Emerging Market Entry and Risk Assessment Process Analysis in a Biopharmaceutical Supply Chain Organization

By

Seth Brian White

B.S. Industrial Engineering
North Carolina Agricultural and Technical State University, 2006

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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and
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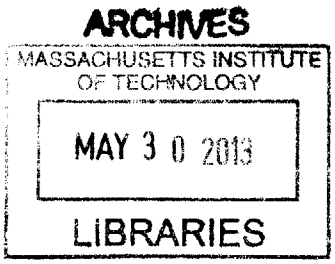

Signature of Author _____
Engineering Systems Division, MIT Sloan School of Management
May 10, 2013

Certified by _____
Qi D. Van Eikema Hommes, Thesis Supervisor
Research Associate, Engineering Systems Division

Certified by _____
Donald B. Rosenfield, Thesis Supervisor
Senior Lecturer, MIT Sloan School of Management
Director, Leaders for Global Operations Program

Accepted by _____
Olivier L. de Weck, Chair, Engineering Systems Division
Associate Professor of Aeronautics and Astronautics and Engineering Systems

Accepted by _____
Maura Herson, Director of MIT Sloan MBA Program
MIT Sloan School of Management

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Abstract

Amgen is attempting to increase the impact that its products make in people's lives. To meet this goal, the company is aggressively working to reach more patients through growth opportunities in international markets and expects to significantly increase its existing footprint and product impact over the next several years. While the current market entry practices for emerging markets are meeting Amgen's needs, rapid expansion poses significant challenges. This thesis explores two primary aspects, the investigation of improvement opportunities in the commercialization of emerging markets and the development of a risk assessment model applicable to new market commercial entry. Both aspects relate to the larger problem of rapid international expansion and support its resolution in different forms.

The assessment of improvement opportunities for emerging market commercialization strives to develop a tangible set of actions the organization can take forth in order to enhance the planning and execution of new market entry. The analysis is accomplished through an in depth study to determine the current level performance for commercial market entry. Based on the current state determination, a future vision is established which incorporates fundamental principles of operational excellence methodologies, integrating various techniques to develop a cohesive approach for improving current entry practices. An improvement roadmap is developed, detailing out specific actions, utilizing a phased implementation approach that allows for making incremental improvements.

The risk assessment model establishes a tool the organization can utilize in order to properly identify risk associated with emerging market entry and enhance the decision making process that occurs at a senior leadership level as to whether or not a country should be entered. A scenario based evaluation methodology integrates cross-functional expertise across the organization assimilating information that is normally isolated to a small group within the company. The model determines risk levels for each scenario, generates a risk report and an output review is conducted with subject matter experts (SME) and functional leads. Scenarios that potentially require remediation are reviewed in a detailed risk assessment and resolved as necessary. Any substantial cost associated with control efforts are incorporated into the financial analysis for the target launch country, providing a better depiction of cost versus reward. Thus, the model increases the firm's ability to make agile risk-informed market entry decisions while providing a standardized method that is scalable cross-regionally.

Thesis Supervisor: Qi D. Van Eikema Hommes
Title: Research Associate, Engineering Systems Division

Thesis Supervisor: Donald B. Rosenfield
Title: Senior Lecturer, MIT Sloan School of Management

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Biographical Note

Seth White was born in New Orleans Louisiana and raised primarily in North Carolina. He attended North Carolina Agricultural and Technical State University, graduating in 2006 with a Bachelor of Science in Industrial and Systems Engineering. Joining ABB Inc. in 2006, he worked in the Power Products Division at a Medium Voltage facility in Greensboro, North Carolina. He then attended North Carolina State University (NCSU), graduating with a Masters of Integrated Manufacturing Systems Engineering. During the course of his education at NCSU, he worked for John Deere Inc. as a research assistant, focusing on manufacturing improvements at the Turf Care facility in Fuquay-Varina, North Carolina. Prior to joining the Leaders for Global Operations (LGO) program he spent over four years as an internal consultant in the Quality and Operational Excellence division of Corporate Development at ABB Inc. Upon completion of the program, he plans to work for Amgen Inc. in Thousand Oaks, California.

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1 Company Background

In 1919, Hungarian agricultural engineer, Karl Ereky, developed the term biotechnology, combining biology and technology, to mean the application of biology to convert raw materials into useful products for humans. The biotechnology industry began during the 1970s in California and Amgen was founded less than a decade later. Amgen primarily produces biotechnology medicines in the form of large, complex molecules comprised of proteins as compared to small molecule medicines comprised of chemical compounds.

The chapter will provide an overview of the company, followed by a review of the international expansion effort and conclude with the organizational structure relevant to the thesis.

1.1 Amgen Overview

Amgen is a market leader in discovering, developing and providing human therapeutics within the biotechnology industry. With a primary organizational mission to serve patients, the company has repeatedly put the patient first. Amgen's products have changed the medical industry, helping patients fight serious illnesses such as cancer, arthritis, kidney disease, bone disease and other potentially devastating ailments. Amgen is an active innovator with a number of promising new medicines in its robust pipeline. The company is committed to advancing science-based medicines and continues to demonstrate its commitment through sustained innovation, attained in part through university research and strategic partnerships.

Amgen utilizes precise manufacturing of biological medicines to construct a portfolio of nine primary products under ten brand names distributed across markets worldwide: Aranesp® (darbepoetin alfa), Enbrel® (etanercept), EPOGEN® (epoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim), Nplate® (romiplostim), Prolia® (denosumab), Sensipar® (cinacalcet), Vectibix® (panitumumab) and XGEVA® (denosumab).

Amgen is a California based corporation, founded in 1980, with its headquarters in Thousand Oaks, California. Currently, Amgen supplies its life saving therapeutics in over 75 countries, employs approximately 18,000 employees globally, and has revenues of approximately $17.3 billion (2012). Additional information regarding Amgen can be found at www.amgen.com.

1.2 Reaching More Patients through International Expansion

A primary corporate goal over the past several years at Amgen is to increase the number of patients that have access to the company's lifesaving medicines. As a United States based company, Amgen has traditionally focused on the domestic market and European markets. Some emphasis has been placed on international markets but the organization is arguably underpenetrated in the international market space compared to its competitors and parallel markets. To close this gap in international market penetration and more importantly reach more patients, the company has embarked on an effort to aggressively make its products more accessible in international markets. This consists of an international expansion effort that sets forth to significantly increase the number of countries in which the company operates and to increase the product offerings available in existing or newly entered countries. The drawback to the rapid international expansion effort is that such an initiative presents a significant challenge to the company when there are a limited number of resources allocated to new market entry activities. The result has created a segmented regional structure, in varying states of maturity, which have independently developed standards for how entry should be assessed and execution conducted. Proper management and reporting of the regions has proven to be difficult as each region has continued to grow in scale and individual regional complexities are beginning to have an adverse impact on the organizations ability to effectively penetrate new markets.

1.3 Organizational Structure

As a relatively young company in the industry, Amgen has made a substantial impact in a short amount of time. Having the feel of a startup but with the scale of a multinational organization, Amgen has been able

to make agile decisions and remain quite profitable. The company is comprised of three primary divisions: Research and Development, Operations, and Marketing. Within the Operations organization, the Global Supply Chain (GSC) group is responsible for actualizing the goal to increase market penetration in international markets with the close collaboration of the International Quality group. The GSC group consists of functions that support planning, scheduling and distribution, as well as internal improvement groups tasked with enhancing the entire value chain cross-regionally. The international expansion efforts within the GSC group are comprised of five primary units: European Union, Middle East Africa, Latin America, Asia (Region 1, Region 2, Region 3, and Region 4 respectively) and Alliance Management. Each unit supports global delivery of Amgen products produced at the company's manufacturing sites. During the internship European Union, Middle East Africa, and Latin America regions were currently active in commercialization efforts for international markets and the Asian region is in the strategic development phase. The Alliance Management group primarily utilizes partnerships with third parties to manage and distribute products within specific markets. For the purposes of this thesis, the concepts employed are only applicable to the European Union, Middle East Africa and Latin America regions due to their current state of development. It is worthwhile to mention that at a corporate level, Global Operations Teams (GOT) have oversight for specific products within the Operations division, yet depending on the unit, varying structural forms are utilized for resourcing within the GSC regions. Certain regional units establish resources based on product type, aligned with the GOT structure, whereas others are oriented by geography.

1.4 Thesis Outline

This document is organized into six chapters:

- Chapter one provides an overview of Amgen and the biotechnology industry. Pertinent background information is provided relating to Amgen's products, mission and organizational structure.

- Chapter two describes the context of the problem faced by the organization, the objective of the project and how the research was conducted.
- Chapter three gives an overview of the literature that was consulted to formulate the two research areas into a cohesive structure.
- Chapter four details the Emerging Market Entry Process Analysis utilizing the DMAIC Six Sigma improvement framework to describe the process.
- Chapter five describes the Emerging Market Entry Risk Assessment Model, reviewing the previous process, model development, functionality and limitations as well as a recommended process for sustainment.
- Chapter six closes the thesis with key takeaways that were provided and potential future work from each research area.

2 Introduction

The content presented in this thesis outlines the results of a six month internship with Amgen Inc. from May 2012 to December 2012. The internship was championed by the Global Supply Chain (GSC) group with a task to investigate the impact of Amgen's international expansion efforts on the company from emerging market entry commercialization. Two major problems were targeted as a result of rapid emerging market entry, including market entry practices that were not effectively executed, and management's lack of complete information to make risk-informed entry decisions.

During the six month period the internship was based at the company headquarters in Thousand Oaks, California. However, due to Amgen's current network, many sites across the globe were involved extensively. This consisted of a cross-functional and multi-site team to develop and streamline an approach which could be utilized to resolve the targeted challenges associated with rapid international expansion due to emerging market commercialization. Additionally, a pilot project was conducted to develop and validate an Emerging Market Entry Risk Assessment Model (EMERAM) which could be used to enhance management decision making, but piloting was omitted for improvements identified for the execution of market entry practices.

2.1 Problem Statement

Amgen has embarked on an effort to increase the impact that its products make in people's lives. To meet this goal, the company is aggressively working to reach more patients through growth opportunities in international markets and expects to significantly increase its existing footprint and product accessibility over the next several years. While the current market entry practices for emerging markets are meeting Amgen's needs, rapid expansion poses two significant challenges that have been targeted and will be explored for the commercialization of new markets:

1. Market entry processes are underdeveloped for emerging markets and lack alignment across the regions and functions established in the company, thus impacting the effectiveness of commercial planning and execution.
2. The current risk assessment method for emerging market entry needs maturity to ensure objectivity and provide purposeful risk-informed management decision making.

In order to successfully increase the impact the company and its products make at a global level, Amgen must continue to expand its international footprint into emerging markets. The desired expansion can only be accomplished if the company is able to overcome the challenges associated with highly variable regional practices and local market requirements. Without such improvements, the organization will face substantial costs and decreased efficiency. To overcome such obstacles, Amgen must embrace the integration of operational excellence principles into emerging market entry commercialization practices and introduce an enhanced emerging market entry risk assessment framework.

2.2 Project Objectives

The thesis will explore the risks and challenges associated with emerging market entry commercialization for a biotechnology company such as Amgen. The results of the thesis will provide valuable insight into methods which can be incorporated to enhance the effectiveness of Amgen's international expansion efforts through two primary research areas and associated objectives:

1. Emerging Market Entry Process Analysis
    - Investigate and document the current emerging market entry commercialization process to assess opportunities for improvements.
    - Utilize Six Sigma improvement Define-Measure-Analyze-Improve-Control (DMAIC) methodology to establish improvement opportunities and report project progress for commercial entry into emerging markets [1].

- Develop future state improvement roadmap with a time bound action plan, to streamline emerging market entry commercialization execution through the integration of operational excellence principles, for execution by the Global Supply Chain unit.

2. Emerging Market Entry Risk Assessment Model (EMERAM)
    - Assess the current risk assessment methodology to evaluate the effectiveness for its use in providing risk-informed decision making
    - Develop a risk assessment model for use in analyzing potential risks associated with emerging market entry commercialization and provide key stakeholders with risk-informed market entry decisions
    - Establish a global platform and supporting process for integration of the risk assessment model into Amgen's governance phased-gate review process

The emerging market entry commercialization process is divided into six business phases: Business Case, Commit to File, Submit File, Commit to Launch, Launch, and Life Cycle Management (LCM). For the thesis, the scope of commercialization phases studied span from Business Case development up until launch. The image shown in Figure 1 provides a visual depiction of the two research areas and the relation to the emerging market entry commercialization process. Each research area sets forth to alleviate the problem of international expansion through rapid emerging market entry yet targets different aspects of the larger problem.

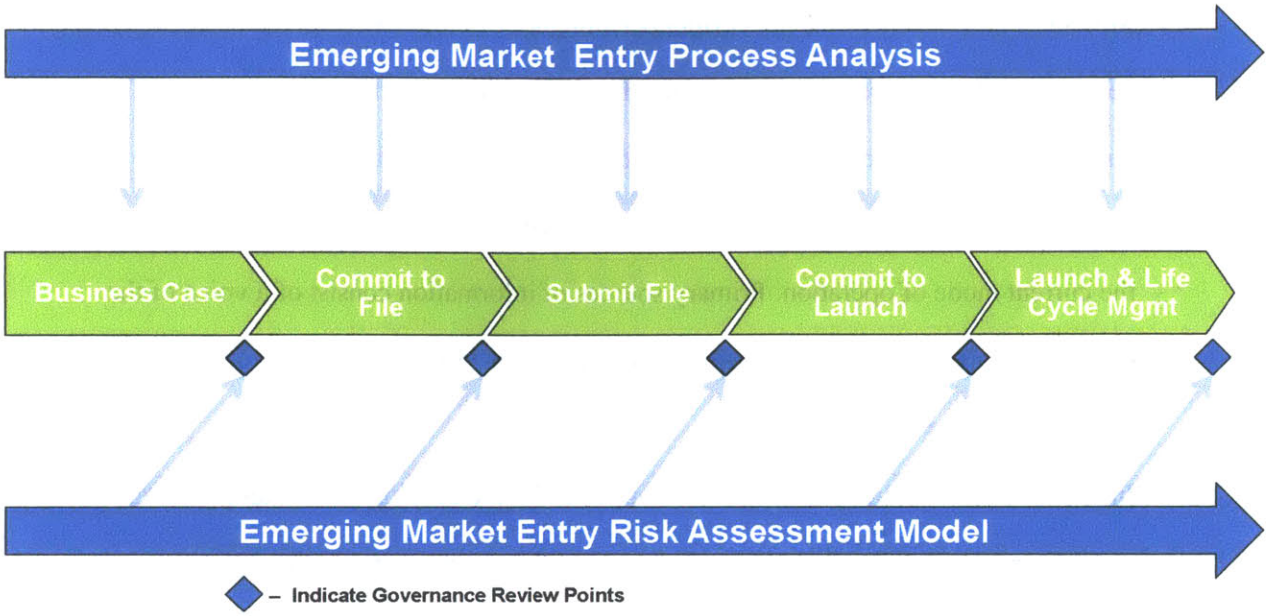

Figure 1: Primary Research Areas and Commercialization Phases

2.3 Research Methodology

Due to the nature of the project and differing target goals of the overall problem of rapid emerging market entry, differing methodologies were used for the respective research areas. Each approach is outlined below:

1. **Research Area 1 Methodology – Emerging Market Entry Process Analysis:**

The Emerging Market Entry Process Analysis utilizes the continuous improvement Six Sigma DMAIC methodology to establish a set of recommendations with a supporting implementation improvement roadmap. The roadmap seeks to establish a path forward by providing time bound tangible actions for the organization to act upon the primary improvement opportunity findings associated with the emerging market entry commercialization process. The research area has five phases with the associated objectives of each phase outlined below:

1) Define Phase – Gain agreement on project scope, deliverables and develop formal research area goal

2) Measure Phase – Determine the current performance of the market entry process, establish new metrics as appropriate and set targets for future state performance
3) Analyze Phase – Discover the primary root causes which inhibit the execution of the market entry process. Integrate varying sources of information to develop a holistic understanding of the current mode of operation. Primary sources of information consist of a voice of the customer analysis, interviews of subject matter experts (SME), data analysis and existing documentation review.
4) Improve Phase – Institute a framework supported by the development of an improvement roadmap containing detailed actions that can be taken by the organization to incorporate improved project management and operational excellence philosophies.
5) Control Phase – Determine efforts that can be made to maintain and enhance improvements to the implementation roadmap as well as opportunities for future work.

2. Research Area 2 Methodology – Emerging Market Entry Risk Assessment Model:

The Emerging Market Entry Risk Assessment Model Analysis utilizes standard risk quantification and management techniques to establish a scenario based evaluation methodology. To develop the model, risk scenarios for emerging market entry commercialization were pre-determined with the support of subject matter experts and held constant for each new entry risk assessment. Components of risk were assessed to determine the most appropriate method to evaluate each risk scenario. Risk quantification methods supported the classification of scenarios utilizing the risk matrix or risk mapping methodology. The research area has six phases with the associated objectives of each phase outlined below:

1) Current state process – Baseline and document the current methodology utilized for evaluating and communicating risks associated with emerging market entry commercialization
2) Define model goal – Determine scope of work to be completed, formal research area goal and applicable modes of entry

3) Model elements and functionality – Determine the aspects necessary to properly identify and assess risks, and incorporate the necessary model functionality to support a robust risk assessment
4) Process for use – Develop a process for proper model usage and create associated documentation
5) Validation and enhancements – Pilot model and make improvements based on pilot results
6) Integration – Develop proposal for integration into companywide review process and align with senior management expectations

3 Literature Review

Prior to developing the emerging market entry process analysis framework and the EMERAM, a significant amount of effort was expended in order to research the existing approaches applicable to each. There is a substantial amount of literature on the topics of operational excellence and risk management practices with a number of differing approaches. Operational excellence methodologies span from approaches such as Six Sigma or the Theory of Constraints (TOC), to those less familiar such as Demand Flow Technology (DFT) [2]. Risk management approaches utilize various methods to quantify, prioritize and ultimately minimize the occurrence of a potential risk outcome. Each approach has limitations and critiques as to why one approach may be more suitable over another. In the following sections, a review of relevant aspects to each topic will be covered.

3.1 Operational Excellence Methodologies

The concept of operational excellence is a philosophy driven by the leadership in a company with a focus on how an organization can utilize continuous improvement concepts to develop a systematic and sustainable approach to making tangible improvements in its long term enterprise performance. The emerging market entry commercialization process can be viewed as a type of production process for which the operational excellence methodologies reviewed in this section are applicable. Generally, metrics are established in the organization which aligns the company to focus on the vital few components of performance that will help the company to achieve its aspirational organization. This can be paralleled to the Pareto principle of focusing on the vital few, to largely achieve the results that are desired since in many instances approximately 80% of effects arise from 20% of the causes [3]. An additional assumption is that the metrics of organizational performance for operational excellence must be aligned with the rewards for individual performance to ensure that there is not a conflict in the incentives that drive individual behaviors [4]. Many methodologies exist for how an organization should go about implementing operational excellence, namely in the form of continuous improvement approaches. Yet no recognized approach is credited with being the dominant model. Rather it is generally more appreciable to

utilize a combination of approaches to attain a desired objective. The Theory of Constraints (TOC) school of thought claims that to make improvement, the process constraint or bottleneck should be the primary focus. That is, in order to achieve the ultimate goal of the company to make money, the limiting factor in the process must be exploited in order to achieve the maximum throughput in the entire system. This can take form internally in the process or outside of the scope of control, those being limitations in market demand or material supply [5]. The lean approach to continuous improvement states that muda or waste should be the focus of improvement. Originally, waste was identified as occurring in seven forms: transportation, inventory, motion, waiting, over-processing, over-production and defects [6]. However, through continued use of the lean methodology, an eighth form of waste has been identified, latent skill or human potential. It is argued that in order to make improvements in the seven wastes, an organization must capitalize on employee creativity [7]. Lean is sometimes compared to the scientific method in which an organization conducts controlled experiments to make change [8]. Through the use of lean, waste can be driven out of the system to achieve enhancements in performance. The Six Sigma approach to operational excellence seeks to optimize the quality of process outputs and to drive variability out of the system through the identification and removal for causes of error [9].

Each of the approaches has been critiqued for having shortcomings as to how best make improvement in a system. The limitation of the TOC approach is that if only the constraint is focused on, then there is suboptimal performance within differing aspects of the process or system. This is a concerning issue, not only from an efficiency standpoint, but in situations where multiple steps in the process are closely constrained or a wandering bottleneck exists. Lean is criticized for not prioritizing where the focus should occur and that with a limited number of resources it is not feasible to drive all waste out of a system. Six Sigma methodology falls short in that it seeks to only optimize a process which may not need optimizing and does not provide a strong set of tools in order to select prioritization efforts [9].

As a result of the shortcomings in each improvement philosophy, there is no dominant framework that can be universally applied to attain the desired results in all types of systems. Instead, it is more ideal to

integrate these philosophies into a cohesive framework which allows for the ability to make overarching improvements as best determined by the desired system enhancement and need of the organization. Utilizing a combination of TOC, Lean and Six Sigma (TLS) can allow for the creation of an improved system. Through the use of TOC, a system constraint can be identified and the organization can focus on the aspects that matter to shareholders. The application of Lean allows for the system constraint to be exploited by removing or minimizing the process waste. Finally, through the application of Six Sigma, the system constraint capacity can be elevated, thus increasing system throughput by systematically optimizing the process at the system constraint, through the removal of waste and enhanced quality. Thus, there is no dominant approach, but rather through the utilization of multiple methodologies, it is possible to achieve a state of operational excellence within a system [10].

3.2 Queuing Theory

Queuing theory is the mathematical study of queues or waiting lines [34]. Amgen's commercialization process for emerging markets can benefit from the application of queuing theory in that there are competing demands for the limited resources in the entry of new markets. Thus jobs can back up the system, constrain resources and overload the organization. A queuing system consists of discrete objects that may be called items which arrive at a given rate into the system, generally denoted as λ [28]. Arrival rates vary but often a Poisson process for the number arrivals (or equivalently an exponential distribution for the time between arrivals) is assumed to provide an arrival pattern which represents a real-life system and provides sufficient accuracy [35]. A Poisson process requires not only independence of time intervals but independence of the time since the previous event on the time to the next event. Thus under a Poisson process it does not matter if there have been one, two or three time units since the last one, the distribution until the next one still remains the same. In this sense the process is what is known as a memoryless process. Within the queuing system items form a queue when a system resource or server is blocked or utilized and enters service at based on the number of servers and mean service rate often denoted c and μ respectively. Once serviced, an item exits or departs the queuing system. Utilization, denoted ρ, is a

measure of system resource usage to the units which arrive at the resource. The formula for utilization takes the proportion of the mean arrival rate over the product of the mean service rate and the number of servers, that is [35],

$$\rho = \frac{\lambda}{\mu \, x \, c}$$

Utilization should be less than one for a system to properly function and if it is greater than one the queue will explode, growing at the rate of arrival as time progresses. A lower utilization rate corresponds to a reduction in queuing for units in the system, but in some cases may be considered inefficient as the system has a larger proportion of time in which is remains idle.

Little's Law is a queuing theory theorem which states that, under steady state conditions, the average number of items in a queuing system is equal to the product of the average arrival rate and the average time an item spends in the system. The formula for Little's Law is shown in the equation below, where L represents the average number of items in the queuing system, λ as the average arrival rate per unit time and W as the average waiting time [28]:

$$L = \lambda W$$

The theorem is regarded as quite simple yet a remarkable result since the relationship is not influenced by the number of servers nor the queue orientation, the arrival distribution, the service distribution, or almost anything else [36]. The simplicity of the formula allows for it to be extremely powerful and useful equation, supporting "back of the envelope" calculations.

3.3 Risk Management Approaches

Risk management is a philosophy which aims to identify, assess and prioritize risk through the organized use of resources, in order to control, monitor or mitigate the probability of an incident's occurrence [11]. Risk management approaches are valuable to Amgen in order to systematically assess and ascertain

relevant risks to the company due to emerging market commercialization. Risk categorization is a method used to systematically organize risks in order to identify the root causes in a consistent manner. There are a number of different suggested groupings to categorize risk which largely varies between literature source and organizations. Such examples can occur due to a variety of factors but are commonly researched in categories relating to financial risks, natural disasters, geo-political risks, intellectual property, and transportation and logistics. The Risk Breakdown Structure (RBS) is a method utilized to logically enumerate risks relating to a specific risk category, into subcategories in order to achieve an exhaustive list of potential failures [12]. A number of risk management standards have been developed by organizations such as the Project Management Institute (PMI) or the International Standards Organization (ISO) as well as government organizations such as NASA or the DOD [12][13][14][15]. Each technique generally varies in form depending on risk application, yet there are several aspects that are common across most approaches. Generally risk management approaches assess risk in the form of severity of a risk and probability of its occurrence. A risk matrix is useful in allocating combinations of severity and probability of occurrence to classify a risk level [14]. Some techniques also include the use of a detectability factor, such as the FMEA methodology [16]. Risks are generally monitored, and progression is tracked through tools such as a risk register, which identifies a risk, assigns action and ownership, and is used to monitor the risk until it is resolved [17]. Additionally, a risk register can be used to create a visual representation to communicate and prioritize risk control efforts in the form of a risk severity plot. An example of a risk severity plot is shown in Figure 2 where each diamond represents an individual identified risk that has a functional owner. Generally it is recommended to take action on risks that are plotted within the top right quadrant. In all forms, risk management seeks to minimize the impact of a risk and communicate risk prioritization to relevant parties.

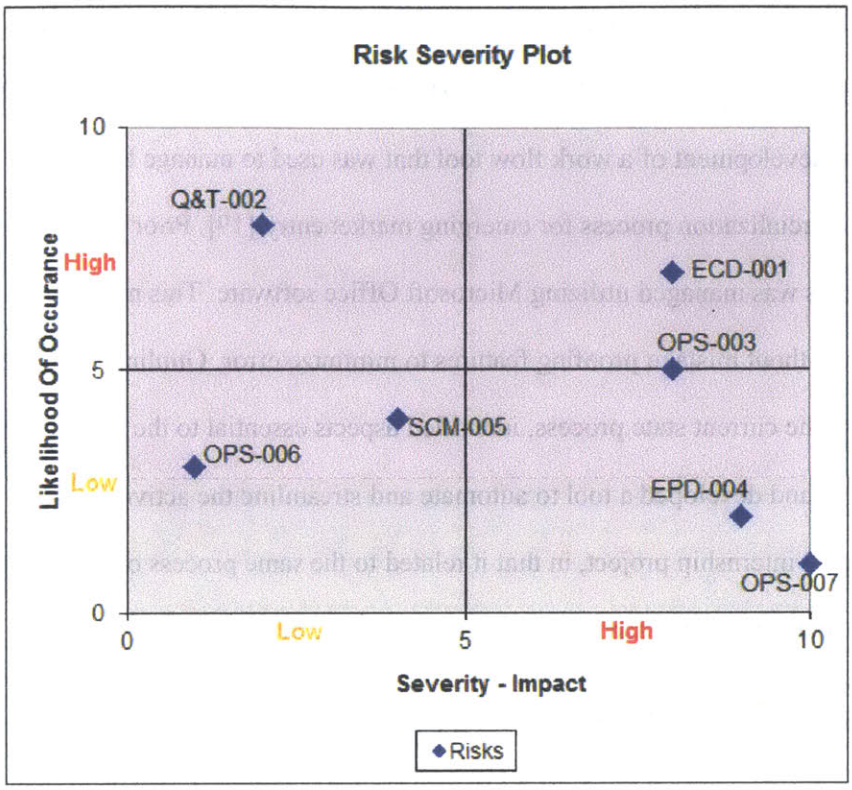

Figure 2: Risk Register Graphical Example

3.4 Review of Related Theses

A number of theses have been written on topics which relate to both operational excellence as well as risk management. The Leaders for Manufacturing (LFM) program thesis, Development of a Total Landed Cost and Risk Analysis Model for Global Strategic Sourcing, by Brian Feller describes the process used for creating a total landed cost and risk model for application of strategic sourcing employed at PerkinElmer, Inc [18]. The thesis provides the details of the aspects relevant to constructing a risk model for evaluating a supplier, considering 20 different factors to develop a risk portfolio. The risk portfolio is useful in supporting the decision making process when multiple suppliers are considered for a sourcing decision. A systematic approach to determining and monitoring risks in a similar method to that of the risk model developed by Feller will benefit Amgen's efforts in emerging market commercialization.

The Leaders for Global Operations (LGO) program thesis, Optimization of SKU Creation Process and Adherence Improvement through use of Workflow Management, by Richard Gimilin, was useful in its review of the initial development of a work flow tool that was used to manage the project management aspects of the commercialization process for emerging market entry [19]. Prior to implementation of the tool, the entry process was managed utilizing Microsoft Office software. This method was a labor intensive approach without mistake proofing features to minimize error. Gimlin's thesis identified the activities mapped to the current state process, identified aspects essential to the commercialization project management process and developed a tool to automate and streamline the activities. Much of his work paralleled the author's internship project, in that it related to the same process of emerging market entry commercialization and delved into aspects necessary to execute new entry.

Finally, the LFM program thesis, Development of a Global Facility Location Analysis Tool, by Briana Johnson provided an approach for a location decision support analysis utilizing the Analytic Hierarchy Process (AHP) [20][30]. The thesis provides a review of the factors associated with facility location and how the use of the AHP process supported qualitative tradeoffs of individual sites in quantitative form to determine an optimal facility location selection. The inclusion of an AHP process or similar methodology can improve the allocation of resources for the prioritization of new target country entries for emerging markets.

3.5 Chapter Summary

After reviewing a number of literature sources for approaches on operational excellence, queuing theory and risk management, two main themes occurred. First, the methodologies for continuous improvement and queuing theory must be integrated in order to develop a robust framework for improvement. Second, the risk management techniques that exist each attempt to minimize the occurrence of a risk event, yet no dominant model or tool has been proven to be substantially more impactful than another. The optimal application of operational excellence, queuing theory and risk management methodologies is found not through an individual approach, but rather through the selection and use of a method that can be

successfully applied in an organization. This means that although certain solutions will bring more merit in one organization, they may not be as beneficial in another. Thus, having a methodology or set of methodologies that can be accepted by the company will directly impact the firm's success with a given approach.

4 Emerging Market Entry Process Analysis

The Emerging Market Entry Process Analysis consisted of an assessment to determine improvement opportunities in Amgen's management and execution of new market entry commercialization for emerging markets. The Six Sigma Process Improvement DMAIC methodology was used as the framework to manage the assessment of this research area. This approach was chosen as it provides a foundation for a structured project approach, specific tools which can be utilized, and is most appropriate when the intent of the project is to make enhancements or improve an existing process due to inadequate performance [21]. In the following sections, the DMAIC phases will be discussed and more specifically, how they were used as the project methodology to understand the current state and determine an approach to improve the emerging market entry process supported by tools of the TLS improvement methodology.

4.1 Define Phase

The define phase was used to gain agreement on project scope, deliverables and ultimately develop a formal project goal. The first step was to develop a clear understanding of the current state process for emerging market entry. This aspect of the project was achieved through a number of actions to investigate and collect pertinent process parameters. The investigation began by focusing on establishing the project team and identifying the project champion. Then a stakeholder analysis was conducted along with informational interviews to collect information at the functional levels of the organization. A review of process documentation, available data and metrics and brainstorming sessions complimented the process to clearly define the problem. A number of process mapping exercises took place utilizing methods such as swim lane process mapping and Suppliers-Inputs-Process-Outputs-Customers (SIPOC) to document the as-is process. The swim lane process map supported the identification of the current state process by segregating functional process activities throughout specific commercialization phases. The SIPOC was exceptionally helpful at determining the primary elements of the complex emerging market entry commercialization process and defining the project scope [22]. The investigation concluded with benchmarking efforts, site visits to the international expansion headquarters and literature reviews of

relevant matters. The current state process map for the emerging market entry commercialization process can be seen in Figure 3 below. It is worthwhile to mention that the site visit to the international expansion headquarters was critical as the vast majority of emerging market entry launches and order fulfillment occur through this location.

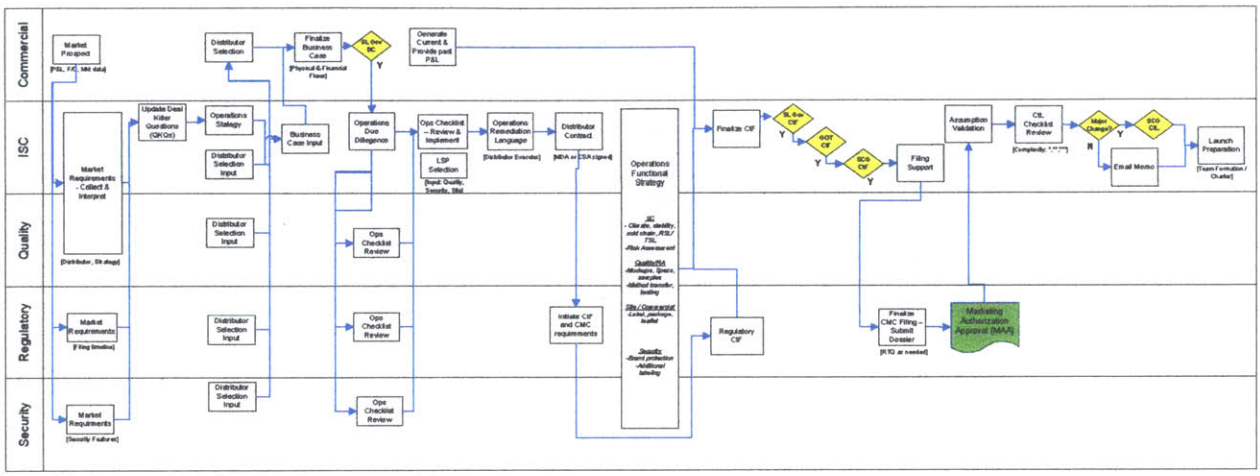

Figure 3: Current State Process Map

After reviewing the relevant aspects of the process, it was agreed that this research area goal would be to develop an implementation roadmap for integrated operational excellence into the emerging market entry process. This would allow for a standardized emerging market entry process to be developed that attempts to maximize process execution in terms of cost, speed and quality. The final output of this phase was a project charter and project timeline for the emerging market entry process analysis.

4.2 Measure Phase

The measure phase was vital in determining the current performance of the commercial market entry process and setting targets for the future. Stakeholder interviews and team focus groups were used to determine and agree upon the project Critical to Quality's (CTQ). This required the involvement of a large number of organizational functions including international quality, global supply chain, transportation, planning and scheduling, shared services, legal, project management, commercial operations and regulatory affairs. An extensive discussion ensued during these meetings, in order to

ensure that there was perceived value in each measurement that would be included. All established metrics related to cost, speed or quality of commercial market entry execution. The specific metrics identified for the project are listed in Figure 4.

Speed	
Cycle Time	BC Initiation - BC Submission
	BC Submission - BC Approval
	BC Approval - CtF Approval
	CtF Approval - File Submission
	File Submission - MAA
	MAA - CtL Approval
	CtL Approval - Launch
Total Throughput Time (TTPT)	BC Initiation - Launch
Work in Progress (WIP)	Number of open filings per region per month
	Number of open filings per project manager per month
	Number of open launches per region per month
	Number of open launches per project manager per month
	Number of open maintenance per region per month
	Number of open maintenance per project manager per month
Utilization	Resource utilization time / Available time

Cost	
Cost of Quality	Prevention Costs
	Appraisal Costs
Cost of Poor Quality	Internal Failure
	External Failure
Cost of Launch	Dollars / Launch
	Dollars spent on due diligence
	Dollars spent on resourcing
	Unplanned resourcing / management intervention
Fees	Customer concessions / discounts
	Legal Fees
	Penalties: liquidated damages, fines
Planning	Dollars of Scrap
	Dollars expended due to Margin Slippage / Erosion
	Dollars expended due to Delays
	Forecast Accuracy

BC = Business Case
CtF = Commit to File
MAA = Marketing Authorization Approval
CtL = Commit to Launch

Quality	
First pass yield	Yield per execution phase
Rework	Percentage of Rework
Scrap	Product scrap

Figure 4: Project Critical to Quality's (CTQ's)

To define performance standards, it was first necessary to determine baseline values for each CTQ. This information was gathered through data mining of information systems and databases then taking the average of each measure. The primary systems utilized were the company enterprise resource planning software and the operations performance database. After baseline values were determined per CTQ, target improvements were set. The deliverable of this phase was to establish the metrics which would be used to assess the effectiveness of the improvements made to the emerging market entry process.

Due to the long duration of the commercialization process, it was not possible to conduct a Measurement System Analysis (MSA) during the course of the internship. A MSA is an experiment beneficial for identifying sources of variation in a measurement. The goal is to validate the repeatability and reproducibility of the system for each identified CTQ [1].

4.3 Analyze Phase

During the analyze phase, the objective was to determine the primary root causes which inhibit the execution of the market entry process. The first step in root cause determination was to establish the emerging market entry process capability. Data sampling and basic statistical analysis allowed for the determination of current launch performance within some degree of statistical certainty. The analyzed data was segmented and stratified by region, resource and product to determine potential trends. It is worthwhile to mention that when analyzing the coefficient of variation for the processing time of commercialization activities associated with emerging markets, values substantially larger than one were determined for regions 1, 2 and 3. The coefficient of variation (C_V) can be used as a measurement of commercialization launch distribution dispersion and defined as:

$$Cv = \frac{\sigma}{\mu}$$

Generally, a distribution with a coefficient of variation of 1.0 or below is considered low-variance [23]. The coefficient of variation values indicate that when the standard deviation of the commercialization process time, for each product launch in the emerging market entry process, is compared to average commercialization process time, it is several orders of magnitude higher. A major component of the variability within the commercialization process can be attributed to various forms of execution delays. Thus, the findings from the process capability assessment determined that the entry process is highly variable based on launch region, resource and organizational priority.

To investigate the opportunities further, a number of Six Sigma and continuous improvement tools were utilized to support deeper investigation. This consisted of a brainstorming session to develop a Current Reality Tree (CRT) to qualitatively identify the root cause(s) of improvement opportunities relating to the commercialization process through the identification of undesirable effects [24]. The outcome from this exercise was that the group of participants viewed themselves as being overburdened with work and thus

their ability to complete a job effectively was negatively impacted. This was primarily associated with the inability of various functions to communicate available capacity and plan launch activities accordingly. A fishbone or cause-and-effect analysis allowed the team to delve further into the causes for resource overburdening [25]. The major themes from the analysis identified complexities in available resources, process variability and information availability as seen in Figure 5.

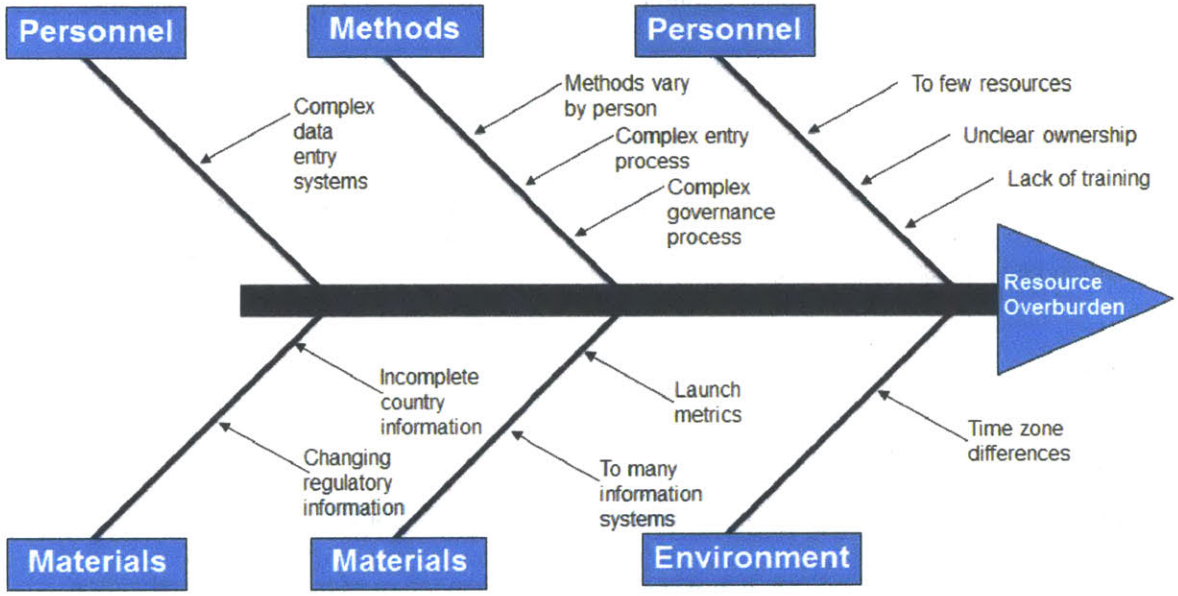

Figure 5: Cause-and-Effect Diagram - Resource Overburdening

Finally a Pareto analysis was conducted to analyze the reason codes for execution delays [3]. As shown in Figure 6, the findings of the Pareto analysis indicate that overscheduling of resources and incomplete information are the major causes of execution delays in the commercial entry process. In essence, this can be attributed to high levels of Work in Process (WIP), which result in overutilization of resources, causing an impact on the quality of work that is performed.

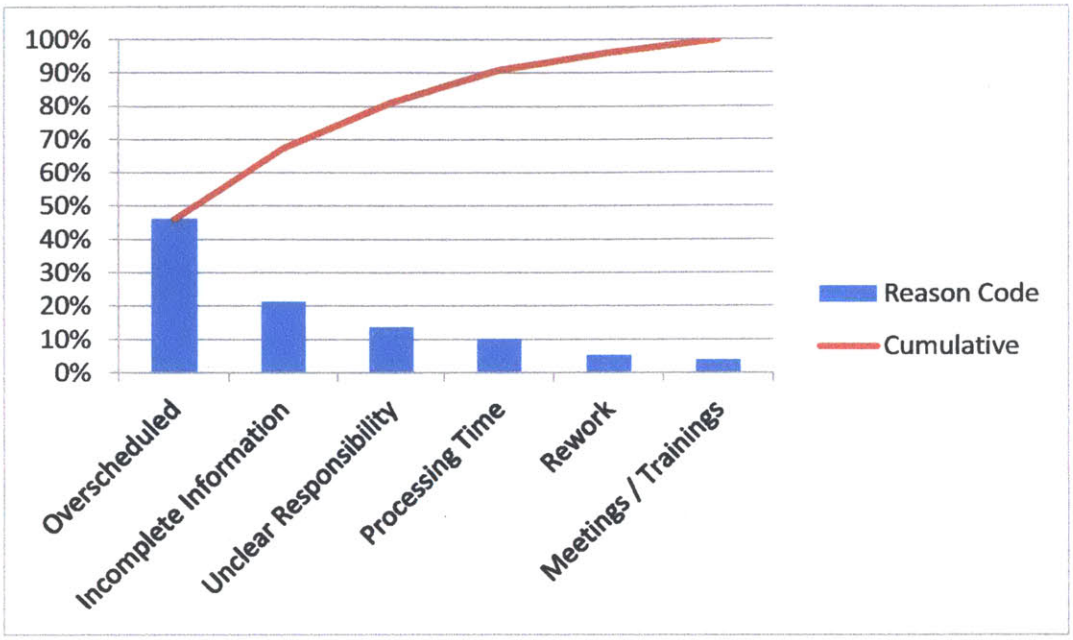

Figure 6: Pareto Analysis of Reason Codes for Execution Delays

After the initial assessment of the process capability it was necessary to conduct a deeper analysis to determine the reasons for execution inefficiencies. The next sections will detail the process for the Value Stream Map (VSM) Analysis, Constraint Identification Analysis and primary sources of variation.

4.3.1 Value Stream Map Analysis

The VSM exercise consisted of a cross functional group of SMEs in a multiday workshop. To prepare for the session, participants were given pre-read information which contained items relating to the project background and current state analysis, and were asked to bring pertinent process documentation and data, and most importantly, an open mind. It is important to note that this was an abbreviated VSM exercise due to the resource constraints and conflicting priorities of the organization. A detailed description of the VSM process can be found in, Learning to See, by Mike Rother and John Shook [26]. An image of the VSM under development can be seen in Figure 7 below.

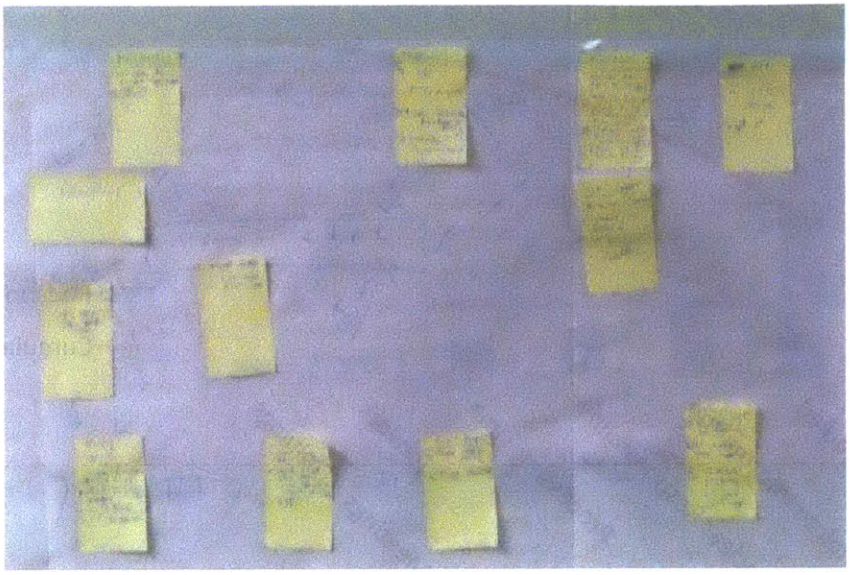

Figure 7: Value Stream Map under development

The VSM analysis provided detailed insight into the material and information flows which comprise the emerging market entry commercialization process. This was important as the initial process map and SIPOC created during the define phase omitted pertinent details such as cycle times, WIP and customer demand, which was then translated to the required takt time needed to meet launch demand. Further the VSM activity allowed for potential identification of the process constraint which is critical to proper management and execution of the launch process and will be discussed in the next section.

4.3.2 Constraint Identification and Management

The VSM analysis was a useful input into the identification of the emerging market entry process constraint as it provided indicators as to where the process bottleneck may exist. The initial identification of the constraint was based on the average cycle time duration for each process step and the average WIP level prior to a given process step. Based on this analysis the constraint is identified as being located prior to the file submission at the local country regulatory organization. Aside from the cycle time and WIP analysis, this is somewhat of an intuitive occurrence as the review duration of this step in the process is outside of the organization's control. The regional aggregate of average cycle time as a percentage of total throughput time, and associated WIP levels as a percentage of the entire WIP, is shown in Figure 8.

Commercialization Phase	Cycle Time %	WIP %
Business Case	28%	30%
Commit-to-File	21%	16%
Submit File	33%	38%
Commit-to-Launch	19%	17%

Figure 8: Cycle Time and WIP Constraint Identification

Upon further analysis and validation of the speculated process constraint, an interesting occurrence was discovered. In several emerging market entry launches, the process constraint was not found within the local country regulatory organization, but was found at various points further upstream in the process, most commonly the business case and due diligence steps. Such a finding warranted a deeper investigation to uncover the true process constraint. Queuing theory supported this observation through an understanding that within a serial system the relative value of WIP to throughput time is not necessarily an indicator of the system bottleneck. Through the consultation of literature on constraint management, primarily the Theory of Constraints (TOC), it was found that the emerging market entry commercialization process must be properly managed in order to gain control of the entry process and minimize high variability in execution performance. Fluctuations in product and volume mixes, as per individual commercial market, result in the wandering bottleneck phenomenon. A process step is designated as a bottleneck when it has a work load larger than its capacity. This phenomenon is an outcome attributed to the overuse of resources and can be observed through the high WIP and resource utilization levels. The consequence of high WIP and resource utilization levels is that over long periods of time the system bottleneck shifts from one resource to another [27]. To properly treat this process symptom, it is necessary to eliminate variability due to self-inflected plans based on the need to keep WIP or utilization levels high. A simple solution proposed for remediating the wandering bottleneck phenomenon is to limit the amount of WIP in the entire system at a given time. If implemented successfully, the result is a system that maximizes throughput by proper allocation of work based on available capacity. Treating the emerging market entry commercialization process in order to minimize

the wandering bottleneck phenomenon allows for proper development of the future state commercial entry process. This will be discussed further in Section 4.4 Improve Phase and the Future Commercialization Vision.

4.3.3 Identification of Variation Sources

After identifying the process constraint locations, it was essential to determine the sources of variation in the commercialization of emerging markets to make improvements to the process. Three primary findings are attributed to the inefficiencies in the current state commercialization process:

1. Lack of Standardization
2. Prioritization
3. Resourcing

The first finding, lack of standardization, is an important source of variation and a pertinent finding since it is not possible to make improvements to a process unless it is stable and under control. For the emerging market entry commercialization process to be stable and in control, actions were taken to analyze opportunities in which the process and its governance could be standardized. To clarify, the governance process is a periodic review of pertinent country launch information conducted by the leadership team in a phased gate model. The output of the governance process is a "go" / "no-go" decision or any rework required before proceeding to the next phase of implementation. The primary elements determined that contribute to the lack of standardization consist of aspects relating to an ill-defined market entry and governance process. Most notably, there are no formally established policies, procedures or guidelines detailing how the process should work and when aspects of a given step should occur. There are also no clearly defined roles or responsibilities for the various parties involved in the commercialization process. As a result, market entry processes for emerging markets vary significantly between regions as they are in essence, "homegrown" and customized, as a given region develops over time. It is a complex organizational structure in which certain regions are organized, based on geography

or product. The outcome of the standardization analysis identified that there are inconsistent processes and procedures which vary significantly between each established region., Thus, the total duration of the emerging market commercialization process is negatively impacted by the lack of process standardization, resulting in incomplete or incorrect information that is provided to governance for entry assessment review.

The next major finding, prioritization, identified sources of variation in how the organization plans and monitors the launch activities for emerging markets. From a planning perspective, the company based project plan timelines on corporate company goals for entry into new markets. The resultant approach presents potential problems for the execution of commercial market entry. Without an analysis to understand available capacity which support emerging market launches, project plans can generally be expected to fail. The metrics and associated incentives established in the process are created such that they support volume or number of launches and do not monitor effectiveness of the process. Over time, the organization has attempted to cope with the overburdening of resources, yet constraints in capacity limit the ability of the firm to manage the launch and ultimately delay a new country commercial entry. These occurrences have become the norm causing unrealized planning schedules, diminished responsibilities and limited accountability for results. If a launch schedule is not compromised, then the plan is maintained through excessive cost generation. This generally occurs through additional resources and by deprioritizing ongoing launch activities, creating excessive WIP and multitasking.

Unwarranted WIP has negative implications on throughput time, thus causing unnecessary process delays. This is demonstrated in Little's Law through the equation below, where L can be regarded as the system WIP, λ as the throughput time and W as the cycle time [28]:

$$L = \lambda W$$

Further, as proposed by Goldratt in his novel, Critical Chain, excessive multitasking delays a task duration due to unnecessary work and lack of focus that is required when changing between tasks [29].

The excessive WIP levels can be observed in Figure 9 utilizing Little's Law, the commercialization average target throughput time and the average cycle time per business phase to calculate a target WIP level which is then compared to the actual level for each region.

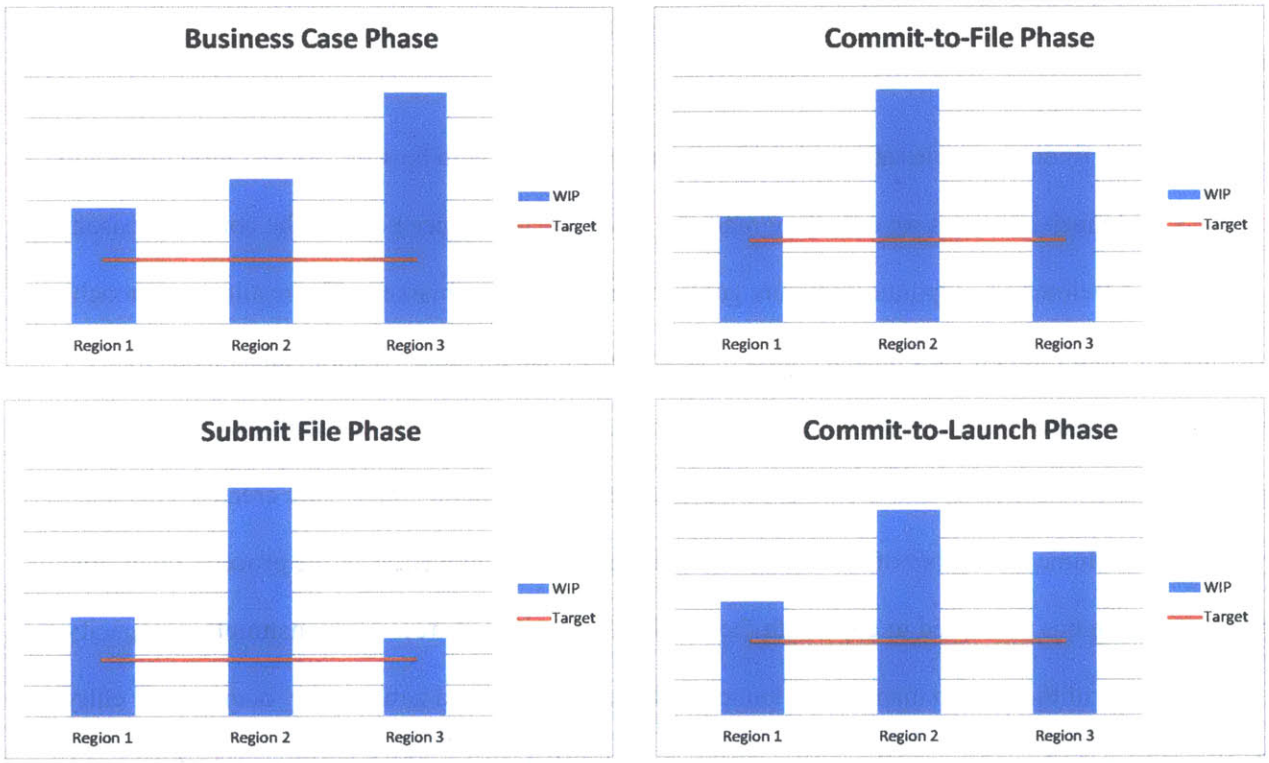

Figure 9: Work in Process (WIP) by Region by Business Phase

Finally, the selection of commercialization efforts and the target launch date for a given country is made solely by the commercial organization. There is little to no involvement of the various functional counterparts in the Operations and Regulatory organizations. This is problematic, again due to capacity limitations and the lack of information sharing or knowledge transfer that occurs when having a collaborative selection process. The impact to the process is that there is a feast or famine effect where observable volatility occurs through the peaks and valleys in the number of jobs over an annualized time period. Figure 10 illustrates the variation in workload fluctuations across the established regions.

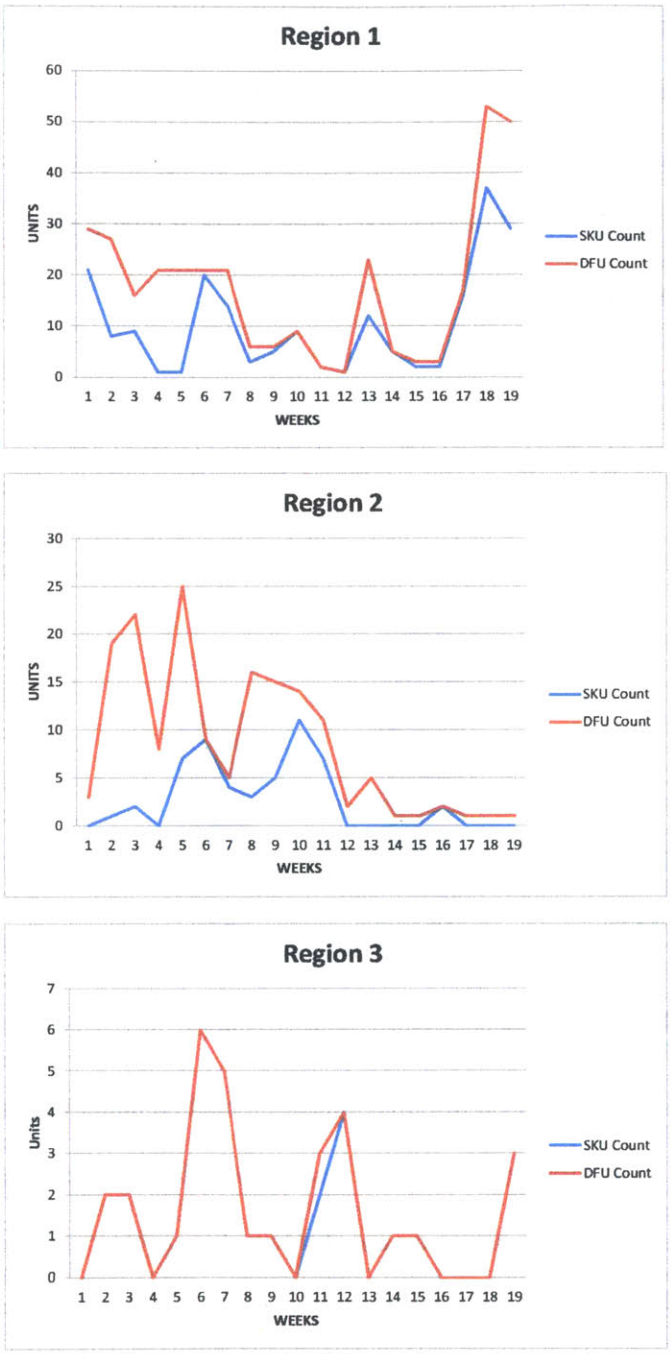

Figure 10: Launch Variability by Region Over Time

The final primary finding, resourcing, identified potential variation improvements that could be made to the allocation and management of resources for commercialization efforts. Project resources for launch activities are assigned based on the region an individual worker is assigned. With three regions active in emerging market commercialization and a limited number of resources within each region, this type of

allocation would be appropriate if commercialization efforts were equally dispersed across the regions. Further compounding the issue is the fact that resources within regions are assigned to a specific set of countries. Currently, region two and three represent the vast majority of emerging market commercialization efforts. Figure 11 below shows the percentage of total commercialization launch efforts segmented by region number.

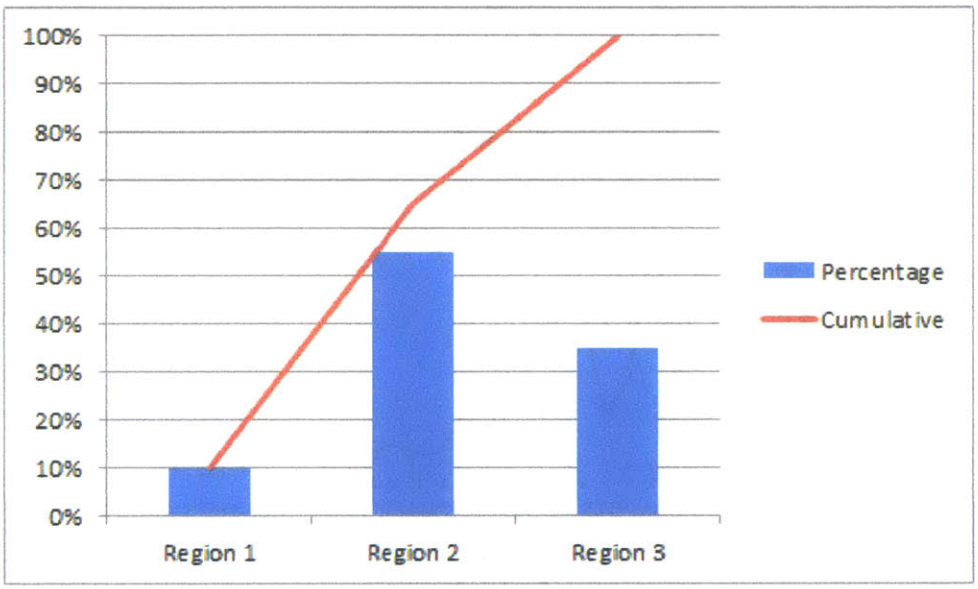

Figure 11: Percentage of Total Commercialization Launch Efforts by Region

The result of a regional and country based resource allocation method under the current commercialization plan is an imbalanced resource utilization workload across the established regions. This causes resource contentions when assigning country launch projects to a given individual resulting in overburdening of resources, limited information sharing and potentially compromising the quality of work performed.

The last aspect of the resourcing finding was that the organization has not identified the process constraints. Although this was discussed earlier in the chapter, the analysis and corresponding planning has not been performed by the organization. This means that without an analysis of available capacity and the determination of the process constraints, the organization cannot effectively plan and execute against

the constraint. The implications are a reduction in system throughput, inadequate resourcing at the process constraints, and over resourcing in other aspects of the market entry process.

4.4 Improve Phase and the Future Commercialization Vision

The improve phase consists of instituting a framework which an implementation roadmap of detailed actions can be taken by the organization to attain a future vision of integrated operational excellence for the commercialization of emerging markets. The aspects were broken down into each emerging market entry commercialization business phase within project scope: Business Case, Commit to File, Submit File and Commit to Launch. The roadmap was developed in three sequential improvement phases, which coincided with the primary sources of variation findings discussed in Section 4.3.3.

The first improvement phase established was standardization and governance. This phase entails activities that should be undertaken by the organization to create clear process guidelines as to how work should be performed and when. Specifically, the first action in this phase will be to institute policies, procedures and guidelines necessary to have a standardized emerging market entry commercialization process as well as the supporting governance review. Further actions will need to be taken to achieve a standardized process, which includes detailed process flows, supporting SIPOC, and clearly defined roles and responsibilities to delineate work per function per individual. Finally, it is critical to introduce a workflow tool to autonomously manage the process, streamline the inputs and provide standard cross-regional project plans. More information on the introduction of a workflow tool for emerging market commercialization can be found in the thesis, Optimization of SKU Creation Process and Adherence Improvement through use of Workflow Management by Richard Gimlin [19]. From a process standpoint the above actions support a consistent and repeatable process which allow for the standardized execution of emerging market commercialization entry and provides a basis for advanced continuous improvement. Additionally, with the advent of standardized entry practices and governance review process, the idea of governance by exception is achievable. The "governance by exception" philosophy helps support the proper use of senior leadership's expended time on emerging market decision-making and avoids

overburdening by only conducting a governance review if a set of criteria are not met or an exception is raised.

The second improvement phase developed was prioritization. The prioritization phase focuses on aligning the organizational functions to properly select, schedule and monitor emerging market launches. The first aspect of this phase is to develop a country pre-selection commercialization business phase and methodology in order to prioritize the launch sequence of target countries. This is important since the current method considers the emerging market process to have infinite capacity, assuming there is the ability to handle as many launches simultaneously as needed to meet company entry goals. Two methodologies were proposed in order to facilitate the process. The first method for country pre-selection is the use of the Analytic Hierarchy Process (AHP), a Multi-Criteria Decision Making (MCDM) methodology. AHP allows for an objective assessment to be made based on a set of predetermined criteria which are jointly agreed upon cross-functionally and weighted prior to selecting a new launch country. The benefit is that it provides an unbiased valuation of how a country should be prioritized and limits resource intervention on a per launch instance since it can be setup in an autonomous manner. A detailed description of the AHP process and its application in strategic decision making can be found in, Strategic Decision Making: Applying the Analytic Hierarchy Process by Navneet Bhushan and Kanwal Ra [30]. The second method proposed requires a more resource intensive effort of cross-functional personnel on a per launch basis, but would be generally more familiar to the individuals in the organization. This method requires a semiannual review process of proposed country launches for emerging markets and agreement upon their priority through a democratic voting system. From a theoretical perspective this process would be less ideal than AHP, but may be better received by the organization in practice.

The next focal area of the prioritization improvement phase focused on developing a methodology to determine and communicate system capacity. Introducing the concept of capacity load planning would be beneficial in supporting country pre-selection, and in general, the organization, since it creates a formal resource modeling methodology. Additionally, commercialization launches can be scheduled based on

available capacity and reallocated to different time periods when a given time interval is overscheduled, thus balancing the load over time. An example of the capacity load planning and the process described above can be seen in the three-step approach in Figure 12.

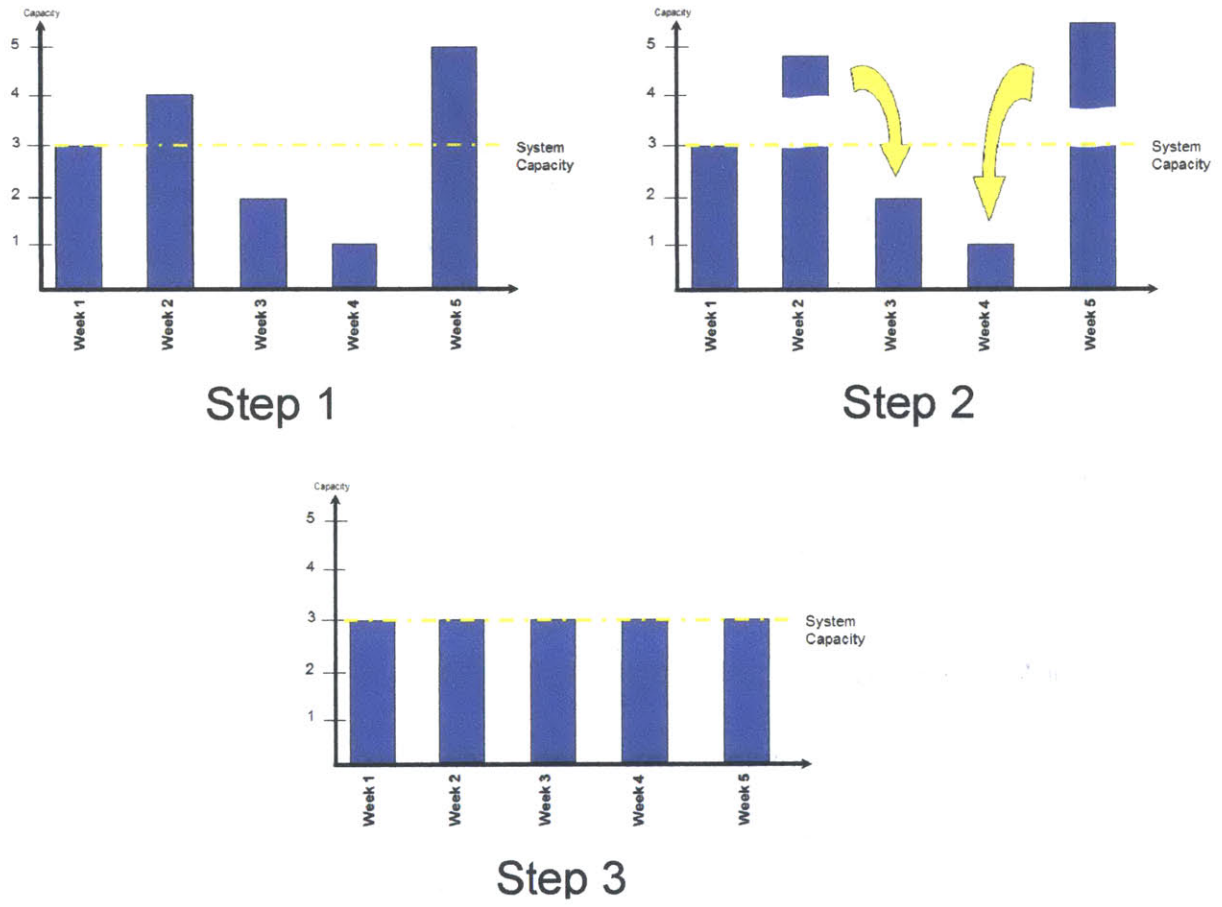

Figure 12: Capacity Load Planning Example

Generally, load planning should be based on no more than an 80% utilization of available time for emerging market commercialization, but may vary depending on the assumptions used to determine utilization rate. A load plan designated at 80% or less utilization avoids overburdening of resources, allows for the allocation of miscellaneous activities, incorporates allowances for process inefficiencies and most importantly, does not overload the system. As seen in Figure 13, as utilization and variability increase, average flow time rapidly increases tending toward infinity for values above 80% utilization [31].

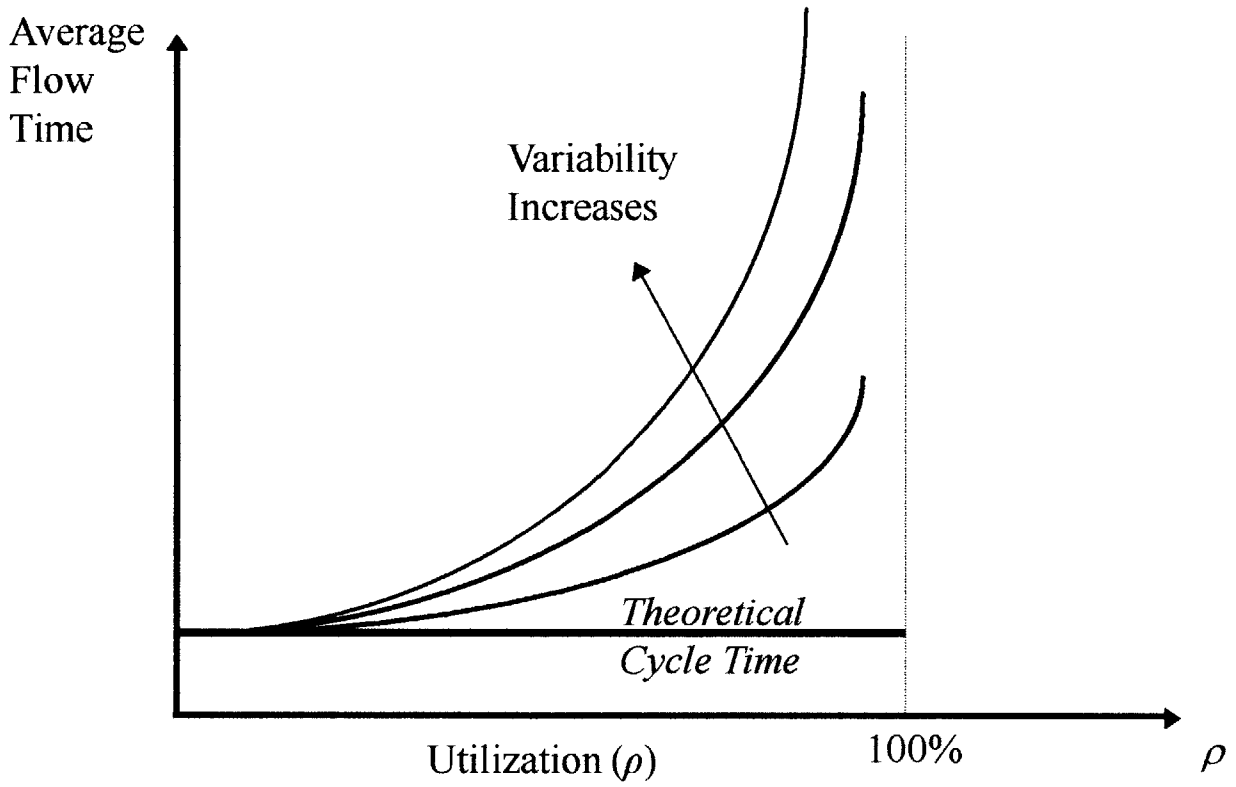

Figure 13: Throughput Delay Curve [31]

The final aspect of the prioritization improvement phase is the introduction of operational efficiency metrics which monitor commercialization effectiveness in terms of cost, speed, and quality. These metrics should replace or augment the current measures which assess emerging market entry progress through the commercialization phases, in terms of activities that support the overall volume and adherence to schedule of launches. The 4.2 Measure Phase section provides details on the proposed metrics in Figure 4.

The last improvement phase created is resourcing and flexibility. This phase of improvement focuses on activities to better manage the use of resources and provide flexibility in how they are utilized. The first aspect of this phase is pooling and prioritization. A portion of the pooling process needs to be developed by creating two emerging market job pools, a filing job and a launch job pool. The establishment of two separate job pools is necessary due to the long durations and variability in cycle time between the filing and launch commercialization business phases. Creating two job pools allows for a decoupling of the

planning and execution processes. Decoupling these points is beneficial since detailed plans that allocate specific resources for a time period of many months in advance of execution, will commonly incur conflicts and the plans generally collapse prior to being actualized. Emerging market entry jobs are prioritized in the pools using a color coding system of green, yellow and red to indicate completion progress. The measurement for each respective color is calculated based on the percentage of job completion divided by the time remaining until the job is due at the process constraint. A job color status of red indicates a critical status with less than 33% of the time remaining until the project is needed at the constraint. Similarly yellow and green comprise the other two thirds of the remaining time, with yellow signifying a warning or monitor status and green meaning a normal status.

After creating the job pool, the final portion of the pooling process should be introduced. This involves introducing a cross-trained resource pool that would allow the emerging market regions to act as a single unit. The approach is beneficial for planning and execution purposes by providing flexibility in the assignment of resources as opposed to the segregated regional structure that the organization currently utilizes which limits adaptability to unplanned volatility. As previously mentioned in section 4.3.3, the current regional structure causes imbalances in workload, over or under-utilization of resources, and lack of information sharing or silos of knowledge.

The final aspect of the resourcing and flexibility improvement phase is the introduction of constraint management. After identifying the process constraints it is possible to conduct proper planning around them to maximize system throughput. In most instances of emerging market commercialization efforts, the constraint is located prior to the file submission or during the business case phase. To execute constraint management, a Constant Work in Process (CONWIP) system should be established. The CONWIP system's goal is to pull work through the process by limiting the number of open emerging market entry jobs in the system at a given time. New emerging market jobs are introduced on a one in, one out, basis. This means that once the system reaches the CONWIP limit, new work is introduced into the system only when a job exits the system, thus creating a pull effect. A CONWIP system is typically

managed through the use of cards, similar to a kanban card system, but provides less control over individual process steps. The benefit of the CONWIP system as compared to a kanban system is that it is less intensive to implement. More information on a CONWIP system can be found in the article, CONWIP: a pull alternative to kanban by Spearman and Hopp [32]. Generally a reduction of 50-66% of the average number of jobs in the current system is an appropriate starting point [33]. This number can then be refined over time in order to protect the constraint and avoid decreasing throughput. A theoretical graphical example depicting WIP as an asset or liability is shown in Figure 14. As an example, if the current system WIP level is 12, a 50-66% reduction would be a CONWIP value of four to six open commercialization jobs. After implementing the CONWIP system, an improvement in total throughput time should be attainable. This can also be substantiated through the application of Little's Law, since there is a direct impact on throughput time when adjustments are made to WIP levels and cycle time is held constant.

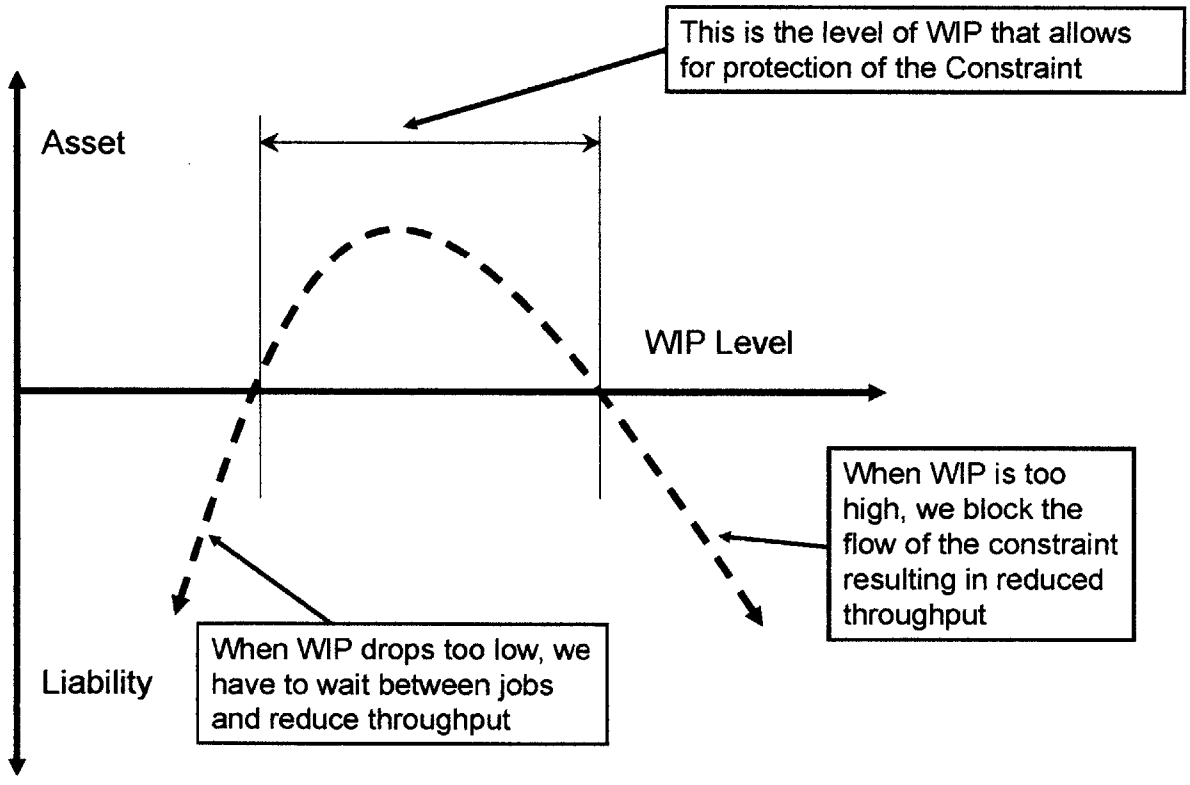

Figure 14: WIP as an Asset or Liability [33]

The development of all three improvement phases should be conducted in the sequential order discussed above. If followed, the approach would allow for manageable incremental improvements to be made to the emerging market commercialization entry process, thus enhancing the efficiency of the overall process. Figure 15 provides a visual representation of the implementation roadmap discussed in this section, delineated by implementation phase.

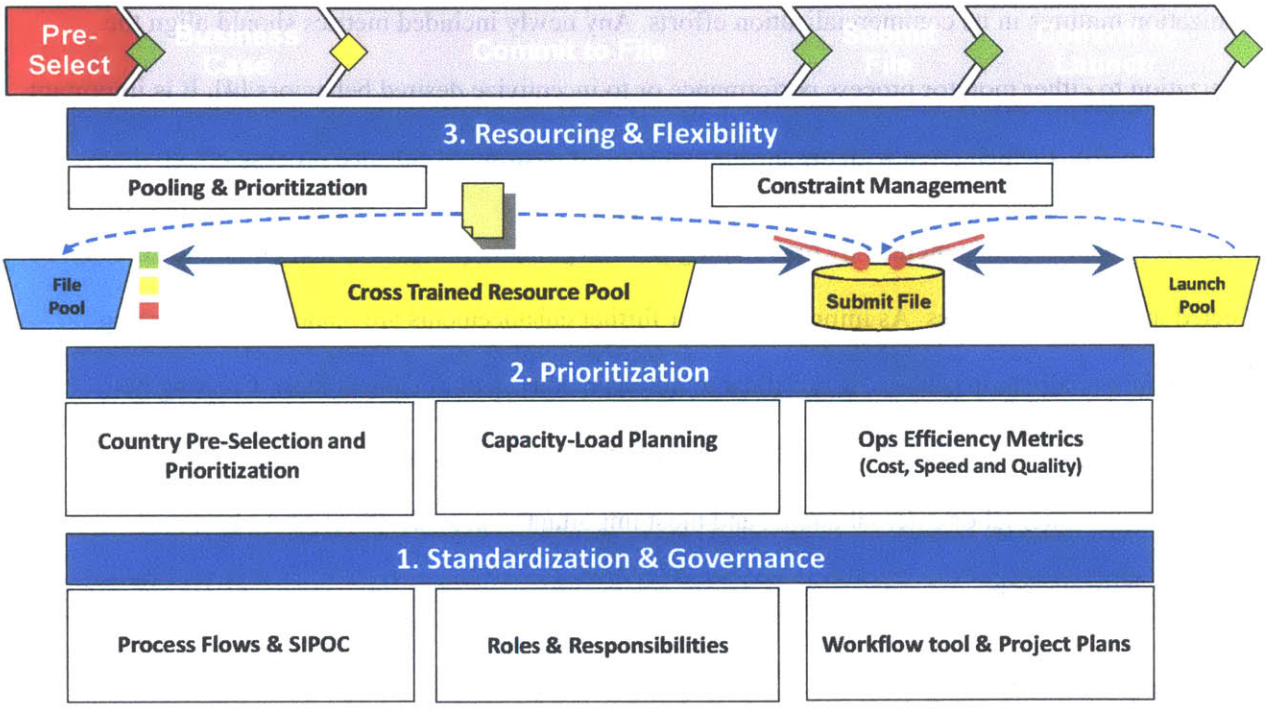

Figure 15: Implementation Roadmap for Future State Vision of Emerging Market Entry Commercialization

4.5 Control Phase and Future Work Opportunities

The final phase of the Emerging Market Entry Analysis was the control phase. Since a pilot was not conducted, this phase focused on efforts that could be made to maintain and enhance improvements to the implementation roadmap as well as opportunities for future work. The first aspect of the control phase was the recommendation of conducting pilots during and after roadmap implementation. Piloting would provide valuable insights into how effective the improvements are in terms of tangible metrics as well as the receptiveness of the organization. The latter of which can heavily influence the results attained in

measurable improvements. Additionally, piloting would help identify further enhancements that the organization may desire to include, in addition to those described in the implementation roadmap.

The next aspect of the control phase focused on establishing new or additional measures for continuous improvement. A number of CTQ's were proposed to better monitor effectiveness of the emerging market entry commercialization process, yet there may be opportunities to enhance those recommended as the organization matures in its commercialization efforts. Any newly included metrics should align the organization to either monitor process performance or to incentivize desired behaviors [4]. It is important to establish metrics which align with organizational goals if desiring to enhance process effectiveness.

The control phase should conclude by maintaining process policies, procedures and guidelines with those reflected in the actual process. As improvements or further enhancements are made to the emerging market commercialization process, it is critical to maintain consistent documentation. Creating new or refreshing existing documentation supports knowledge retention, the onboarding of new staff, preparedness for internal or external audits, and most importantly, provides an ongoing basis for continuous improvement.

4.6 Chapter Summary

The Emerging Market Entry Analysis allowed for the creation of a detailed emerging market entry commercialization improvement framework with a supporting implementation roadmap, in which the company can take tangible actions. The Six Sigma DMAIC methodology was an invaluable approach that supported the planning and creation of the improvement framework. Although a pilot was omitted from the research area, efforts were made to ensure alignment with organizational plans and receptiveness. Proof of concept will be required through future pilot efforts and further enhancements can be included by the company as desired.

5 Emerging Market Entry Risk Assessment Model (EMERAM)

The Emerging Market Entry Process Analysis facilitated the Emerging Market Entry Risk Assessment Model (EMERAM) development by providing an in-depth understanding of the commercialization entry process as well as the pertinent aspects that are critical to the development of a successful model. The end goal of the model was to develop a robust risk assessment platform which could be used to standardize risk assessments across the company regions. Additionally, the output of the model endeavored to enhance management decision making by providing purposeful risk-informed information for entry decisions into emerging markets. In the following sections, the process for development and integration of the model into the organization will be discussed.

5.1 Current State Risk Assessment Process Overview

Prior to the project, there was no formally established risk assessment model that existed in the organization for commercial entry of emerging markets. There was, however, a process in place for a risk assessment method that integrated the findings of the various functions' country intelligence and due diligence efforts. The information was then compiled into an assessment to highlight potential risks, but the analysis was highly dependent upon the resource and region involved. Generally, aspects were assessed which pertained to Good Manufacturing Practices (GMP) or Good Distribution Practices (GDP), compliance and regulatory concerns, or distributor suitability matters. The entire risk assessment methodology was based on subjective determinations of severity of failure and likelihood of occurrence, without complying with the company risk management standards for making such a valuation. The output of the previous risk assessment process was escalated to the leadership team in a governance review as deemed appropriate by the subject matter expert (SME). No formally established process for determining issues existed, nor was there a cross-functional review of the output to determine if an issue should be escalated accordingly.

5.2 Development of a Risk Model for Emerging Market Entry

To initiate the development of the risk assessment model, the first step was to formally define the project goal and scope of the work to be completed. Since there were many shortcomings in the existing risk assessment process, it was desired to create a completely new process in which the Emerging Market Entry Risk Assessment Model (EMERAM) would be the cornerstone. The scope of the new risk assessment model and supporting process would be limited to the company's non-core markets, primarily emerging markets. The model would only include existing commercial products in three modes of entry and would exclude pipeline or developmental products. The three modes of entry as they pertain to the EMERAM are as follows:

1. New country entry – new product entry into a country which the company does not already conduct business
2. Existing country entry – new product entry into a country which the company does already conduct business
3. Pre-Registration Sales – new product entry into a country where the local regulatory agency for the given country has determined that there is a medical need for a product or products, without the need to formally commercialize to distribute the product(s). Generally, a grace period is associated with this mode of entry, lasting between six months to several years.

After defining the project goal and scope, it was necessary to determine the aspects which are relevant to properly assessing emerging market commercial entry risks. This was a challenging process, as it is desirable to create a robust model, but also to maintain a proper level of attributes to avoid creating an overly complex tool. To begin the process, informational interviews and brainstorming workshops were conducted with the support of SMEs in the operations, regulatory and commercial organizations to attain anecdotal information regarding aspects that had presented challenges in previous emerging market launches. This was complimented by a review of the enterprise risk management framework to enhance the understanding of approaches familiar in the organization and ensure alignment with company risk

management standards. A detailed review of country launch information followed the framework review, and included aspects such as the due diligence reports, country intelligence information and business cases presented during the governance reviews. Additionally, participating in active governance review meetings supported the collection of pertinent risk aspects. A simultaneous literature review of risk management techniques and aspects was conducted, reviewing academic works, prior theses on the subject of risk management, and professional publications. The model was developed using an iterative process, which involved creating a usable tool and making refinements based on user and workshop feedback. The above steps support the development of specific elements that should be considered as well as developing a functional model, which will be discussed in the following section.

5.3 Model Elements and Functionality

This section will review the primary elements and functionality of the EMERAM. The model was developed using Microsoft Excel to allow for rapid development and revisions without the need for extensive support of the information systems organization. The EMERAM is intended to standardize and streamline the risk assessment made for commercial entry into an emerging market country. Using a scenario-based evaluation methodology with predetermined risk scenarios, the end result of the model analysis is a risk profile scorecard for a given target entry country. The model is comprised of 109 scenarios which are divided across four focal areas as appropriate. The following describes the four focal areas:

1. Security and Safety – Aspects relating to risks associated with the reputation and integrity of company products due to theft, diversion or counterfeiting in the target launch country
2. Quality and Operations – Aspects relating to risks associated with ensuring the quality and operational standards to ensure uncompromised product efficacy when operationalizing in the target launch country
3. Regulatory and Compliance – Aspects relating to risks associated with legislative matters required to conduct business in the target launch country

4. Business Environment – Aspects relating to risks associated with market potential, geopolitical stability or intellectual property in the target launch country

Using the Risk Breakdown Structure (RBS) allowed for the creation of 77 risk categories that are divided across the four focal areas to facilitate a rationale assessment [12]. The risk categories are designed to align with the risks articulated by the company at an enterprise level. The risk categories and their respective focal areas are shown in Figure 16.

Figure 16: Model Focal Areas and Risk Categories using Risk Breakdown Structure (RBS)

Each scenario is evaluated based on two components of risk consistent with standard risk management frameworks, such as the Department of Defense (DOD) Risk Management Guide for Acquisition, which evaluates the severity of failure and likelihood of occurrence [15]. The scenario is scored by a five point numeric rating criteria using the values 1, 3, 5, 7, and 9 (1 = low and 9 = high) to evaluate severity of failure and likelihood of occurrence. Detectability of a given scenario, which measures the ability to recognize a risk, was intentionally omitted since it is not necessarily applicable in all established

scenarios. Where applicable, the detectability determination is incorporated into the likelihood of occurrence evaluation, taking into consideration existing mitigation and control efforts. As an example, a risk scenario that results in an impact to product quality due to a temperature excursion, is detectable using a control of temperature sensors, whereas a scenario, in which an import test failure occurs, may not have a control which is detectable. Scenario assessments are established utilizing country intelligence and due diligence information. The evaluation is made by one or more SME as appropriate based on individual expertise or functional allocation. Commentary is required for the severity and likelihood score in order to provide and document rationale as to why a given valuation was made. Generally it is desirable to have a cross-functional determination of a scenario in order to integrate information that may be held by a given function and not commonly known to create a cohesive assessment. In instances where multiple inputs are provided by experts the most conservative valuation is taken, meaning the worst-case credible outcome is used for the scenario score. For example, if a "likelihood of occurrence" score was assessed by a quality SME as a nine and by a regulatory SME as a five, the score of nine would be taken for the scenario evaluation. This presumes that the valuations by each expert were reviewed in sufficient detail and that the score of nine was, indeed, a credible worst-case outcome. To enhance the ease of use and standardize the model SMEs have provided recommendations for the severity of failure score for each established scenario. Justification is included for the severity of failure recommendation to document how the score was rationalized. This is possible because the model scenarios have been predetermined and recommendations have been provided under a variety of circumstances. As a result, when conducting a new assessment for a target entry country, the experts generally only provide input to assess the likelihood of occurrence as this value will vary significantly between countries. It is possible to deviate from the recommended severity of failure score, but a reason code should be selected with supporting rationalization provided, and a detailed review should ensue before a final score is accepted

The risk level for an evaluated scenario is determined using the 5 x 5 risk matrix methodology, in which varying combinations of severity of failure and likelihood of occurrence risk scores determine a risk level

score of low, medium or high [14]. The risk level scores and how each corresponds to the selection of severity and likelihood scores are shown in Figure 17.

Likelihood of Occurrence	Severity of Failure: 1 Trivial	3 Slight	5 Moderate	7 Major	9 Severe
1 Remote	Low	Low	Low	Low	Medium
3 Improbable	Low	Low	Low	Medium	Medium
5 Uncommon	Low	Low	Medium	Medium	High
7 Probable	Low	Medium	Medium	High	High
9 Frequent	Low	Medium	High	High	High

Figure 17: 5 x 5 Risk Matrix and Associated Risk Levels

Risk level scores of low or medium do not require action, but rather it is recommended that low risks are accepted without need of resolution and medium risks are reviewed to determine if further action may be warranted. A risk level score of high, mandates that further action is taken in the form of a detailed risk assessment to determine implementation of controls that minimize, mitigate or eliminate the risk. Risks which are unable to be remediated must be communicated to senior leadership through the governance process to determine if it may be deemed appropriate to accept the risk without further action. There is no time period designation in which a high risk must be escalated or resolved since the risk assessment model is used to determine perceived potential risks rather than evaluating risks which are currently actualized by the firm.

After all scenarios are evaluated and the associated risk levels are produced, a risk profile for each of the four focal areas is generated to provide a visual representation of the risk assessment. Baseline risk levels have been established for each risk category within the four focal areas utilizing prior launch data in order to provide context as to the meaning of the risk profile. A radar diagram chart is used to generate the risk profile using the maximum risk level score for each scenario in a given risk category. The diagram is scaled using values of 0, 1, 2 or 3 corresponding to no risk, low risk, medium risk or high risk respectively. The risk profile is automatically generated in Microsoft Excel and displayed in a dashboard report to develop a country scorecard. The report is then compiled into a Microsoft PowerPoint template to generate a management summary which is used at a governance review. An example risk profile is shown in Figure 18 for the Quality & Operations focal area.

Figure 18: Example Quality & Operations Risk Profile

5.4 Process for Using Model

To support the proper usage of the EMERAM it was necessary to develop process documentation in the form of guidelines, detailed process maps, definitions and working examples. Below outlines the high level process steps and a detailed description follows:

1. Risk Scenario Evaluation
2. Generate Risk Level and Risk Profile
3. Cross-functional Output Review
4. Detailed Assessment of High Risk (if applicable)
5. Incorporation of Control Costs or Risk Register Monitoring

To begin, a risk scenario evaluation is made through model inputs that are determined using country intelligence and due diligence efforts for each focal area as they pertain to the target product(s) or country. Inputs consist of severity of failure and likelihood of occurrence scores with associated rationale and where applicable reason codes with associated justification for recommended severity deviations. Based on the model inputs, risk levels for each individual scenario are generated. Individual risk scenarios are aggregated into corresponding risk categories where the maximum within a category is taken. A risk report is generated containing information pertaining to the assessment process utilized, risk level detail by scenario, and summary information including statistics and risk profiles for each of the four focal areas. A detailed review meeting of the output is conducted by a cross-functional team of SMEs and leads for each focal area. Consensus is reached as to the accuracy of the assessment and identification of any necessary scenarios which require resolution. If a high risk was determined, a detailed risk assessment is required if it is not readily resolvable and is recommended to be completed using a Failure Modes and Effects Analysis (FMEA) or comparable methodology [16]. Mitigation or control efforts that are required in order to reach an acceptable risk level incur significant costs in order to do so and are reflected in the target country financial analysis or profit and loss statement. Inclusion of considerable costs into the country profit and loss statement ensures that risk related activities are properly reflected when making a

decision to enter given target country. When resolution of an identified high-risk scenario is completed, the scenario is re-evaluated using the severity and likelihood scoring to ensure it has reached an acceptable risk level. If it is not possible to develop a control for a high-risk scenario, then the risk is assigned an owner and progress is monitored in a risk register [17]. Utilization of a risk register allows for a risk portfolio to be created which provides visual representation of risks related to emerging market entry and can be used to monitor all commercialization activities cross-regionally at a network level. A process flow of the described process is shown in Figure 19.

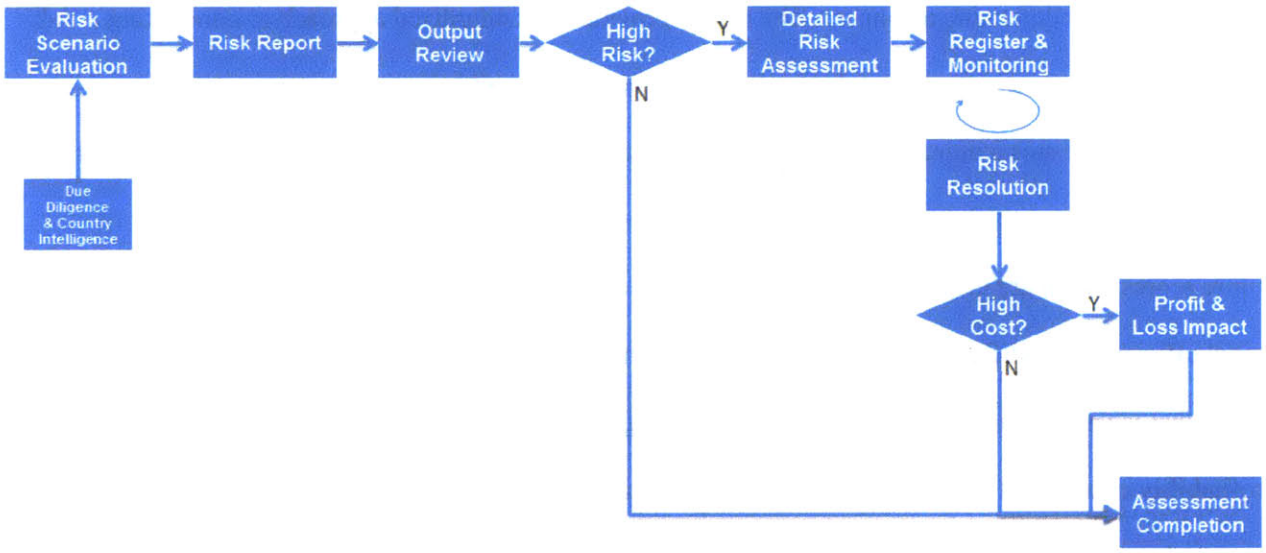

Figure 19: EMERAM Process Flow

5.5 Piloting for Data Collection and Process Improvement

To validate the model, four cross-functional pilots were conducted to seek an understanding of effectiveness and ease of model use, and to make refinements. Utilizing the Toyota Production System (TPS) methodology, following the scientific method, each pilot was staggered throughout the development of the model. The approach allowed for incremental improvements to be incorporated before beginning the next wave of piloting [8]. Additionally, piloting efforts were dispersed across varying regions, countries and products in order to ensure applicability to all established emerging markets. Specifically, countries were targeted that had reached a point in the commercialization process to be

viewed as having a complete set of due diligence and country intelligence information. It is worthwhile to point out that in practice the model will be populated as the commercialization phases progress, yet this approach was intentionally utilized for piloting to avoid incomplete assessments and potentially omit a significant risk scenario.

The piloting results determined 4 out of 436 scenarios to be at high risk levels after the cross-functional model output review. Although the specifics of the identified risks cannot be discussed, the conclusion from the piloting efforts was that the model is a comprehensive tool that effectively identifies risks without over or understating a concern. The model provides a standardized approach to conducting a risk assessment for an emerging market that is detailed in nature without being cumbersome in its use. Furthermore, it creates a more rigorous assessment that requires significantly less time than the previous methodology. This is achieved through use of pre-assessed scenarios with recommended severity of failure scores which are generally exhaustive and applicable to all emerging market launches. Finally, the model efficiently identifies risks that support either control efforts or further monitoring, provides a risk profile that is valuable in management decision-making and reflects the cost of control efforts into the profitability established for a country. Thus, there are tangible financial benefits that are achievable through the model's continued use and model usage can result in minimal cost implications associated with expenditures to conduct a risk assessment. Over time, it is possible to develop a repository of information on past commercial launches which can further enhance the value of the model's impact on the company.

5.6 Model Limitations and Future Enhancements

The limitations and associated enhancements of the EMERAM span from shortcomings due to the platform selected for its development to the variability in requirements associated with emerging markets. One major limitation of the current model is its development in Microsoft Excel. The software is quite effective at the computational and reporting aspects of the model, but is not easily scalable at an enterprise level and does not readily support the workflow aspects that are required. Specifically, there is

limited functionality in gathering input from a large number of experts and compiling the information without manual intervention. The manual aspect of this process can take a significant amount of time from an individual and excludes additional time needed for follow-up and feedback efforts that are expended during execution. Since this is a substantial limitation of the model, there are efforts being made post-internship to transition the model into Microsoft SharePoint. The transition into the new software will allow for the establishment of an automated workflow to capture assessment input and provide notification systems and enhanced reporting functionality.

Another limitation of the model is the fact that not every scenario established is applicable to all launch instances. This is mainly a consequence of having pre-assessed risk scenarios and various modes of emerging market country entry that occur in the company. As an example, if the company desires to enter directly into a country, as opposed to utilizing third parties, then aspects that relate to utility service integrity are relevant whereas distributor capabilities are not. Due to the current level of sophistication and experience using the model in the company, it was desired to not filter scenarios by mode of entry. Future enhancements of the model will incorporate a selection filter by entry type in which a given selection will only display the applicable scenarios.

An additional model limitation that was intentionally incorporated is the inability to have user generated risk scenarios. The implications are that aspects which are viewed as special circumstances cannot be generated by a SME. This was necessary in order to have a standardized risk model for emerging markets that is consistent in every launch and region. During piloting there were no occurrences of a need to enter a special circumstance risk that was not captured at a macro level in the risk model, however through continued use it would be expected that such instances may occur. The current process established to resolve the omission of new scenario generation is a formal review by the focal area leads to determine accuracy and applicability, yet it may be more desirable to incorporate a feature to facilitate the ease of generating a new scenario.

The remaining enhancements to the model were primarily a function of scope limitation and the need to integrate them into a developing governance process. One such enhancement would be the incorporation of interlocks that identify mandatory scenarios which must be completed prior to a certain phase of governance review. This is similar to the idea of filtering scenarios based on mode of entry, but would require the determination of scenarios that senior management would like examined prior to a given governance review phase. Another improvement to the model would be to further refine the generalized baseline risk profiles that were created by establishing baseline risk profiles for each region. Regional baselines would allow for a more relevant comparison to the local market and generally be more familiar to the leadership for a specific region. Finally, as the scope was limited to the commercialization phases up until product launch and limited to only existing company products, there is an opportunity to extend the model to post entry considerations as well as pipeline product introduction.

5.7 Sustaining Emerging Market Entry Risk Assessment Model

Although a process was established for the EMERAM's use, it is necessary to develop a plan for integration into the organization to actualize the model at an enterprise level. This consists of a three-phased roadmap approach shown in Figure 20.

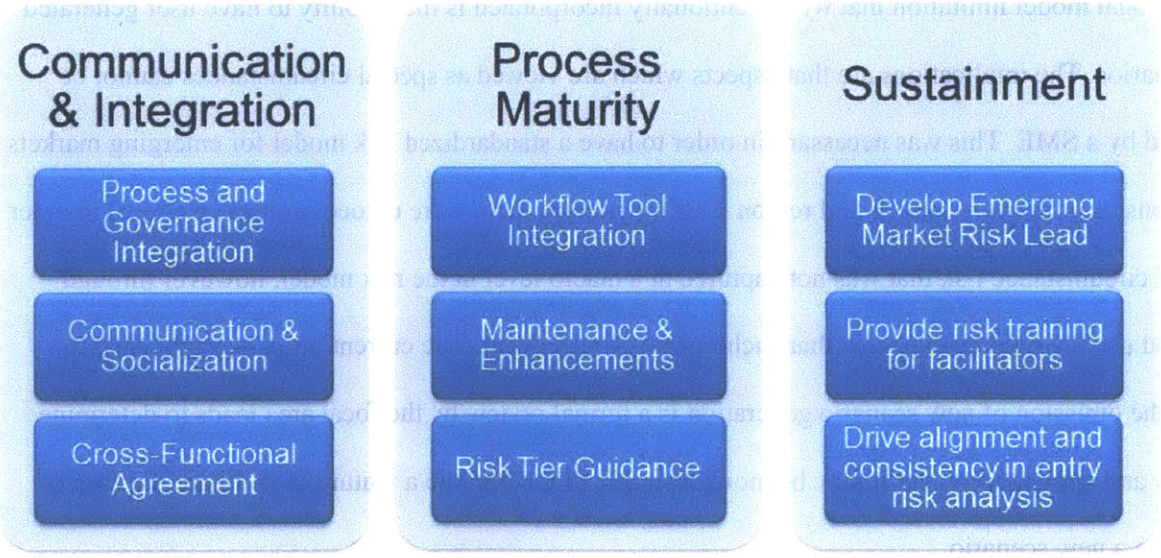

Figure 20: Roadmap for Integration, Maturity and Sustainment

The Communication and Integration phase of the roadmap focuses on efforts required to substantiate the model as a formally agreed upon way of integrating the process in the future. Initially this phase requires the integration of the proposed EMERAM process into the governance review process as well as any desired refinements. The proposed process for integration of the model into governance is outlined in Figure 21. In each commercialization phase a workflow is run of the entire model. In all instances this occurs five weeks prior to a governance review, with the exception of the Commit to Launch phase which is conducted three weeks prior to governance and serves as a final validation of the prior phases. Initiators of the model at each commercialization phase are chosen based on business need or launch commitment. Two weeks prior to a governance evaluation, focal area leads review the output and high risks are escalated appropriately. Focal area leads are responsible to ensure control cost efforts are included in financial analysis or profit and loss statement for the target launch country.

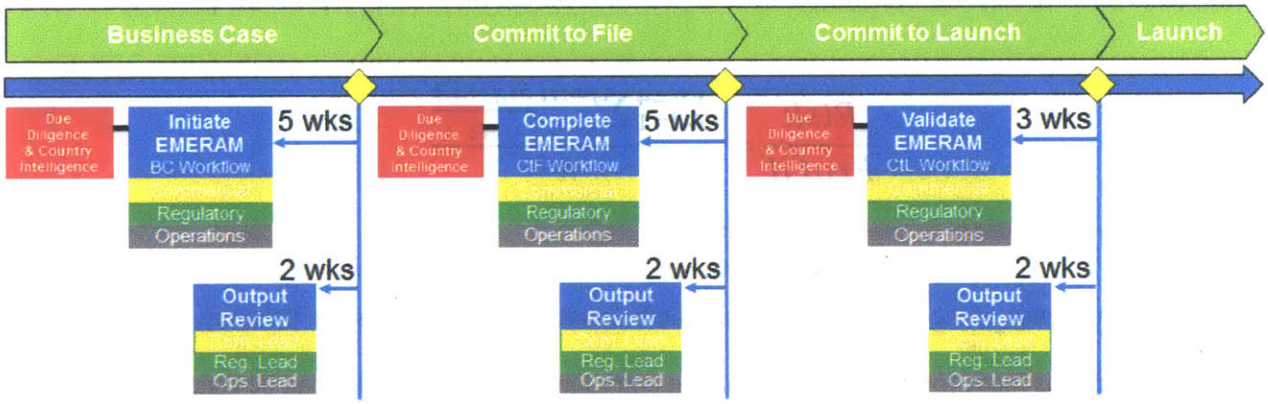

Figure 21: Proposed Process for Model Integration into Governance

The Communication and Integration phase concludes through efforts that are required to communicate the existence of the model, the approach on how to use it and further socialize the model within the organization, particularly at a senior leadership level. Finally a cross-functional commitment is needed in which the output is the establishment of an agreement that officially solidifies the model as a mandatory step in the process for emerging market entry.

The next phase of the roadmap, Process Maturity, centers on efforts needed to scale the model to an enterprise level. The first aspect of this phase strives to develop the Microsoft SharePoint workflow tool which allows for streamlined usage of the model. Next, necessary maintenance and enhancements to the model become the goal. These will be driven by the leads for each focal area and based upon feedback and experiences incurred during model execution. Finally, the phase concludes with the establishment of risk tier guidance. This concept aims to establish country risk tiers based on a risk to profit ratio. The numerator of the risk to profit ratio is calculated by summing the product of severity and likelihood for each risk scenario in a given focal area, then dividing it by the number of risk scenarios in the focal area and completing this for all four focal areas and taking the total sum. The denominator is based on the steady state annual profit for the target emerging market entry country. The equation for the risk to profit ratio is shown below, where i is the focal area number, S is the severity of failure score, L is the likelihood of occurrence, N is the number of risk scenarios for the focal area, and π is the profit.

$$\frac{Risk}{Profit} = \frac{\sum_{i=1}^{i=4} \sum_{j=1}^{j=Ni} \frac{Si,j * Li,j}{Ni}}{\pi}$$

Note: The numerator is divided by N_i since L_i is not a probability

Through continued use of the model, data points can be established which provide meaning through relative comparisons made to past emerging market entry launches. Tiers of risk can be established based on the risk to profit ratio and drive further action as needed per risk tier. The overall benefit to the concept is that risk tier guidance allows the organization to identify a potential high risk entry country when high risk levels have not been identified for any of the individual risk scenarios.

The final phase of the roadmap, Sustainment, strives to maintain the model and supporting process for permanent use within the organization. The initial aspect of this phase is to develop a position and appoint a resource committed to emerging market risk. This role would be performed by an emerging market risk lead and who would have responsibility for monitoring risks associated with emerging market entry at a network level across all regions. Additional responsibilities would include: ensuring proper use and

updates of the model, communicating risks to management and the company risk network and maintaining documentation associated with the model. The next aspect of this phase is to provide risk training for facilitators and focal area leads. This is a necessary step in order to support the scalability of the tool and proper output reviews compliant with company risk standards. Finally, through the prior steps and appropriate model usage, the organization should be able to attain a level of alignment and consistency in emerging market entry risk analysis.

5.8 Chapter Summary

The Emerging Market Entry Risk Assessment Model (EMERAM) and supporting processes have improved the state of the organizations risk analysis through the incorporation of a structured and repeatable approach. Through the use of pre-determined risk scenarios with recommended severity of failure scores, a rigorous model has been developed which does not overburden resources in order to gain valuable output. Four staggered pilots with improvements incorporated into the model between each wave of piloting supported the proof of concept. While a significant amount of work was conducted by the author, the true value in the model came from integrating the expertise of all of the SMEs who live the emerging market entry commercialization process on a daily basis. Without this support, the model would be very limited and therefore not applicable in many launch instances.

6 Conclusion and Next Steps

As Amgen continues to pursue its goal of reaching more patients through growth opportunities in international expansion, rapid emerging market commercialization causes a number of challenges relating to scalability of current practices and complexities associated within each region. This thesis is comprised of two strategies, managed in separate research areas, to develop potential solutions to the challenges encountered, the investigation of improvement opportunities in the commercialization of emerging markets and the development of a risk assessment model applicable to new market commercial entry. Each research area proved to be a rather complete and rewarding experience. Though the research areas were separated in scope, based on specific deliverables to be accomplished, both areas complimented each other in enhancing the author's understanding and providing a complete depiction of the commercial process for emerging markets. This was primarily due to the fact that both research areas provided a solution to the macro problem faced by the organization and international expansion through rapid emerging market entry. Due to the nature of the project, concluding thoughts and next steps for each research area will be discussed separately.

6.1 Research Area 1 Conclusion - Emerging Market Entry Process Analysis

The Emerging Market Entry Process Analysis sought to conduct an assessment of improvement opportunities for emerging market commercialization by providing a tangible set of actions the organization can take forth in order to enhance the planning and execution of new market entry. The Six Sigma Process Improvement DMAIC methodology was used as the framework to assess this research area and report progress to the leadership team. This DMAIC method was selected as it provides a foundation for a structured project approach, with specific tools that can be utilized and is therefore most appropriate when the intent of the project is to make enhancements or improve an existing process due to inadequate performance. The analysis was accomplished through an in depth study to determine the current level performance for commercial market entry. This consisted of aspects such as the SME engagement, data analysis, root cause analysis and process improvement tools. The current state analysis

allowed for a future vision to be established which incorporated fundamental principles of operational excellence methodologies, integrating various techniques to develop a cohesive approach for improving current market entry practices.

The results of the Emerging Market Entry Analysis provided a detailed emerging market entry commercialization improvement framework. A supporting implementation roadmap was created to guide the organization, specifically the GSC group, in executing a tangible set of actions through incremental improvements. The goal of the framework is to integrate operational excellence into the commercial entry process and ultimately improve the planning and execution process for new market entry. Although a pilot was omitted from the research area, efforts were made to ensure alignment with organizational plans and receptiveness. A substantial effort was made to communicate and involve cross functional representation concerning the concepts employed and validation of the proposed methodology for improvement. Further work is needed in order to formalize the proof of concept through future pilot efforts. Based on piloting efforts further enhancements to the proposed framework for improved emerging market entry commercialization can be included based on changes to the international expansion landscape or as desired by the company.

6.2 Research Area 2 Conclusion - Emerging Market Entry Risk Assessment Model

The Emerging Market Entry Risk Assessment Model (EMERAM) established a tool and a proposal for a supporting process that integrates the model into the organization to systematically identify risk associated with emerging market entry. The model complements the governance review process by providing adequate details on a target country that results in a risk-informed decision making process that occurs at a senior leadership level as to whether or not a country should be entered. The model utilizes a scenario based evaluation methodology to integrate cross functional expertise across the organization by assimilating information that would normally be isolated to a small group within the company. Scenarios were established through direct engagement of SMEs, reviews of prior launches and literature reviews of relevant topics including past theses. Risk levels are determined for each scenario, based on the

combination of severity of failure and likelihood of occurrence, and a risk report is generated. The model output is reviewed cross functionally with the SMEs that conducted the assessment and functional focal area leads. Scenarios identified as potentially requiring remediation are reviewed in a detailed risk assessment and resolved as appropriate. If there is substantial cost associated with control efforts needed to mitigate a risk, the costs of such activities are incorporated into the financial analysis for the target launch country. Thus, the model enhances the organization's view of the ramifications associated with incremental entry of a new country by providing a depiction of cost versus reward for the target launch country.

The EMERAM and supporting process improves the organization's risk analysis through the incorporation of a systematically structured and repeatable approach to conducting risk assessments. A robust model was created through the use of pre-determined risk scenarios with recommended severity of failure scores that do not overburden resources in order to gain valuable output. Validation of the model occurred through four staggered pilots with improvements incorporated incrementally between each new wave of piloting. The results of piloting revealed that a rigorous model was established that does not over or understate a risk concern. Instead, it provides an accurate depiction of pertinent risks relevant to the organization if the decision is made to enter a target country. Furthermore, the model developed increases the firm's ability to make agile risk-informed market entry decisions while providing a standardized method that is scalable cross regionally. A detailed review of future enhancements of the existing model was provided in section 5.6, but most notably efforts should be made to transfer the tool from Microsoft Excel to a platform that better supports the work flow aspects needed for properly scaling the tool at an enterprise level. Finally, work will need be established to actualize the roadmap for integration, maturity and sustainment of the EMERAM, in particular establishing an agreed upon process for incorporating the model.

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