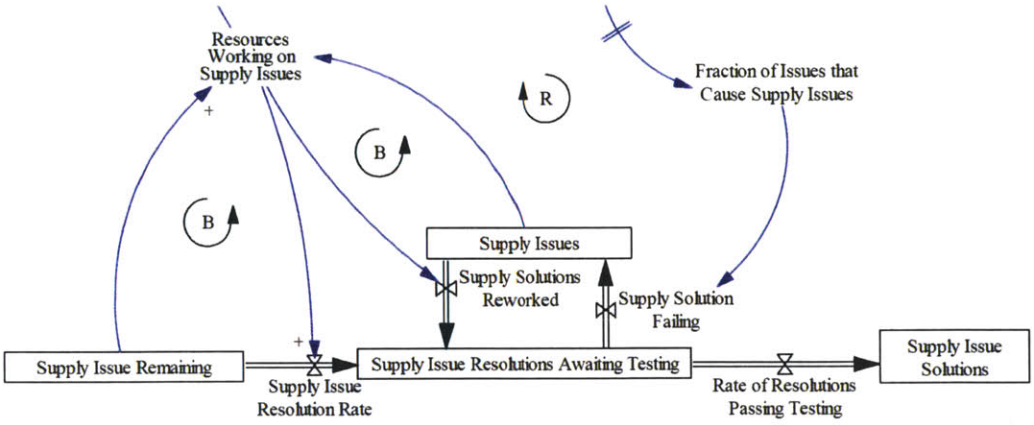

Figure 10: Supply Issues Base Case

3.2 Assumptions

As this model is adapted from Repenning's (2001) production development model, the assumptions behind the model are similar. Firstly, we assume that if additional time and effort are spent on the upfront product launch, in particular in process development, there would be fewer change requests needed after launch. As the knowledge of both the technology and the end-to-end system increases, then production projects are better designed. Research shows that when resources have adequate time to spend on project work, not only can they complete more projects during the year (Wilson & Perumal, 2010) but they also help reduce the uncertainty in the outcome of the project (Galbraith, 1974). Likewise, if additional time is spent fixing production issues and these issues are effectively communicated to the integrated parties, there would be fewer supply issues downstream. Second we assume that production issue resolution will take priority over product changes and product launch design, and supply issue resolution will take priority over production issues resolution. As supply issues may affect customer service levels, they will take precedence in resource assignments. Lastly, we assume that product launches are in fixed, overlapping intervals. This is rule in the pharmaceutical industry with new product launches and capital projects. We also see this behavior in other industries as well, such as the automobile industry (Repenning, 2001).

Additionally, this model is looking at the internal uncertainties of information flow, and the companies' reaction. There are additional external factors that can cause production and supply issues (in the

pharmaceutical industry, this could be a shutdown by the FDA or issues with the 3rd party logistics provider (3PL) shipping goods). These are not modeled in the base case.

3.3 Implications of the Base Model

The model represents a phenomenon seen in many companies at different levels and different departments call "fire-fighting" which causes the formation of "Tiger Teams." Tiger Teams are created to fix urgent issues in the system, pulling resource away from daily tasks. In a normal year, resources will work on both product launches and issue resolution. With resources allocated correctly and the right amount of project management, even with some issues occurring the system will remain relatively stable and will be able to recover. However, if shocks are introduced to the system, such as products using new manufacturing techniques, it can be very difficult for this non-linear system to recover. In other words, if the system starts out with low productivity, it will launch into a negative reinforcing loop, making the Tiger Team state the steady state of the system (Repenning, 2001). Assigning resources to solve issues outside of their organizational position creates a classic dynamic phenomenon where things get better before they get worse. Specifically, the project improves, but eventually the system as a whole degrades since there are a finite number of resources. The delays in the system (between launch and CR, and production issues and supply issues) and lack of connection among resources, make it difficult to link these consequences. Additionally, we see as resource utilization increases, the time per task increases because resources are spread too thin (see **Figure 11**). This ends up perpetuating the Tiger Team phenomenon further.

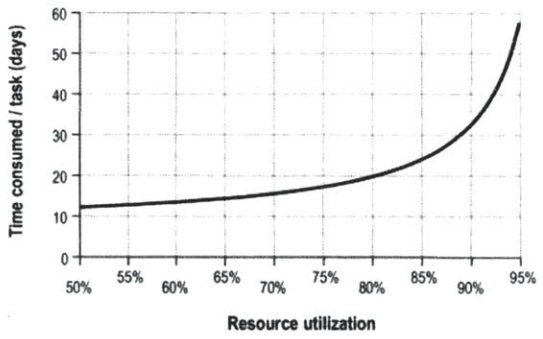

Figure 11: Total Time Consumed per Task
(Wilson & Perumal, 2010) **Figure 60**

3.4 Adding in Organizational Complexity, Process Complexity and Communication factors

Although it is hard to truly quantify the total costs of the Organization/Process complexity face, conceptually we can see how it affects the dynamics of the process and supply issue system (see **Figure 12).**

As *Organizational Complexity* increases, the number of issues *Solutions Causes Change* increase, because the production issues are more integrated to multiple departments. Likewise more *Organizational Complexity* will cause *Supply Issue Failing* sign-off to increase for the same reason. When companies have complex organizations, issues tend effect multiple groups, even though visibility of these interdependencies are not always clear. Thus the amount of *Resources working on Production*

Issues will increase and *Communication Effectiveness* will decrease. As *Process Complexity* increases, the *Fraction of Changes from Launch* will increase because the product launch window is finite and companies have to prioritize the features of the product and production process. Lower priority features are implemented after launch. Additionally, with *Production Issues*, if *Process Complexity* is high, the number of resources required to solve issues will increase further draining the system of resources. As issues flow downstream through the supply chain, complexity creates additional constraints. *Process Complexity* will decrease *Supply Issue Resolution Rates*.

However, by decreasing the impact of complexities we can increase communication effectiveness and vice versa. This, in turn, prevents production issues from turning into supply issues because the value stream is better prepared and able to make contingency plans. Thus, supply issue resolution rates will also increase. If we look at these additions to Galbraith's information processing view (1974), this concept is the organization dealing with uncertainty.

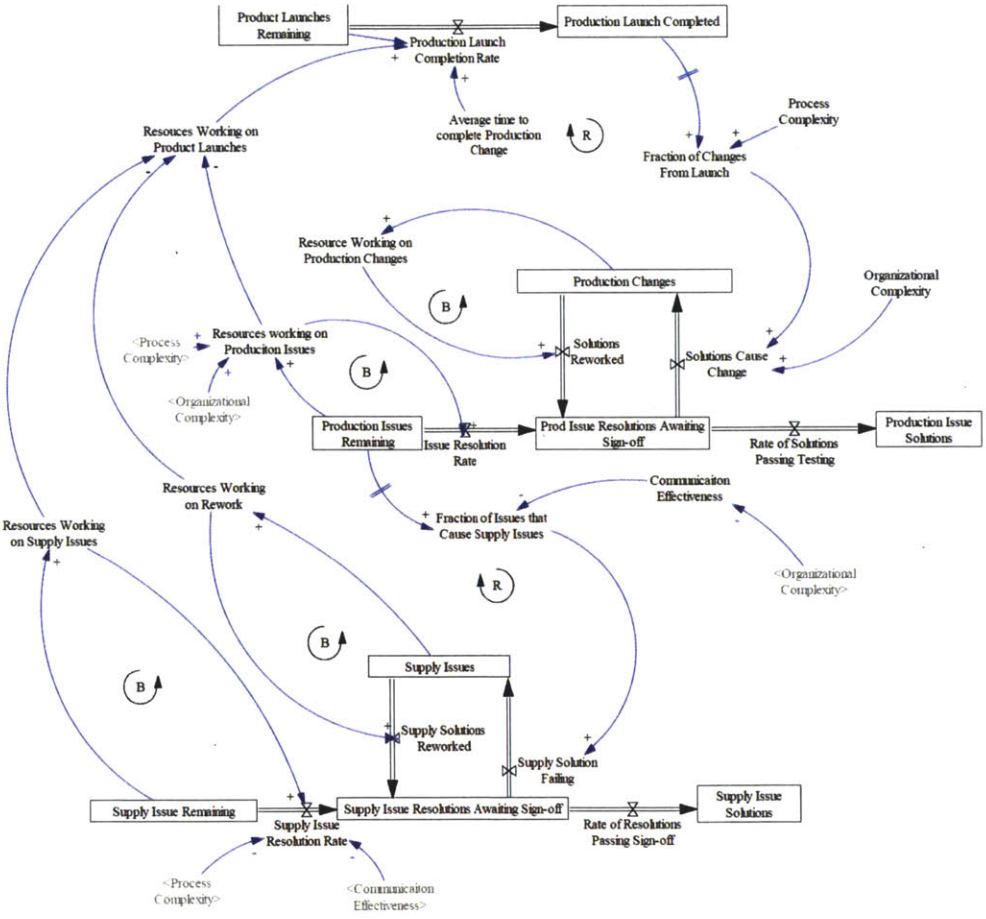

Figure 12: Model with Complexity and Communication Factors

3.5 Summary

In this chapter we presented the generic model of production and supply issue build up in a complex organization. The model uses the assumption that organizational and process complexity create a negative reinforcing loop with each other (Wilson & Perumal, 2010), which then diminishes the positive effect of communication. In subsequent Chapters we will prove that this model is a fit to Novartis Pharma TechOps and can be used to make decisions on organizational changes.

4 Chapter 4: The Pharmaceutical Industry and Novartis Pharma

Organizational Process theory tell us that structural change is needed when either the business environment has changed, making present structure ineffective and/or current linking and alignment mechanisms lead to under-performance (Mortensen, 2010). TechOps in not currently in a position where the organization structure is completely obsolete, but with continuous changes in the industry and in manufacturing techniques, they are making a pro-active change so they will be ready for the future. This chapter details the trends in the industry and the background of Novartis relevant to the organization change.

4.1 The Pharmaceutical Industry Background – Related Trends and Challenges

The Pharmaceutical Industry has been facing significant changes and challenges over the past decade, and will continue to see these trends for years to come. These include:

1. Increasing stringency of the regulatory bodies: The FDA now requires that a drug not only work as specified on the given indication, but must also be safer and more effective than any other drug on the market for that indication. And just recently (July 2011), they published a regulation establishing a new safety-reporting standard for clinical trials. (www.fda.gov, 2011)
2. Increase in global competition: Growth of pharmaceutical manufacturing and research in countries and government manufacturing requirements for local sales.
3. Patent expiration of blockbuster drugs: 2010's top selling drugs (Pfizer's Lipitor and Sanofi-Aventis' Plavix) will be coming off patent in the next two years.
4. Diminishing levels of new drug approvals: According to a study done by BIO[1] Phase 3 approval rate from 2006-2010 was 80%, down from 93% in previous years. There has been speculation that this is a corollary to #1 and #3 above. The theory is that most of the small molecule drugs targeting ailments that affect large populations have already been discovered, patented, and/or are already being commercially produced.

Although there is counter evidence to #4, (FDA reports show that 2011 approvals will meet or exceed 2010 levels), the trends produced two major shifts in the industry:

1.) Research and development (R&D) of lower volume, orphan classed indications and biotech (large molecule) products. Orphan drug approvals nearly doubled from 1997-2010 compared to 1983-1996. FDA approval success rate from 2006-2010 was 15% for biologics versus 7% for small-molecule drugs (BIO).

2.) The value creation of products is no longer in the early phases of clinical trials, but rather in the later stages and the ability to scale-up and manufacture a continuous, uninterrupted supply. The main cause of

[1] BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,100 members worldwide. The mission of BIO is to be the champion of biotechnology and the advocate for its member organizations - both large and small. (www.bio.org)

the stricter regulation mentioned above is safety. Therefore, manufacturing innovations and techniques such as quality by design and design for manufacturing will prove very valuable to the future of the pharmaceutical industry. Additionally, once products are commercialized, the security of the supply chain is extremely important to the safety and efficacy of drugs. Thus techniques and steps in the manufacturing and supply chain process that impede counterfeiting are also very valuable.

To combat these challenges and face these new trends to the benefit of the company and industry, Novartis is building up their biotech capabilities and well as focusing on process improvements and innovations in manufacturing. New techniques of manufacturing will, in turn, cause changes to the global operations as a whole, as they adapt to the changing trends and processes.

4.2 Background of Novartis Pharma

Novartis AG was created in 1996 through the merger of Ciba-Geigy and Sandoz, and currently is composed of six commercial divisions: Pharmaceuticals (prescription drugs), Sandoz (generics), Vaccines and Diagnostics (V&D), OTC (over-the-counter consumer products), Alcon (vision, acquired in 2011), and Animal Health.

The Novartis Pharmaceuticals (Pharma) is the largest of six divisions of Novartis AG (see **Figure 13**) is responsible for 60 key marketed products and, in 2010, acquired 13 major regulatory approvals United States, Europe and Japan. Pharma has sales and operations in over 80 countries, and achieved net sales of $30.6 billion USD in 2010, 60% of total Novartis sales.

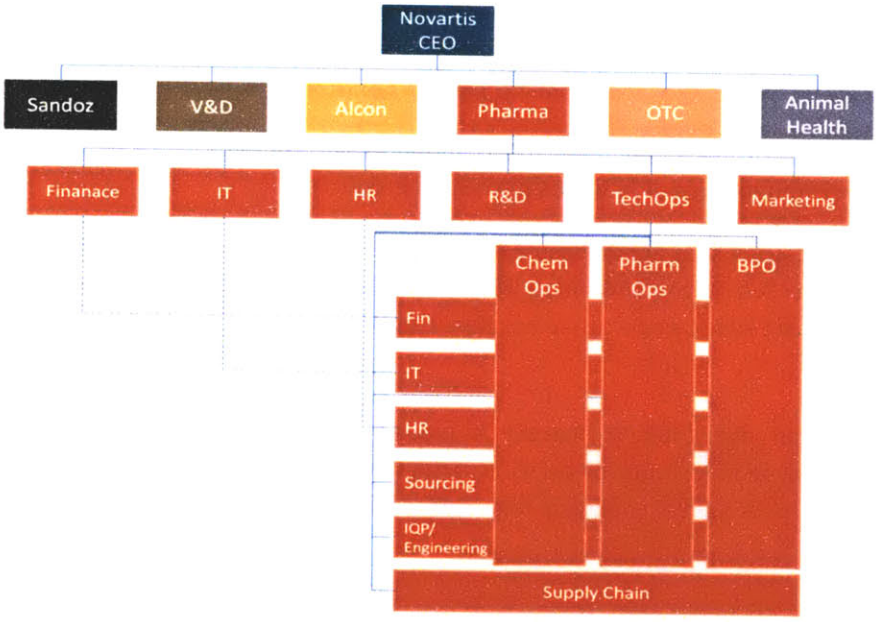

Figure 13: Novartis Pharma Organizational Structure

Within Pharma, Technical Operations (TechOps) is responsible for all commercial product manufacturing, distribution, fulfillment, and facilities management. They are also responsible for aspects of new product launches and Phase 3 clinical production. TechOps manufactures over 12,000 SKUs for millions of patients worldwide.

Globally, TechOps is organized into corporate support functions (including Finance, HR, QA, Legal, etc.) and three distinct operational functions:

1. Chemical Operations (ChemOps), responsible for manufacturing small molecule APIs
2. Biopharmaceutical Operations (BPO), responsible for manufacturing large molecule drug substance and some preliminary packaging
3. Pharmaceutical Operations (PharmOps), responsible for manufacturing drug product, fill & finish and final packaging.

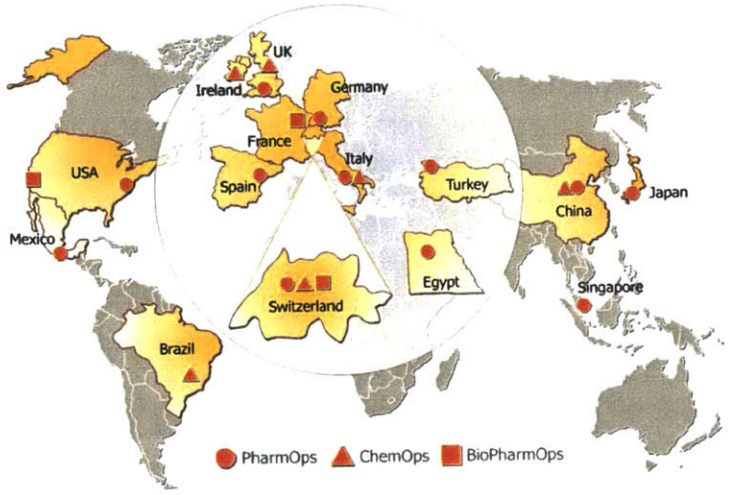

Figure 14: TechOps Global Network

Additionally, TechOps is expanding their External Supply operations. This group manages relationships with third party manufacturers of Novartis's patented products.

Almost all manufacturing sites are dedicated to a single operational function, and therefore operate autonomously from each other. This along with the global operational organizational structure has posed some challenges to the future goals of the business that will be discussed in subsequent sections.

4.3 Summary

In this chapter we introduced the pharmaceutical industry and Novartis AG. We gave an overview of the Pharma organization and the TechOps division. With the complexities and uncertainties of information in the industry, TechOps is a great candidate to compare its operations to the dynamic model presented in Chapter 3.

5 Chapter 5: Understanding Organizational Complexity through Current State Analysis of TechOps Organizational Structure

In order prove that TechOps is a good fit to the model, we first look at the current state of the organization. The objective of the current-state analysis is to understand how TechOps is organized today. Specifically: What does the organizational structure look like? What are the communication patterns among the global groups? How does information flow through the system, where are the biggest pain points and bottlenecks in information? How does this organizational structure fit with the future goals of the business? We will also use Wilson & Perumal's Process/Organization complexity checklist to show that TechOps is justified in trying to tackle the complexities in their system through organizational redesign (2010).

5.1 TechOps Organizational structure

TechOps is organized in a matrix-type structure where each of the three distinct operations has corporate functions servicing them. These departments, such as Finance, Strategy, Human Resources (HR), and Information Technology (IT) have fairly standard roles, with reporting lines to both the operational head and functional heads. The Innovation, Quality, Productivity (IQP) group, which serves and Novartis Pharma's internal Lean manufacturing consultants has both a global and operational role. The only truly "cross-functional" group is the global Pharma Supply Chain Management (PSC), who is responsible for all non-manufacturing steps in the production process, including inventory, logistics, and transportation.

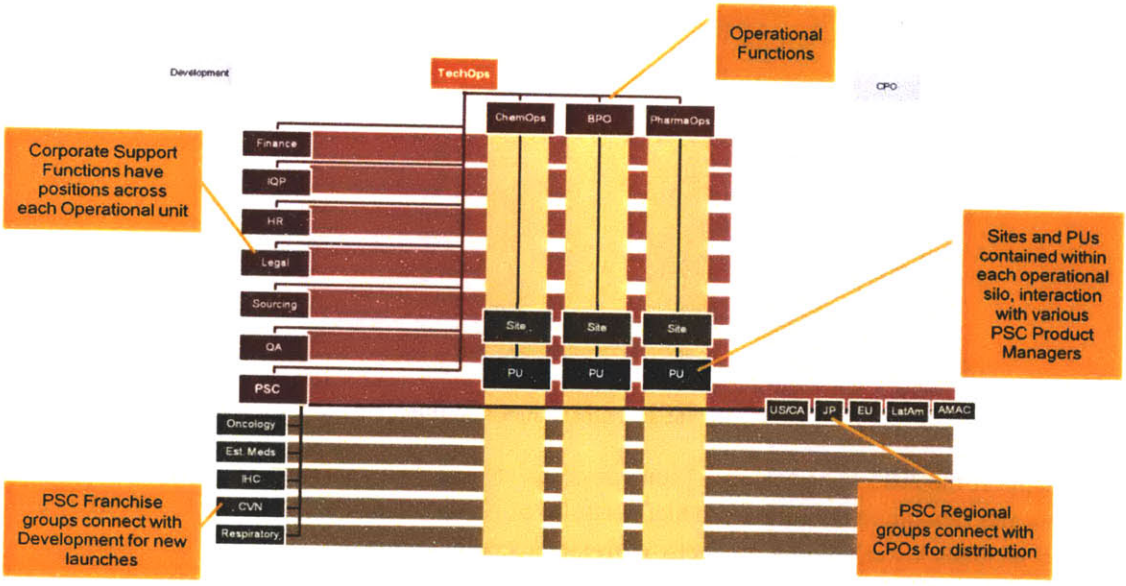

Figure 15: Current TechOps Organizational Structure

Unlike other TechOps divisions, PSC is organized very similar to the rest of the Pharma organization by business units (or franchises) responsible for product categories and product lines, and regional units responsible for order delivery to the country pharmaceutical organizations (CPOs)

Each dedicated manufacturing site reports into the global Operations head. Budgets, financial planning, information systems and metrics are set up along the operational reporting lines and geographies because

sites are dedicated to an operation. Through interviews and observations we learn that these operational divisions do not allow for globally optimal production schedules for products and are not in line with the future manufacturing plans of Novartis Pharma.

Each manufacturing site contains several process units (PUs). There are three levels of hierarchy within a process unit and the PU Heads report to the site head. Because each Novartis site is dedicated to a specific operation, Site Heads then report to the respective global operational head, who then reports to the head of TechOps. With only 6 layers between floor operators and the head of Global TechOps, Novartis is a fairly flat organization compared with other life-science companies we studied.

5.2 Initiating the Need for Change: TechOps Strategic Vision and Key Initiatives

The 2015 vision for TechOps is to become a world class, patient driven, supply network. This was updated from the 2010 vision of being a world class manufacturing organization.

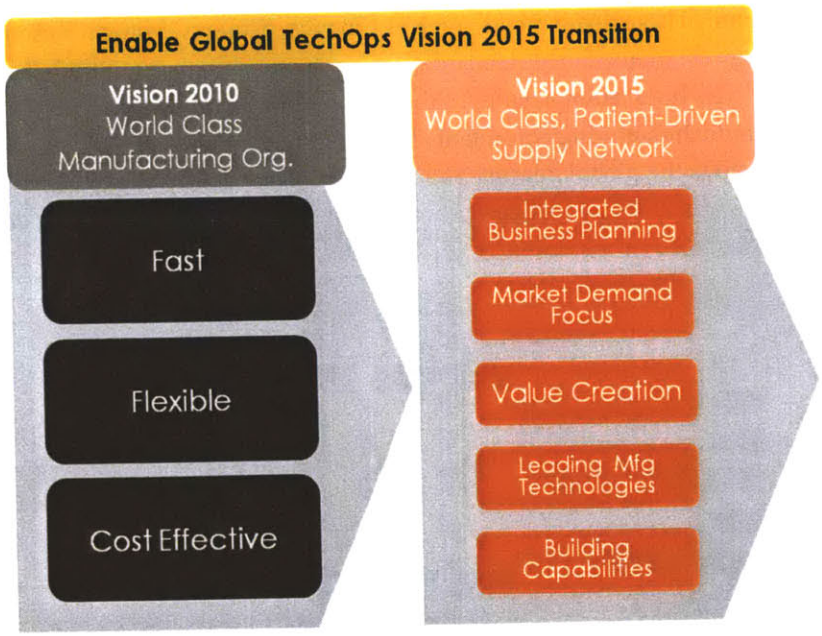

Figure 16: TechOps Vision Transition

In order to support the 2015 vision Global TechOps needs an organizational structure that will allow it to be responsive and flexible to the future product portfolio of Novartis and the Life Sciences industry as a whole which includes lower volume products, introducing continuous manufacturing techniques and higher demand variability.

TechOps has specific goals for each pillar in the new vision and has created global initiatives to meet these goals:

- Integrated Business Planning – creating global strategies and operational processes, and new product launch processes that involve cross-functional teams to increase flexibility
- Market Demand Focus – Understanding the customer needs and TechOps current limits to delivering, enhancing demand networks to smooth forecasting
- Value Creation – value based procurement, network optimization, working capital optimization

- Leading Manufacturing Technologies – quality beyond compliance, innovative technologies such and continuous manufacturing
- Building Capabilities – Improving change management and talent development

Three initiatives in particular demonstrate the direction in which Novartis is headed, and will help show the needs for organizational change at the global level.

5.2.1 Process Oriented Organization (POO)

To reach the goals of the 2010 vision, a large initiative took place last over the past several years called Process Oriented Organization (POO), in which each manufacturing and packaging site redesigned its organization structure from focusing on a functional hierarchy to focusing on the production process as a whole. This initiative put in place new leadership roles (Process Units Heads) and new cross-functional, self-directed teams (Process Units) at each site. The goal of POO is to empower the workforce to make decisions, eliminate unnecessary hierarchies that lead to bureaucracy, and create transparency and visibility across processes.

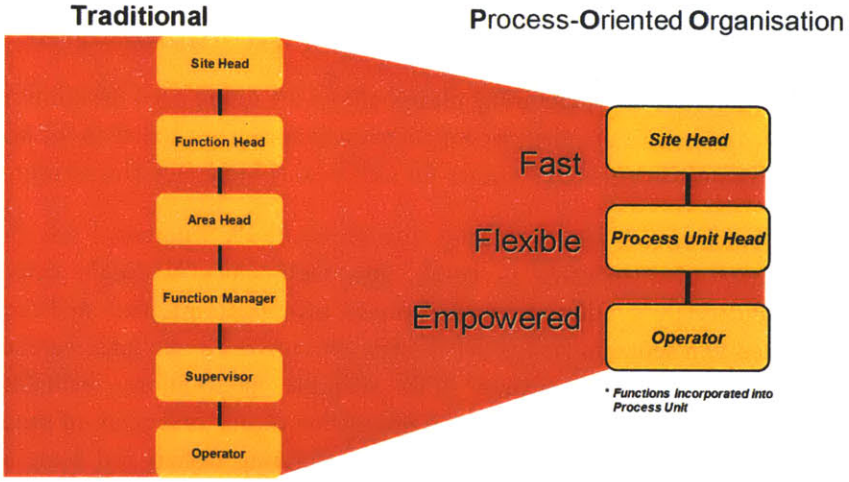

Figure 17: POO (Novartis Pharma, TechOps copyright 2009)

This structure works well locally, but the does not consistently roll up to the global organization. Each site remains somewhat isolated among the processes for which they are responsible, and there is little visibility on how certain actions will affects upstream and downstream tasks in the long run. Additionally due to the vast differences in size, product lines, and facility design, there is a sentiment that cross-site knowledge transfer is of little value and thus rarely happens outside of the IQP group. There are only a few key roles that are responsible for cross-functional communication. These resources become overworked and spread very thin because they are dealing with a variety of issues, many of which are outside their official roles and responsibilities. We begin to see from these observations that the model is a good fit for TechOps.

5.2.2 Complexity Reduction and Brand Rationalization Initiative

Novartis Pharma produces tens of thousands of SKUs. Many of which are the same product, but different dosage forms and package sizes, each of which requires additional manufacturing planning and production change-overs, which add to TechOps costs. The Complexity Reduction Initiative is looking specifically at reducing product complexity by eliminating non-profitable and redundant SKUs. They have added the element of Brand Rationalization which is a process to identify the current customer needs at a local level and to streamline the product offering based off of those needs. The idea is to give the marketing and sales force teams accountability for the profitability (not just the revenue generation) of the SKUs they sell. Please refer to Kevin Leiter's and David Hilliard's LGO theses for more details on the Product Complexity Reduction and Brand Rationalization Initiative and the outcomes from their research.

The existence and visibility of this initiative shows that Novartis has a lot of waste in it systems. Complexity grows in the product/process face, but it hides in the organization/process face (Wilson & Perumal, 2010) (Wilson & Perumal, 2010) (Wilson & Perumal, 2010). This paper explores what additional complexities are causing less than optimal operations in TechOps and how the organization can change in a productive way to combat these issues.

5.2.3 Continuous Manufacturing

The third initiative, Continuous Manufacturing, clearly shows the future need for more streamlined global organization. The pains of traditional pharmaceutical manufacturing are stated on the home page of the MIT School of Engineering Novartis-MIT Center for Continuous Manufacturing (Trout, 2012):

> The batch-based manufacturing system currently employed by the pharmaceutical industry is costly and inefficient. A drug's active ingredients are synthesized in a chemical manufacturing plant and then shipped to a separate facility where they are converted into large batches of pills, liquids, or creams. With multiple interruptions, including transport to separate locations, the production of just one batch of drugs can take weeks. What's more, the manufacturing design and scale-up required to produce a new drug can be financially unsustainable and exceedingly time-consuming.

The idea of continuous manufacturing is to eliminate the costly and risky batch processing of today's drug manufacturing and create a product that can be produced in an unbroken flow (See **Figure 18**). Not only will this dramatically reduce the risks of contamination, because the APIs are not being moved from facility to facility, but it will also decrease the time and cost of setting up a new facility, as the footprint of a continuous manufacturing plant is much smaller than the traditional chemical and pharmaceutical facilities. Additionally and important to our study, continuous manufacturing also eliminate a lot of non-value added steps from changeovers and transportation.

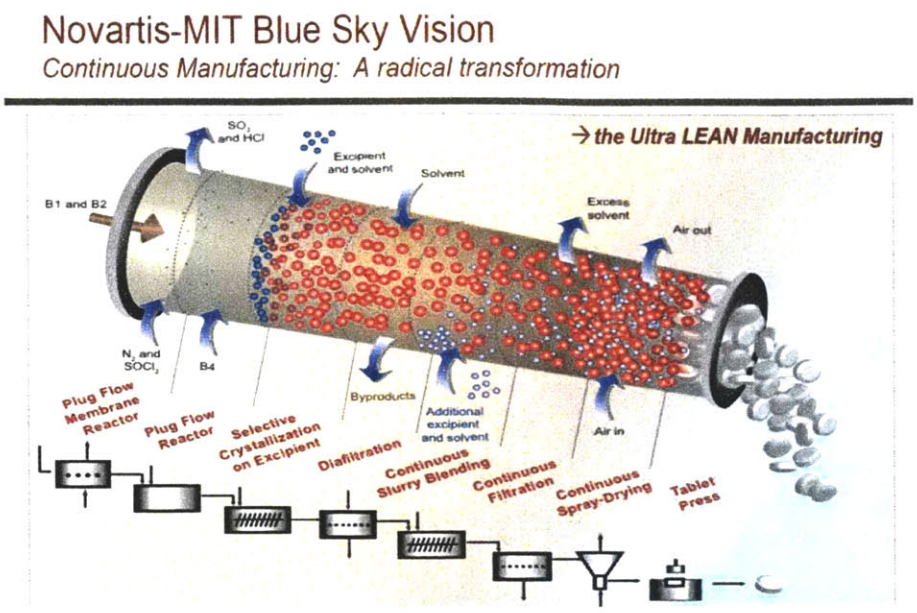

Figure 18: Continuous Manufacturing Diagram
(Novartis Copyright 2011)

Novartis has been working closely with MIT to develop this technology over the past 10-years, and there are plans to move the prototype facility on to the Novartis campus in the next few years.

5.3 Diagnosing Organizational Complexity

What is missing in the execution of Vision 2015 is a true understanding of how the different units within TechOps currently interact with each other and where the gaps are from the vision. As the company moves towards continuous manufacturing techniques the misalignment with the organizational structure will create additional complexities that will have further impact on the organization as a whole, possibly sending TechOps into the undesirable downward spiral demonstrated by the dynamic model in Chapter 3.The current manufacturing facilities and operational departments are a result of the batch production processes that are currently in place. But how does Novartis move towards a global organizational structure that will be conducive to continuous manufacturing without disrupting the current products? How are these initiatives integrated? How is the information passed among the teams? How does it affect day-to-day activities? By looking at the three key initiatives in Novartis TechOps, we can begin to understand how information and communication flows through global TechOps will play a key role in creating an organization with common goals. Additionally, while the Complexity Reduction project is looking at the Product/Process face of complexity costs, we will show why there is a need of also tackling the Organization/Process face as well. As we saw from **Figures 3 & 4** in **Chapter 2,** they are all interdependent. If we look at the model and compare the current state, we see how it is applicable to TechOps. **Figure 19**: Application of Model demonstrates as such:

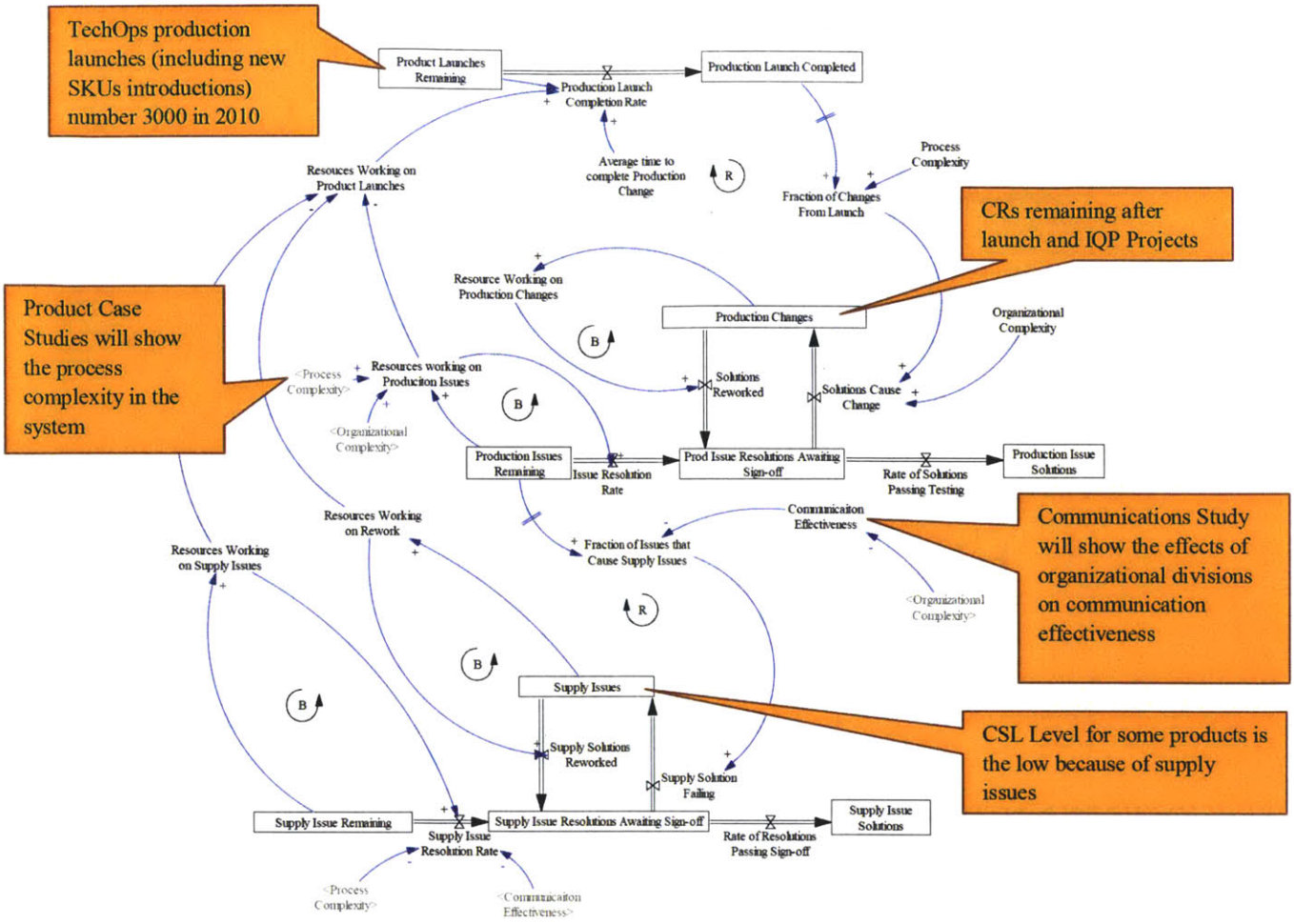

Figure 19: Application of Model

5.4 Application of the Model with TechOps Organizational Complexity

Wilson & Perumal claim that a company can reduce their operating costs through Organizational/Process complexity reduction if the following symptoms listed below are present. Based on interviews, and analysis of the 2011 employee survey,we see that TechOps can check almost all of the boxes below.

Table 1: Org/Process Complexity Symptoms

Symptom	Example at Novartis
No clear end-to end visibility; no one has a clear picture of what everyone does	Through interviews and observations of project management, it became very apparent the lack of end to end visibility. Communication study results in Chapter 7 will show the low levels of cross-functional communication.
Information moves slowly through multiple layers and silos in organization	Communication study results. Employee survey results specifically state that employee believe the information they need to do their jobs in not readily available.
Difficulty understanding trade-offs at cross-functional boundaries	At quarter end, inventory is pushed from operations into PSC which create a false sense of accomplishment for one group
Little outcome from a lot of activity (e.g. accountability is blurred,	Many projects happening simultaneously with similar goals, not way of tracking outcome, lessons learned, whether or not the

Symptom	Example at Novartis
decision rights unclear, more resources needed that initially planned)	objectives were met
Diminished customer service levels	Customer Service Levels are the lowest they have been in years for several products
Complex uses of IT systems weighs down processes and decision making rather than streamlining them	Example of use of multiple systems, difficulty in accessing information, no manual or formal training, no incentive to use the various software programs. No standards from site to site in software except SAP, however there are also multiple instances of SAP

(Wilson & Perumal, 2010, p. Ch. 7)

Additionally, although, leadership is very aware that there are functional divisions that focus on technologies and not brand,, lack of communication and poor end-to-end visibility, it is also difficult to change a large, complex system overnight, thus we need to look at root causes and attack the complexity from within the organization. For example, PSC which sits between ChemOps and PharmOps organizationally has no ownership over the actual production planning and forecasting; the usual points of contention among the groups. Figure **19** illustrates how the model fits with Novartis TechOps. From the model fit we will recommend methods to incentivize the groups to work together on a regular basis, not just when there is a crisis, and a Tiger Team is needed. Otherwise, as the model shows, TechOps could fall into the negative loop from which it may be unable to recover.

5.5 Summary

This chapter details the trends in the industry and the background of Novartis relevant to the organizational change. We talked about how the pharmaceutical industry is changing through increasing regulatory restrictions and the target indications. We then detailed Novartis and TechOps' current state organization structure and key initiatives that affect communication and organizational and process complexity including POO, Product Complexity Reduction and Continuous Manufacturing. Examples prove Novartis behaves like the model, and reduce the impact of its Organizational complexity can yield positive results.

6 Chapter 6: Understanding Process Complexity through Physical Product Flow, Information Flow and Value Stream Mapping

In this chapter we will delve deeper into the process complexity face by looking at 2 product production processes. The goal of the case studies is to the further understand how the model fits with TechOps and to find out where the gaps are between process and organizational structure, thus helping us design a better future organization.

One of the biggest factors of process complexity at Novartis is the vast differences among the production processes for various products. The batch processing within each operational function and manufacturing site has allowed for shared process steps, allowing the POO to work well at a local level. However, as we look at the branded production processes from a global level, production process are very different, and need to be treated as such. In order to create a concrete example of the Organization/Process face and the communication gaps between them, we look at the global TechOps and case study two products that represent the breadth of TechOps manufacturing. We compare the communication frequency, information flow for each product, and examine the differences and similarities of organizational behavior among these groups.

Figure 20 illustrates the generic order management process at Novartis Pharma from the virtual order flow from CPO to PSC to Manufacturing to the physical product flow from DS to DP to FP manufacturing through PSC for customer distribution. Here, complexities arise from:

1. Inconsistencies among how CPOs order products across different countries and brands
2. The order entry process from global to local SAP instances
3. The hand-offs and sign-off requirements from PharmOps and PSC.

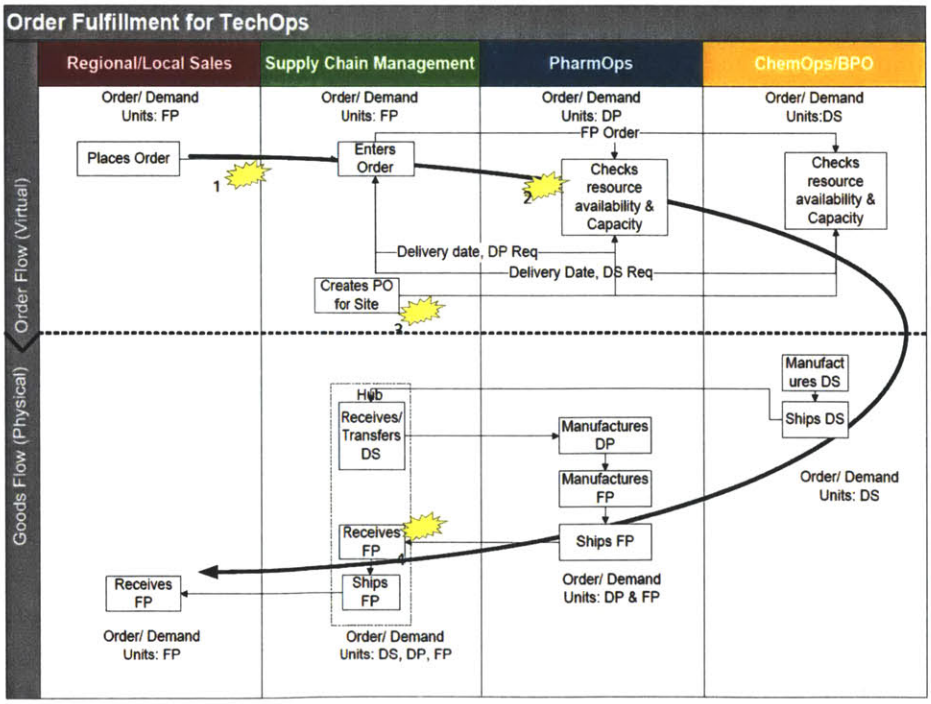

Figure 20: TechOps Order Fulfillment Process

Although the high level process is similar for most products, each brand, product, and SKU have their own deviations in the end-to-end production and distribution. However, when we look at the information flows, we see differences that are less logical. For example, depending on the product, location and planner, users may have several different ways of tracking and scheduling the product. Each planner has their own method of determining the product schedules, some use Excel, some MS Project, etc. This lack of standardization makes it difficult to track a product end-to-end, and even more difficult to hand off to new users. The information flow adds to the organizational/process complexity.

To develop an accurate picture of the process complexity, we looked at two products that encompass a good sample of the breadth of Novartis's future production pipeline. For confidentiality reasons actual names and numbers are not used, but the relative proportions are.

To conduct the product case studies, we interviewed people involved in the operations of the product including the PU head, Life-Cycle manager, and Production Planners. We mapped the product flow and the information flow for each product to help define the Process Complexity of each product. From this exercise, we can concretely see from just two products the amount of NVA embedded in the end-to-end system stemming from the batched design of the production process.

6.1 Product 1: Small molecule product with high growth potential

The first product ("Product 1") is a small molecule product. This product has large growth projections over the next several years, and so TechOps IQP has launched global project looking to reduce the overall production lead time for this product. Initial results show dramatic opportunity for improvement.

Figure 21 represents the global product flow of product 1. This product has 4 key raw materials that are sourced from various suppliers. The drug substance (DS) is manufactured in two different ChemOps facilities. The DS from both facilities is then shipped to the storage hub. All the DS is built to plan in a push system based on a consolidated global forecast. When customer orders are received, PharmOps then requests the DS from PSC, who owns the inventory to manufacture the drug product (DP) and finished product (FP).

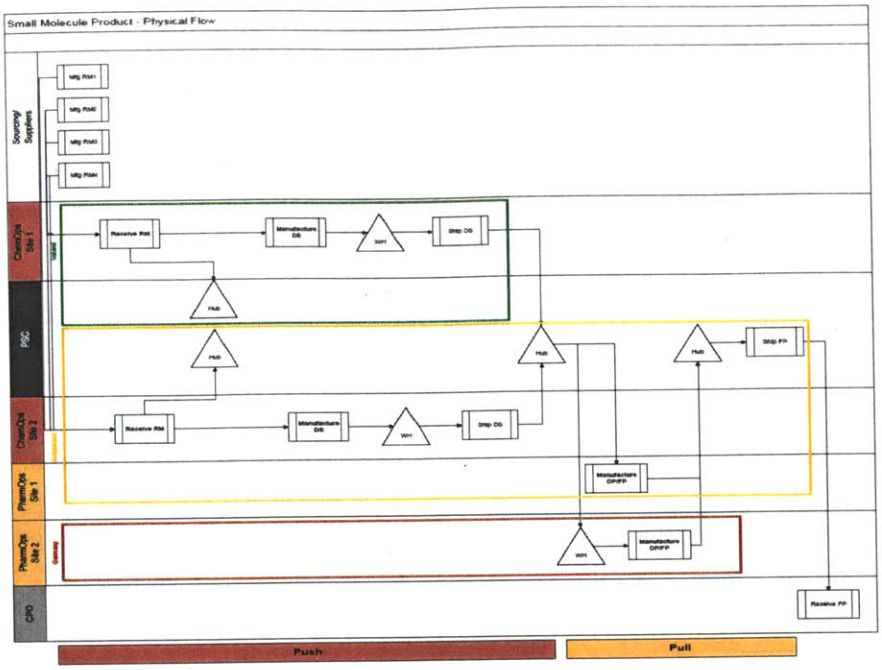

Figure 21: Product 1 Production Process

The information flow starts much earlier than the physical product flow. CPOs send their forecast to PSC, where forecasts are compiled and strategic plans (~5 years out) for production are made. In this process, forecasts are received in different ways from the CPOs and each planner has their own way of compiling the forecasts. Operational (2-3 years) and tactical (1 year) plans are made. ChemOps produces to plan. When raw material (RM) is received, production begins. Each major step in the process has QA/QC inspections and batch records that need to be signed off. Regulations are very strict with batch records, and again the process of physically filling out the batch record is different from site to site. Some plants have automated systems while others are more manual. Batch record accuracy is so important that metrics are actually measured on how correct the batch record was filled out. Technically, the manual reviews of the batch record are considered NVA in the process, yet are an important metric at the site level. While regulations require precise batch records, these additional steps can easily be completed with information systems eliminating the error-prone manual labor.

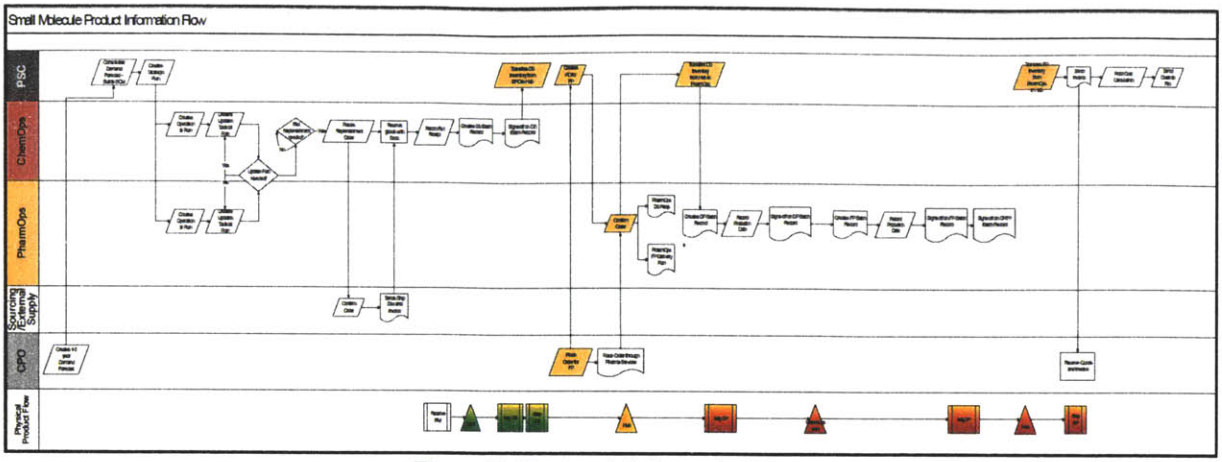

Figure 22: Product 1 Information Flow

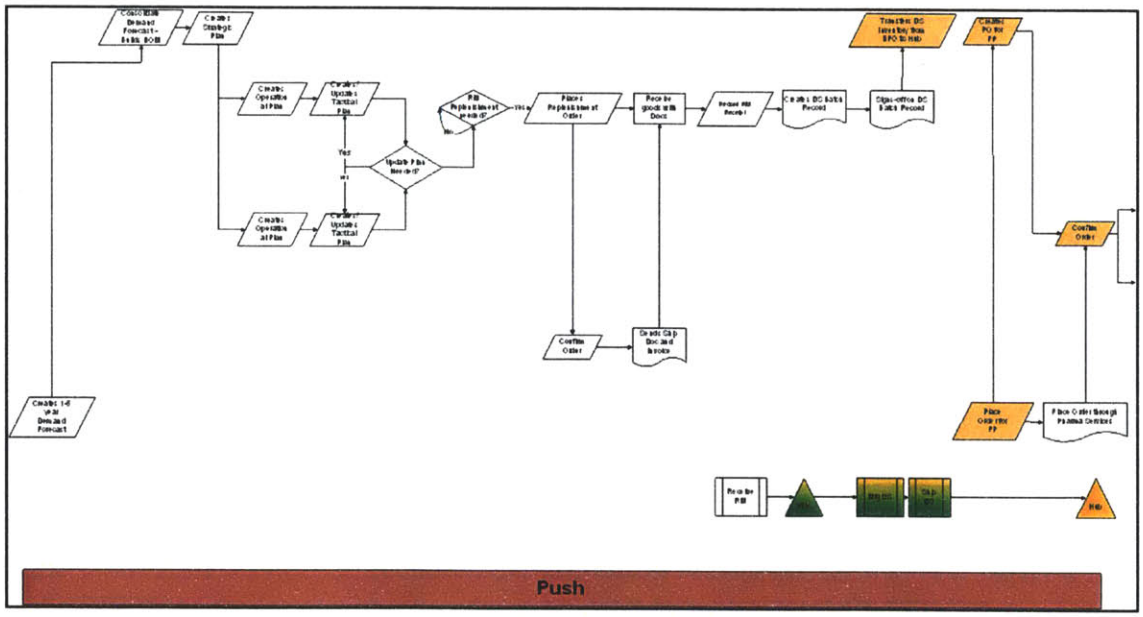

Figure 23: Product 1 Information flow for Push Process

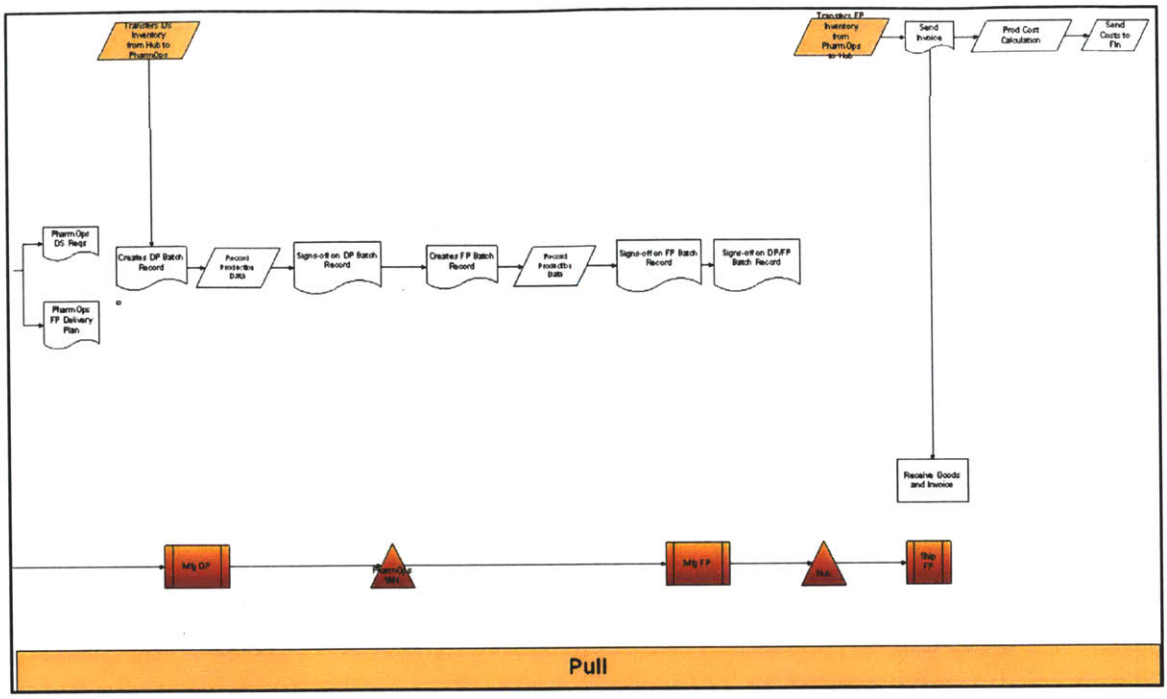

Figure 24: Product 1 Information Flow for Pull Process

When we map the value stream, the process complexity becomes more obvious. As we see from **Figure 25**, a production process that has a critical path of 24 days currently has a lead time of 200 days. That yields a process complexity ratio (NVA/VA) of 9! In other words there is 9 times the NVA than there is VA. The target is to move the complexity ratio down to 3.

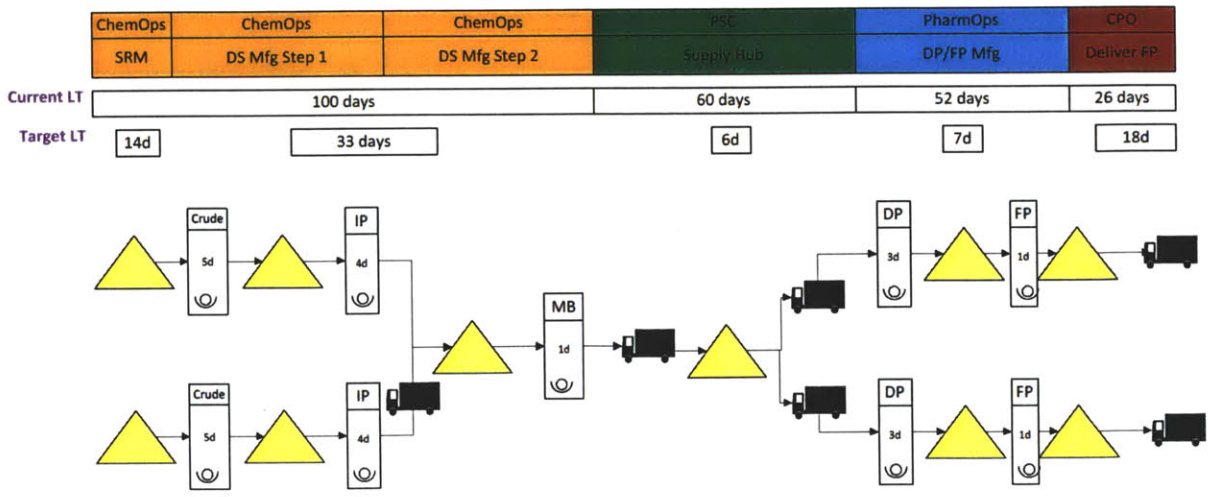

Figure 25: Product 1 Value Stream Map

Because each product is different, the complexity ratio is great way to measure how well the process is functioning and keeps complexity costs manageable levels.

6.2 Product 2: Large molecule product with high value but low volume

The second product ("Product 2") is a large molecule product. This product is being developed in a multiproduct facility, so coordination is among the various stakeholders are important. Organizationally the development model for this product requires additional management because the product is split between clinical and commercial production divisions: Development and Supply Chain, respectively. So a lot of coordination and communication is necessary to keep the product managers aligned. The communication study presented in **Chapter 7** shows how those two roles in particular (the Life-Cycle Manager and Operational Planner) are responsible for 90% of this coordination, which can lead to resource bottlenecks we saw in the generic model in **Chapter 3**, when there is not visibility across the supply chain.

Currently, only a small percentage of Product 2 is for commercial distribution. The rest is for Phase 3 clinical trials. What makes this particularly complicated is that demand for the clinical product is much more unstable than the commercial product. Doctors are able to change number of dosages and sample sizes very quickly during clinical trial, and the production lines need to be flexible to those needs. This creates another need for open communication across TechOps divisions, and end-to-end product ownership. Additionally, Novartis needs to be flexible to support the pipeline as the demand becomes commercial.

6.2.1 Physical Flow

Similar to the small molecule products, the push-pull boundary of the large molecule product is between DS and DP manufacturing. For large molecule products, since they are made from proteins, the strategic raw material is the working cell bank (WCB). The working cell bank is housed internally at Novartis Biologics Process Science and Production group (NBxPSP). Although the product moves to 3 different locations in the process, the distance travelled is actually quite small compared to the small molecule products. The bottleneck in production process comes from the centrifuge machine during the DS manufacturing.

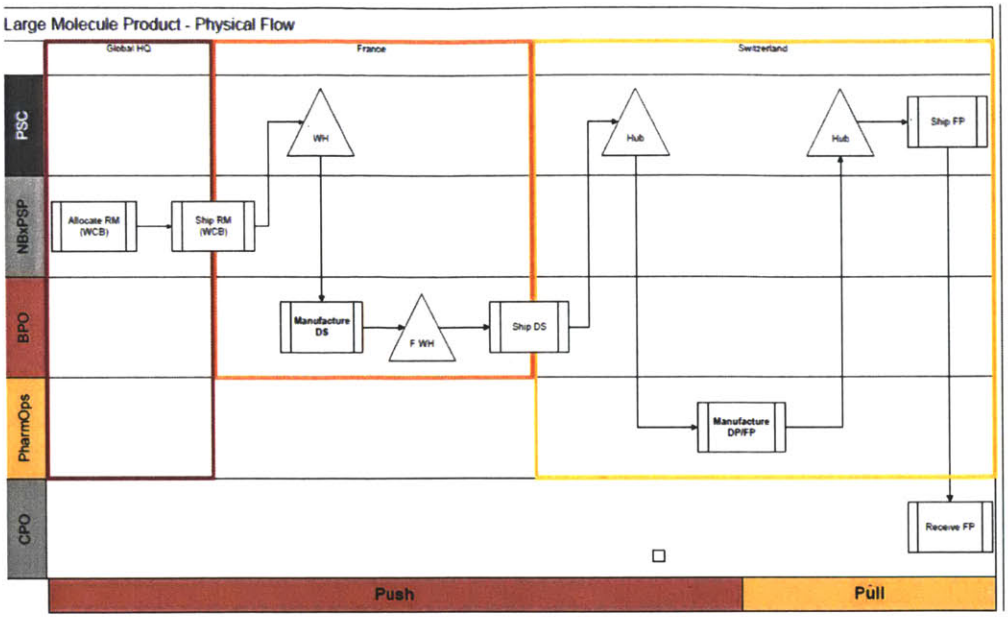

Figure 26: Product 2 Production Process Flow Diagram

6.2.2 Information Flow

Again, like the small molecule product, the information flow begins well before the production process. With this drug in particular, because it is a lunch product, the coordination between PSC and Site operations is quite tight, and there is a lot of communication between these groups. However, as the model suggests, the effectiveness of the communication is hindered by the Organization/Process complexity and resource constraints, thus as the product comes out of launch phase, Novartis need to be careful not to lose this level of communication.

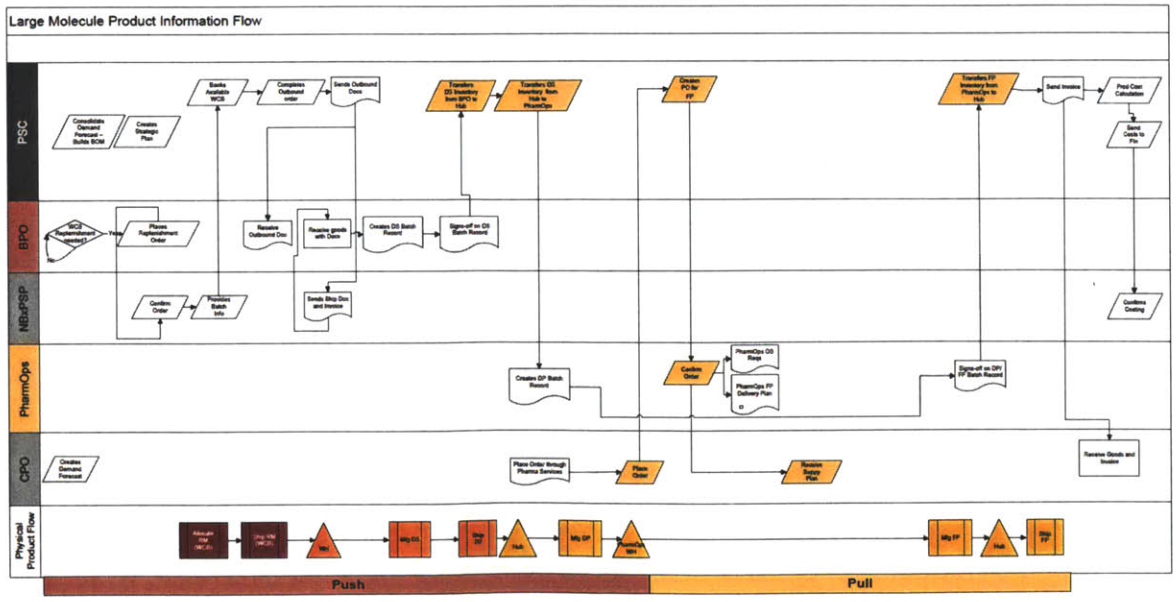

Figure 27: Product 2 Information Flow Diagram

Information flow begins with the demand forecast and the strategic plan. Because the product is made in a multiproduct facility, it is coordinated with other product lines. A reorder point is set by the planner in their own local system, which needs to be manually coordinated with the inventory management system. If RM is low, they will call several people to coordinate placing the order. They order is confirmed by NBxPSP offline and then the order is placed in the system to book the available WCB. This begins the coordination of the information and the physical product flow. NBxPSP provides required batch information and documentation on available WCB to PSC. PSC completes outbound orders in SAP for BPO and sends outbound documentation to both BPO and NBxPSP. Shipment documentation is received with the physical product. There is also a separate system at the BPO facility that tract the RM sorting. Once the DS is manufactured and shipped to the hub, a stock transfer is done in SAP from BPO to the PSC hub. Then DP/FP is manufactured, again with batch records processed locally, using local standards and equipment. The physical product stays in Switzerland but the ownership of the product moves between departments, which make information coordination particularly important.

6.3 Application of Model with TechOps Process Complexity

When we look at both the Product 1 & 2 processes through the model, we see multiple points where process complexity hinders communication effectiveness and brings about conflicting interests, which in turn causes the system difficult to manage. Based on our discussion with PU heads and technology leads at Novartis, there are have been several production changes that cause issues. And we found that the more complex the process, and thus the less end-to-end visibility, the higher the likelihood of production changes to cause productions issues, again tying directly back to the model.

Product 1 is a great example of the complexities in the physical process flow. The amount of NVA is a direct result of production growth in organizational structure that is divided by functions. As Wilson & Perumal express repeatedly in their book, we cannot separate the complexities of the system, they are all interrelated. The amount of NVA in Product 1 production is a great example of where organizational and process complexities collide bringing about a costly process. Organizationally there are numerous suppliers and multiple facilities. Process-wise, there are multiple batch processes and variations of the product. ChemOps handles production based on the network, while PharmOps production is based on the individual sites. Since the processes are different and have different priorities, without end-to-end ownership, standard coordination, and open communication it is hard to understand the downstream effects of changes. This causes additional confusion on coordination because, as we will see in the next chapter, there is very little communication between the ChemOps and PharmOps globally. While the IQP group helps improve processes at the sites, they do not ultimately own the implementation and sustainability of that process. As the demand for this product grows for the future, TechOps will need to adapt their organization so they will not fall in to the negative loop the model illustrates.

Product 2 is a great example of complexities in the information flow. The first point of contention is simply that the strategic planner is responsible for one product in this facility, where the operational planner is trying to optimize the production process unit, with the multiple products. They thus have conflicting metrics. As we look further into the information flow, we see multiple information systems being used, that are not always in sync. The enterprise planning system has multiple instances. PSC is using the global instance where BPO and PharmOps use their local instances. The operational planner, for this PU uses MS Project to manage the plan, and then has to reenter information into SAP. Other planners for other process units use their own home grown spreadsheets. While Novartis has

sophisticated software available, the adoption rate is low because the users are not held accountable for using the system. Additionally, IT is not judged on the fulfillment of the end user requirements of the system. With high value products, data accuracy and trust in the system is imperative. As Gailbraith suggests, Novartis must build effective vertical information management system (1974) to combat the of the Organizational/Process complexity and grow for the future.

Complexity can be a competitive advantage. For example, the functional operational network of Novartis allows issues to be isolated at a single site. However, global management still needs to be aware of the occurrence and severity (how much they affect other process steps) of each issue, so they can react in a timely and effective way to prevent customer service issues.

6.4 Summary

In this chapter we looked at the process complexity in TechOps. We case studied two products: a small molecule product and a large molecule product. We discussed the physical product flow and the information flows and showed that there is a lot of room for complexity reduction. Production issues stemming from poor process visibility again show how TechOps fits with the model, and helps form recommendations for further changes.

7 Chapter 7: Understanding Communication Effectiveness through a Communications Study

Communication is an important factor in any business. In the late 1980s and early 1990s (and continuing into the 21st century) Thomas Allen pioneered studies that quantified the effect of distance, organizational structure, and building architecture on communication. While much of the focus of his and subsequent studies have been on Product Development and Engineering, we can use the same techniques to understand the communication frequency, media and purpose in the Operations group as well. This study will answer the following questions:

- How do people in TechOps truly communicate with each other?
- What media are they using? Are forms of communication going underutilized?
- How and how often do people communicate across departments and sites?
- Are the right people getting connected? Where are the gaps?

The results from the communication study give us a concrete idea of the communication how they affect the impact of supply issues at a global level and tie directly back to the dynamic model.

7.1 Participation

The target participants of the study include directors in Global TechOps. Namely, the heads of each division: ChemOps, PharmOps, BPO, External Supply and PSC, and all their direct reports. Then to coordinate with the product case studies, and understand the differences in communication from product specific teams to global teams, we asked people involved with the production of Product 1 and 2 at the local level to participate. This included resources in PSC responsible for strategic planning and marketing coordination, operational and tactical planners, PU Heads, QA Analysts, and IT. A total of 105 people were requested to participate, of which 62 did.

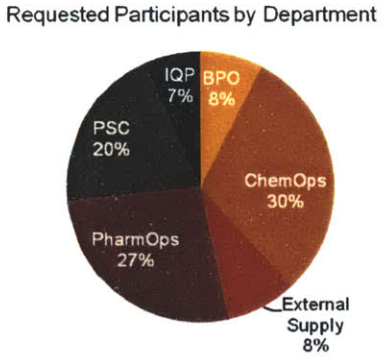

Figure 28: Department Breakdown of Requested Participant

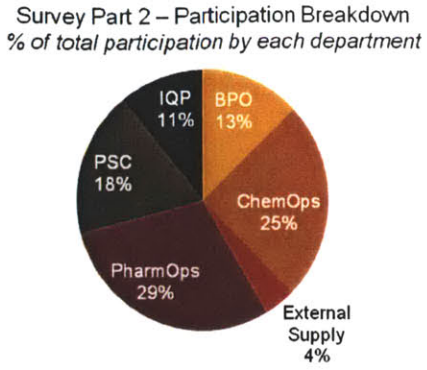

Figure 29: Department Breakdown of Actual Participants

7.2 Survey Design

The study was designed to maximize participation. Therefore, we broke the survey into two parts. The first part was a self-assessment where users were asked what forms of media they use to communicate, and how often they communicate with other departments (See **Appendix B** for detailed survey information). The second part was a daily log. For two weeks, participants were asked to select the people that they interacted with throughout the day, and indicate how they talked to each other. The media choices were:

- Face-to-Face
- Phone (including voicemail you have left and received)
- Email
- Instant messenger (IM)
- SharePoint (share documents, updating schedules)
- Fax/Memo (including inter office mail)
- Other

Figure 30 shows the percent breakdown of the media that is used to communicate. Email is used 50% of the time and Face-to-Face used 25% of the time. Other types of media, such as IM and SharePoint are rarely used.

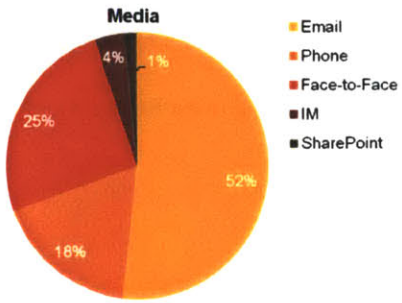

Figure 30: Communication Media Amount

7.3 Assumptions and Caveats

We are taking the participants inputs and extrapolating for the entire population. There are some cases where there are not enough responses to make a strong conclusion, so those are eliminated from the analysis.

While other studies that have been done typically have months worth of data, we unfortunately did not have the time to continue the study for several months. Therefore, we are assuming that this information is representative of longer term communication patterns. Furthers studies need to be done to confirm these patterns. However, the results were very consistent with observations and internal sentiment and accepted by the executive team.

7.4 Results

The communication study results show us what factors affect communication across the organization. We specifically looked at: departments, product teams, organizational level, and physical distance between participants.

7.4.1 Self-Assessment Results

At an aggregate level (looking at all departments together and the global and brand teams together), we see that most communication is scheduled and not ad hoc. Additionally, while the majority of communication is through email, this media is mostly used for on-going business and administrative tasks, while new ideas and technology are discussed face-to-face (See **Figures 31-33**).

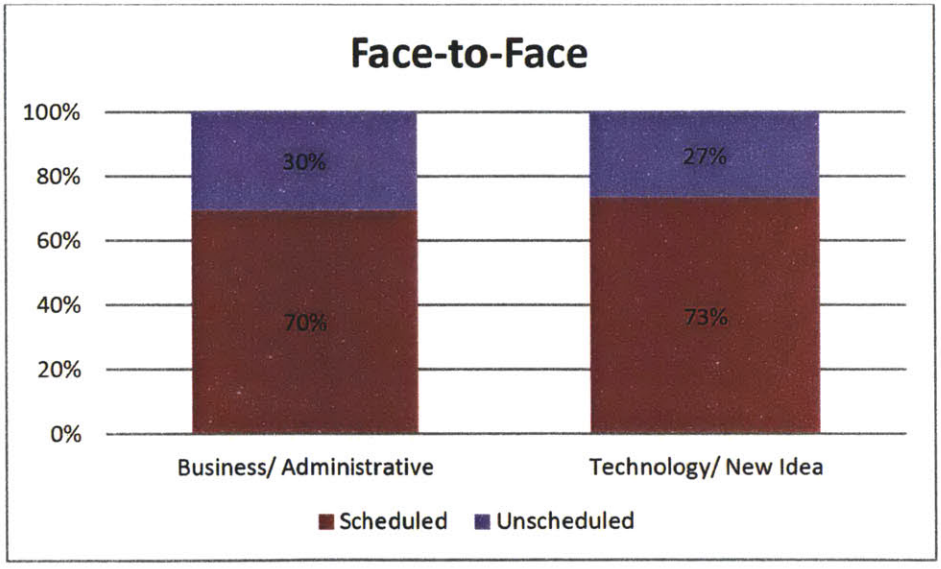

Figure 31: Breakdown of Face-to-Face Communication
72% Scheduled, 28% Unscheduled, 43% Business Administrative, 57% New Technology/Idea

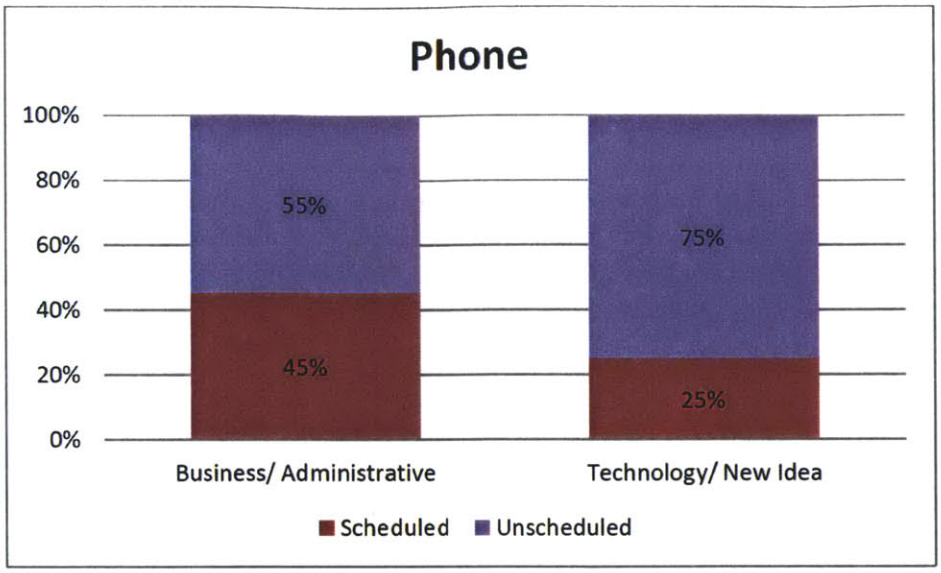

Figure 32: Breakdown of Phone Communication
38% Scheduled, 62% Unscheduled, 66% Business Administrative, 34% New Technology/Idea

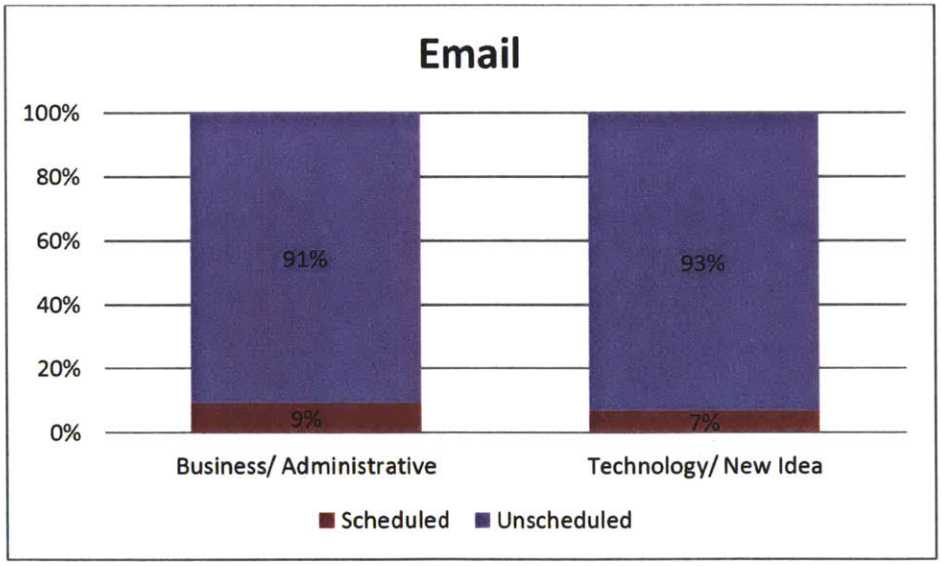

Figure 33: Breakdown of Email Communication Daily Log Results
8% Scheduled, 92% Unscheduled, 69% Business Administrative, 31% New Technology/Idea

7.4.2 Daily Log Results

To analyze the results of the daily log, we construct various Allen curves and netgraphs (heat maps of communication activity) (Allen & Henn, 2007). To create Allen curves, we look at pairs, the likelihood that the two people communicate with each other. In other words, the probability of communication is the percent chance that the pair of resources communicates on a given day. The 23% mean probability

implies that each pair in the global group has only 23% chance of communicating with each other throughout the day.

7.4.2.1 Allen Curves

If we look at the Allen curve of all the participants, we do see a downward trend as distance increases. Although, it not quite as steep as originally expected base on the studies on engineers, so we breakdown the data further into Department to understand where the trend is coming from.

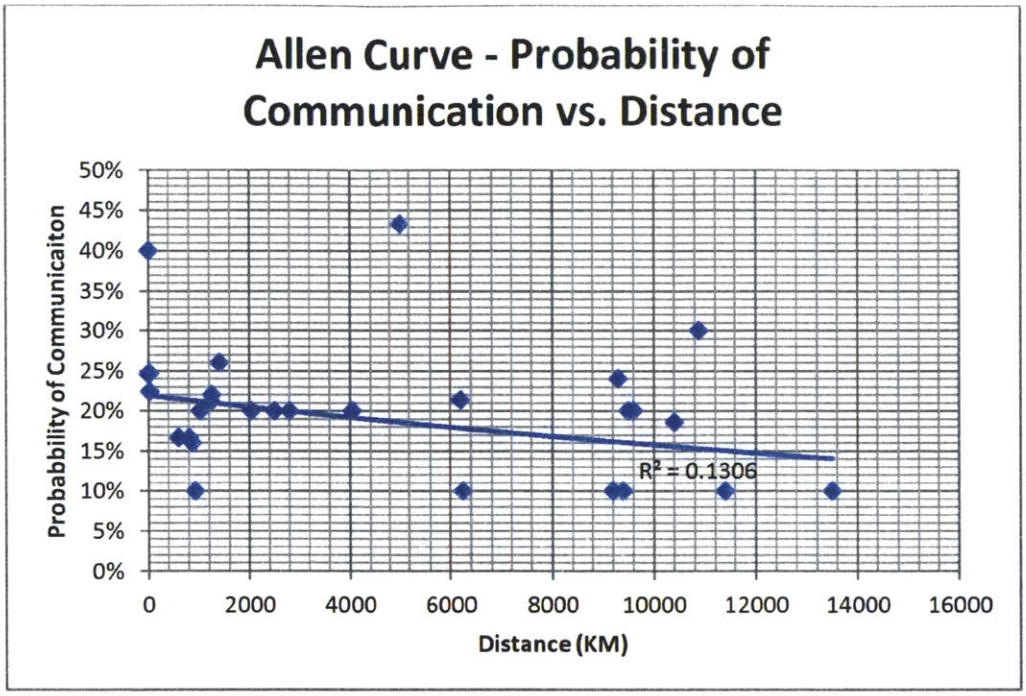

Figure 34: Allen Curve - All Participants

We can map the communication events as a Poisson process, and thus we get an exponential probability density function of the communication frequencies.

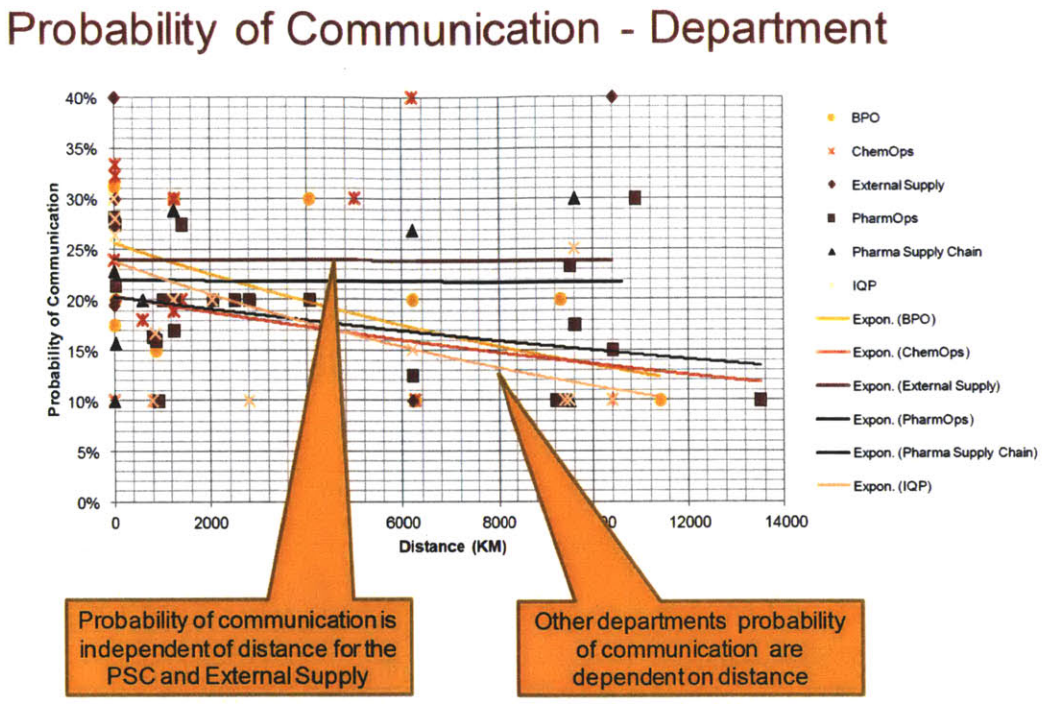

Figure 35: Allen Curve by Department

With the operational departments (BPO, ChemOps, PharmOps and External Supply), we see the same downward sloping trend as distance increases. However with the *functional groups of External Supply and PSC*, we see that probability of communication is almost *independent of distance.*

This gives us a valuable insight into promoting cross-functional communication across the operational departments: incentives must be concretely put in place to promote additional communication. As Galbraith suggests multi-national companies must design lateral coordination and create rules and incentives around for integrating roles, creating liaisons and direct contact (Galbraith, 1974). PSC and External Supply resources own product life-cycles and therefore coordinate with various people across the supply chain. However, there are no metrics in place to measure the effectiveness of this communication or how effectively they coordinate the groups over time. There are no incentives in place for the operational groups to also communicate, which build trust in the system and across parties. Only one cross-functional meeting is scheduled annually with the site heads of the various functions. Additionally, as we see from the model, the amount of process and organizationally complexity in the system creates a negative reinforcing loop decreasing the communication effectiveness.

7.4.2.2 Netgraphs

Another insightful way of looking at the data is through netgraphs, or heat graphs of communication. Again we can see from these netgraphs, intra-departmental communication is more likely than cross-departmental communication, even across distances (See **Figure 36**).

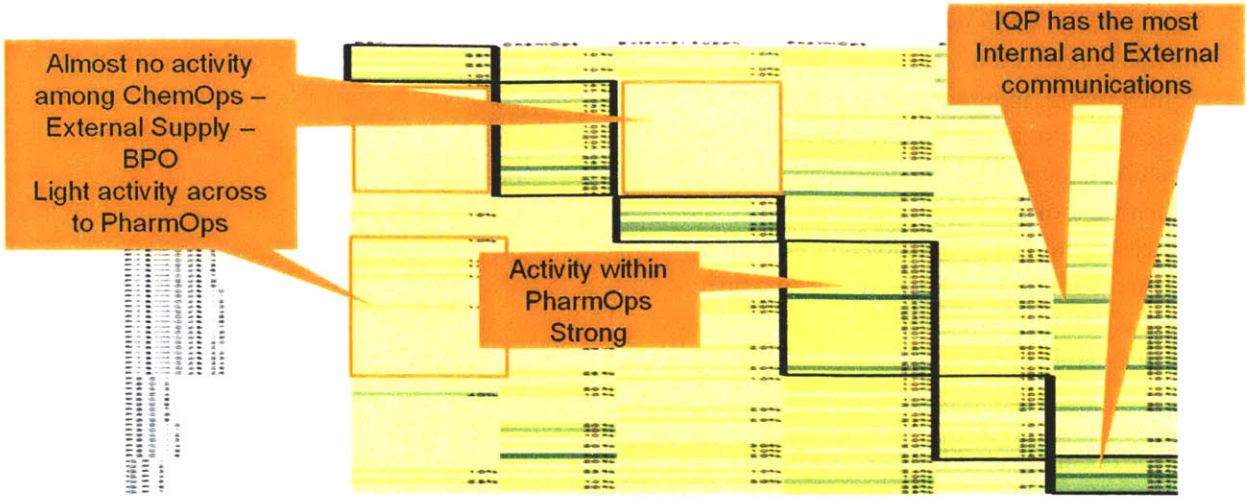

Figure 36: Netgraph by Department

If we look at the trends by organizational level, we see similar characteristics: strong activity within departments but little cross-functional communication, especially among the higher level executives.

Netgraph by Organizational Position

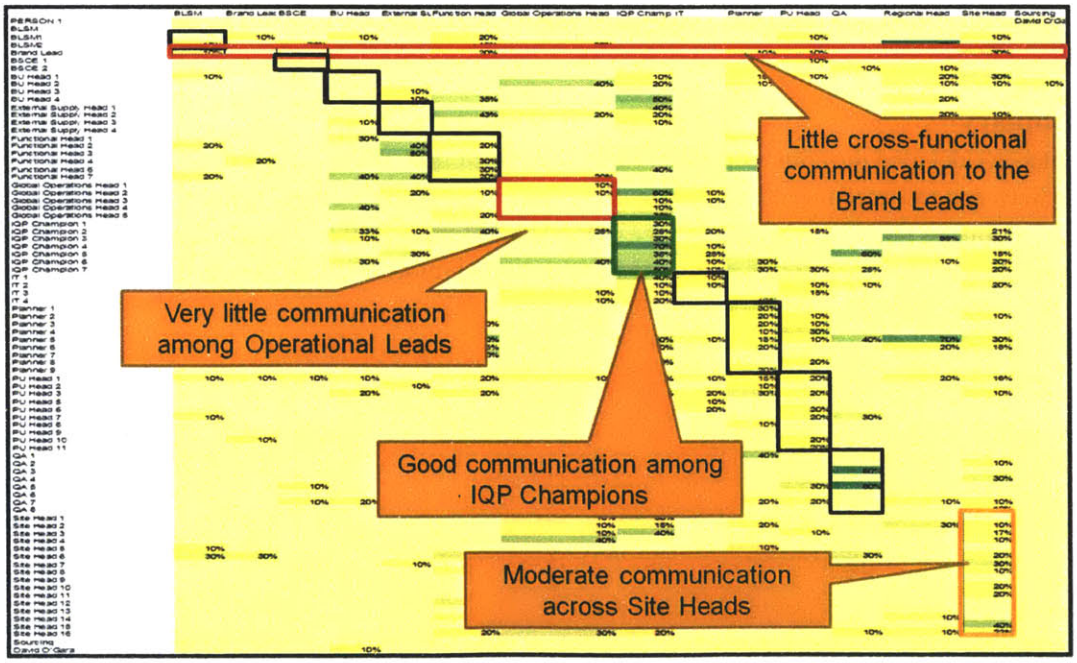

Figure 37: Netgraph by Position

Again, looking at communication by organizational level (Global head, Site Heads, PU Heads, etc.) implies that cross-functional communication at the global level needs to be driven strictly by incentives, roles and responsibilities.

Additionally, when we drill into the results at an individual level, we see that certain roles and project members drive up the global averages. In other words, the resources that have specific incentives to communicate, through their job function and KPIs, are more likely to communicate cross-functionally, which make sense intuitively. Initially, these resources has a positive impact on the overall-cross-function communication, but eventually they become constrained and create a bottleneck in the system. When we look back at tiger teams in the model, the amount of cross-functional communication not only increases, but issues are solved in much shorter period of time. However, as tiger teams perpetuate, resources are constrained and schedule pressure drives to additional organizational complexity, which counteracts the positive effect of communication. Therefore, the management of these resources are key to sustainable future growth.

This is true also for the key performance indicators (KPIs) in the system. KPIs in TechOps are separated by the operation, and have not been globally optimized, Thus have a negatice impact on the organization as a whole, especially if we are looking to increase the end-to-end visibility. But without globally optimal KPIs, it is hard for the leaders to know the true state of the business.

7.5 Application of the Model on TechOps Communication Effectiveness

When we combine the results of the communications study with the product case studies, the dynamic model is a good representation of the future state of the business, if organizational changes are not made.. Therefore, we can use knowledge to make recommendations that helps TechOps control the organizational/process complexity and increase communication effectiveness and resource planning in such a way as to help create an organization that has control over fire fighting. The next chapter provides the details.

7.6 Summary

In this chapter, we detailed the communication study conducted in the fall of 2011. The results show that department lines and resource incentives dictate more so than physical location the amount of communication among global TechOps resources. We showed another fit to the model where communication effectiveness is hindered by overly complicated information processes.

8 Chapter 8: Recommendations, Conclusions and Next Steps

We have shown that TechOps is a complex organization going through an industry transition. Therefore, the dynamic model of production issues and supply issues is applicable. By combing the knowledge of TechOps future goals and innovations with the organizations possible susceptibility to adverse effects of complexity. this chapter will make recommendations for TechOps and next steps. Specifically we are looking for a way to design the global organization is to solve the following issues:

- Poor performance – creates an inward focus as opposed to a customer focus. Leads to poor product availability and customer service levels
- Lack of accountability – difficultly seeing trade-offs that cross functional boundaries
- Lack of information flow – no performance feedback loops for improvement

Additionally the solution must adhere to the following constraints:

1. Support Vision 2015 without losing any technical capabilities and allows for better informed decision making
2. Reduce complexity from an organizational standpoint so other initiatives are aligned to get people the information they need
3. Create an organization that supports the balance between functions and brands in order to not lose technical capabilities
4. Is practical and implementable

Before we make the recommendations, we conduct a 3-Lens Analysis, to ensure that the recommendation will not only fit the future enterprise architecture, but also fit the strategic, political and cultural aspects of the company. By doing so, we ensure that the recommendation will be accepted and sustained.

8.1 3-Lens Analysis

A 3-lens anaylsis is a technique of analyzing organizational behavior through three distinct, but complementary points of view: Strategic Design, Cultural and Political. The *Strategic Design Lens* sees organizations as machines; mechanical systems created to achieve a common goal where actions come through planning. *Cultural Lens* sees organizations as institutions; Symbolic systems of values and routines where actions come through habit. Finally, the The *Political Lens* sees organizations as contests; social systems that compete for resources where actions come through power. This qualitative analysis will help shape our assumptions and relationships in the dynamic model and the recommendations.

8.1.1 Strategic Design

The strategic vision of TechOps is to become a "world-class, patient-driven supply network." TechOps is a cost center, responsible for all manufacturing and distribution for Novartis Pharma, but not responsible for the development or sales of the products. They are continuously trying to find ways to make the supply chain more efficient and have a goal of 10% cost reduction across the board year over year. As stated by the leader during and IQP workshop, "the goal is to optimize the future of Novartis, not modify the past."

To that effect, TechOps is very strategically aware that their product portfolio is changing: their largest brand is going off patent in a few years, and while the volumes will not decrease dramatically, the revenues will. In addition the market for biologics, orphan drugs, and customized medicine is growing rapidly, which equates to lower production volumes and more complex production. Thus they want to create a more agile organization at the global level.

8.1.2 Cultural

As a whole, TechOps is very conscious of the 2015 Vision. The employee survey showed an overwhelming percentage of people (over 90%) thought that the vision and goals were clear and communicated effectively.

POO and Lean have been embedded into the daily lives of the local operations. Employees express their desire to be a company with continuous improvements. There is, however different intensity of this culture at different levels of the organization; and this poses a challenge for organizational change. The study of organizational behavior and process has proven that in order for organizational change to be successful, the motivations and benefits must be clearly communicated and all parties involved need to be aligned and supportive (Mortensen, 2010). Utilizing the strong cultural ties to "Lean" and process oriented organization (POO) to explain the potential changes to the global organization proved extremely affective during the 6-months at Novartis; especially at the lower levels, because it is in a language to which they could relate. As for communication at the higher level of the organization, Lean language is also affective. To discuss long term consequences, the dynamic model is particularly helpful to foster organizational change, as it shows the undesirable consequences if no changes are done.

8.1.3 Political

Organizational change always brings about political tension in any company. Global TechOps' "blue sky" vision eliminates the functional groups entirely and creates a purely horizontal organization. There was obvious push back from the heads of these groups, but they had accurate concerns that a purely divisional organization tends to lose functional expertise. Additionally, while the goal is to prepare for continuous manufacturing, it will be many years before a majority of Novartis's products are produced using this technique. Therefore, instead of dramatic change, a gradual change would be much more widely accepted. A solution must clearly address the concerns of balancing ownership of the end-to-end process and maintaining technical knowledge within a process unit.

8.2 Recommendation: Organization Changes and Tools

We have shown that Novartis's process complexities and organization complexities hinder cross-functional communication which, in turn can lead to supply issues are TechOps move to their future state. However, as we see from the 3-lens analysis, moving directly into an organization structure that is based solely on product lines would not fit strategically, culturally and politically within the organization. Furthermore, since TechOps has been so historically divided across functions, there are few resources that have the experience and insight across the various operations; TechOps needs to build these capabilities into their organization over time.

We aim to find a solution that has both short term and long term benefits. In the short term it needs to fix the supply issues and help improve customer service levels. In the long term it needs to synchronize the supply chain to decrease reaction time and increase flexibility and build end-to-end visibility and

capabilities in preparation for continuous manufacturing, and balance brand optimization with technical expertise.

We recommend that TechOps explore the enhancement of the **Supply Chain Brand Lead** role into an established owner of the end-to-end supply process for identified products, look into establishing a **Manufacturing Services and Technology** (MS&T) group that will own technical process changes among the functions and revise the **Key Performance Indicators** (KPIs) to optimize performance end-to-end, be brand focused, expose complexity and trigger proactive responses. All of these changes should be facilitated by additional communication tools and incentives. **Figure 38** gives a visual to the new organization and **Figure 39** gives the recommended implementation plan.

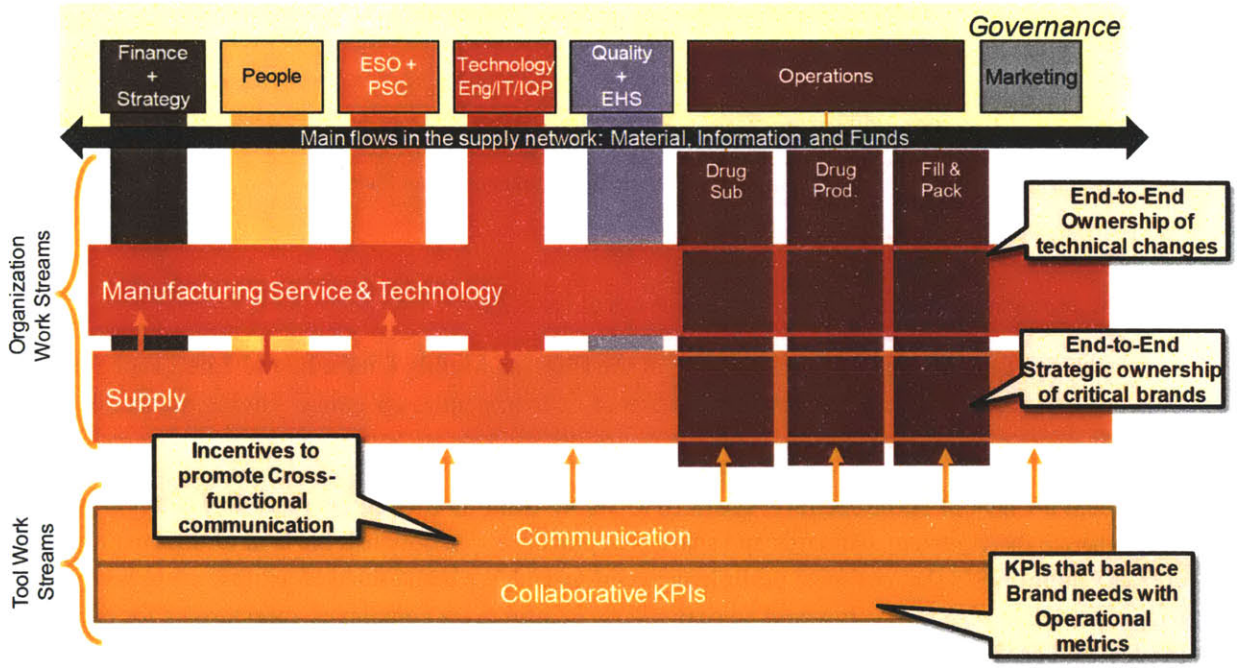

Figure 38: Recommended Practical Vision of TechOps Organizational Structure

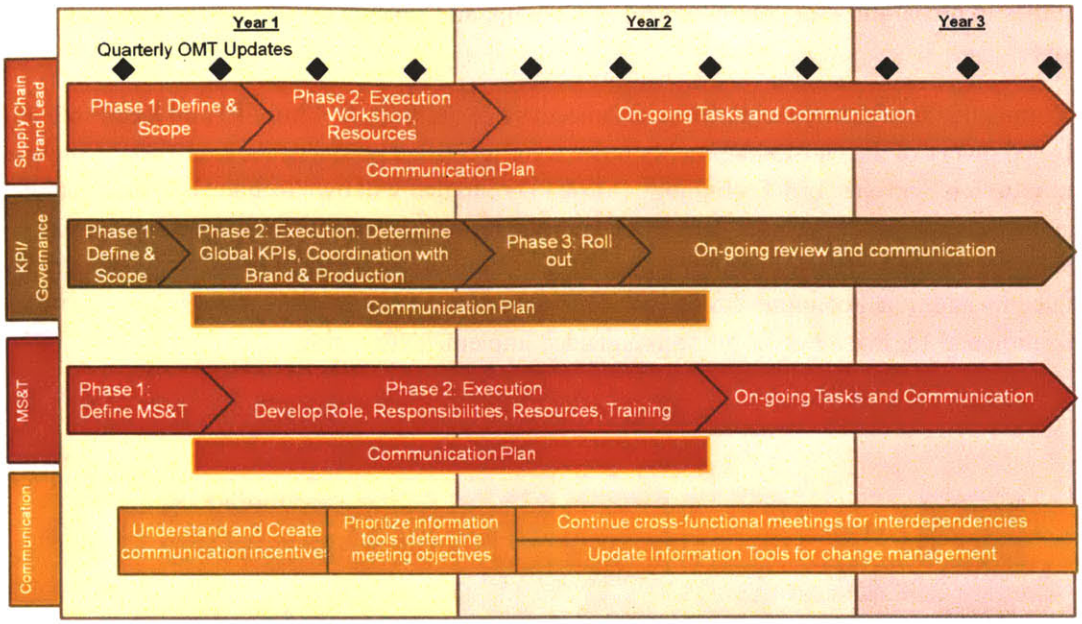

Figure 39: Recommended Implementation Plan

These recommendations directly address the issues at hand:

To attack poor performance, enhance the role of the **Pharma Supply Chain Brand Lead** such that they truly own the strategic vision and implementation of Lean principles on-going. Giving ownership to this role will create a counterpart for the PU heads.

To combat the lack of accountability, establish a **Global Manufacturing Services & Technology group** to set change management standards and share best practices. To diminish the lack of information flow creates **Global KPIs** that optimize performance end-to-end, are brand focused, expose complexity and trigger proactive responses. It would be particularly helpful to set complexity ratio targets for each product and process. This requires determining NVA and VA thus creating a unified metric to show the health of the organization.

8.3 Communication

As Novartis builds trust in the TechOps organization, and reduces the impact of the Organization/Process face with the changes mentioned in **Section 8.2**, communication of the new roles and new KPIs and communication incentive throughout the change process will be a crucial element to the success of the recommended plan as **Figure 40** shows.

Figure 40: Visual Interpretation of Recommendation Interdependencies

By using Novartis's own "Operational Excellence" model, management can create quantitative KPIs and incentives on communication and information sharing. For example, resources may be reviewed on use of IT tools, participation in networking events, and number of times they report an issue constructively.

When communicating the changes to TechOps on a broader scale, management should execute the following steps (Mortensen, 2010)

- Describe main features of the new roles
- Show fit with strategy
- Demonstrate how the organization will evolve with the future vision
- Identify current problems & explain how new structure solves them
- Secure support from key stake holders
- Continuously link to the company culture and values
- Reward appropriate behavior during transition
- Convey sense of continuity & stability

8.4 Follow-on Studies

We have proved that Novartis can benefit greatly from Process/Organization Complexity reduction, and better project management and communication with regards to the product launch and production change processes.

To continue on this path, we recommend TechOps engage in three additional studies in this area:

1. Deep-dive into project management and resource planning – How are resources allocated to the various projects and initiatives? How many projects is one person working on at a given time? What is their utilization? Are project timelines reasonable or will they further persist in the Tiger Team culture? How much project overhead is there? How can we reduce the project overhead?

2. Understanding of projects outcomes – What are the lessons learned from projects? How are they being used to improve future projects? What requirements do managers have to ensure employees are recording outcomes and lessoned learned?

3. Forecasting improvements – what are the forecast errors? How is the global team consolidating product demand forecast? What is the impact of the bull-whip effect? How much of it is coming from internal phantom ordering and how much is external?

8.5 Summary

In this thesis, we proved how the dynamic, nonlinear model shows how product launches, production change requests, production issues and supply issues relate in a global manufacturing organization. We proved the model was a good fit to Novartis Pharma TechOps. By studying its organizational structure, case studying two product processes and conducting a communication study we revealed the organizational and process complexities and inefficient communication structure. We showed that TechOps matched the symptoms of an overly complex organization, and if not improved, may fall victim of the Tiger Team phenomenon. Because it is a good fit to the model, we then made recommendations to combat the specific issues. By also incorporating a 3-lens analysis, we ensure that the recommendation will be accepted and sustained. Finally, we give suggestions for follow-up studies in the field of complexity reduction.

APPENDIX A: Communication Study Details

Part 1: Self Assessment

- Your name (First and Last)
- Department/Location in TechOps where you work (Select one)
- Main form of communication with others
    - Topic (Select one)
        - Business/ Administrative: communication for coordination; scheduling meetings, discussing progress reports, budgeting, etc.
        - Technology/ New Idea: communication for information; discussing process improvements, fixing unexpected production issues, brainstorming, elaborating on new ideas, etc.
    - Scheduled (Select one)
        - Scheduled: meeting set on calendar, regular TC
        - Unscheduled: Impromptu chat, not planned
- Level of interaction with other departments (scale 1-10)
    - 1-3 : Minimal interaction (less than monthly)
    - 4-7: Moderate interaction (between monthly and weekly)
    - 8-10: A lot of interaction (more than weekly, possibly daily)

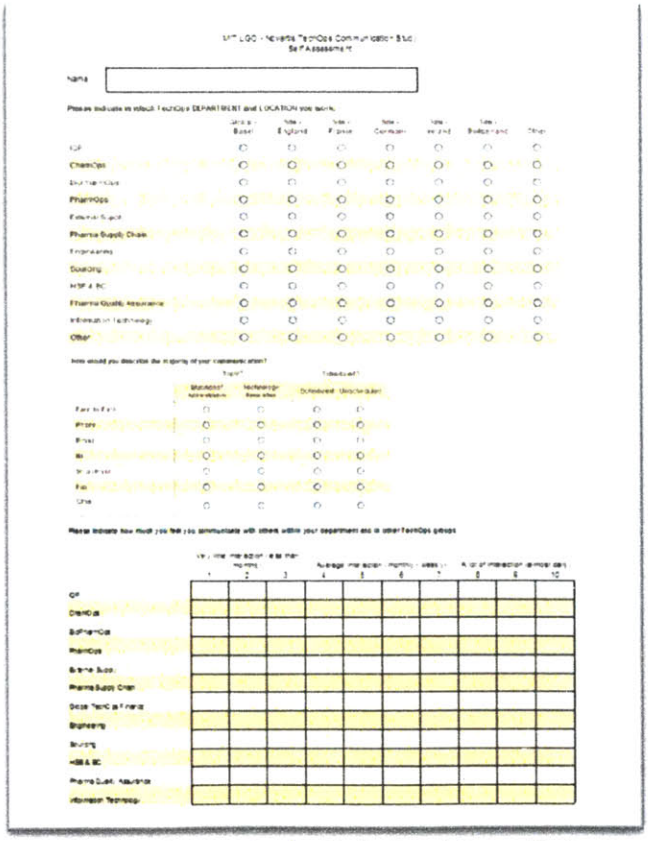

Figure 41: Communication Study Part 1 Survey Design

Part 2: Daily Log

- Names of possible resources are arranged in alphabetical order by the first name
- To find a person, select the letter range of their first name and a list will appear
- Lists contain a sampling people, so you may not find everyone you have interacted with, but please fill out as thorough as possible
- Select the people that you have interacted with throughout the day, and indicated how you talked to them (check all boxes that apply)
    - Face-to-Face
    - Phone (including voicemail you have left and received)
    - Email
    - Instant messenger (IM)
    - SharePoint (share documents, updating schedules)
    - Fax/Memo (including inter office mail)
    - Other

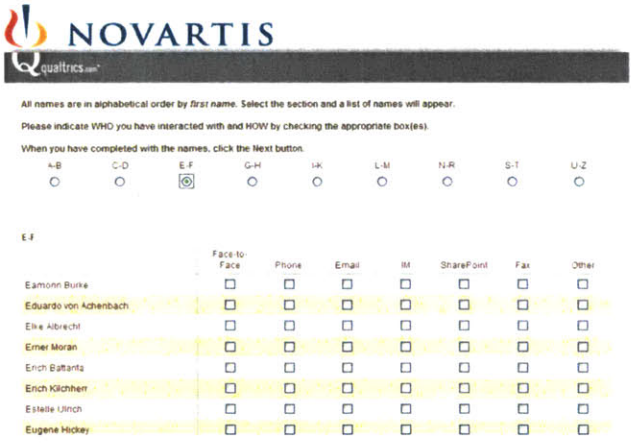

Figure 42: Communication Study Part 2 Survey Design

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