The Effects of Vendor and Quality Control Variability in the Procurement of Raw Materials in a Bio-Pharmaceutical Company

by

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B.S. Manufacturing Engineering Technology
Brigham Young University, 2007

Submitted to the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degree of

Master of Engineering in Logistics

at the

Massachusetts Institute of Technology

June 2011

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Abstract

Pharmaceutical companies have traditionally placed little emphasis on supply chain efficiencies and operations costs. With the changing landscape of expiring intellectual property rights and increased market segmentation, the need for improved supplier relations and inventory management is becoming paramount.

This thesis presents a study of a procurement system within a biopharmaceutical company. The many sources of variation in delivery lead times from both suppliers and internal departments coupled with variation in manufacturing demand, has resulted in excess raw-material inventory at the company. By using discrete-events-simulation software to model the system and its inputs, we generate insights that can help the materials management team maximize their efforts to improve the system performance. In this particular case, it was found that reducing supplier lead time variability was far more effective in reducing the need for inventory than reducing average lead times or even internal lead times from the Quality Control department.

The pharmaceutical company involved in this study would be best served by focusing its efforts on working with suppliers to increase the consistency of delivery for their raw materials. This increased consistency will allow them to reduce total inventory costs by reducing the variability of the raw-material supplies.

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Title: Research Director – Supply Chain 2020

Acknowledgements

I would like to thank the several people who offered their time and thoughts to help me write this thesis. Dr. Mahender Singh, my thesis advisor, laid the groundwork for supply chain research in the pharmaceutical field and helped me to formulate the story that I could tell with the modeling work. Neil Lerner was an incredibly positive teacher that helped me be confident in my abilities and taught me how to better convey my message through writing.

I have to thank the people at ABC Pharmaceuticals that provided their data and insight into their business. Without them, not only would I not have a thesis topic, I would never have been able to grasp the significance of the pharmaceutical industry and its intricacies.

I also have to thank my many friends and classmates who were always willing to listen to me complain about deadlines, lack of progress, or lack of motivation. Those same friends provided so much inspiration and encouragement to continue and to work hard.

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1 Introduction

1.1 Background and Motivation

The pharmaceutical industry is unique from other industries in several aspects. Traditionally, pharmaceutical companies have focused on patient treatment and drug development and not operational efficiency or supply chain effectiveness. Because of high gross margins and the purpose of the drugs, the cost of a lost sale is very high both financially and for the health of individuals. These companies, therefore, have often pushed for high service levels without great consideration of inventory management or manufacturing excellence.

Several trends within the pharmaceutical industry are forcing companies to change, however. Expiring intellectual property rights and increased competition are forcing companies to reexamine their strategies and operations (Singh, 2005). The influence of contract manufacturers who are more effective at managing operational costs is also driving the industry to re-examine its options.

Traditionally, the pharmaceutical companies, also known as big pharma, relied heavily on the discovery of blockbuster drugs – drugs with annual sale of USD 1 Billion or more - for their success. But of late this model has been challenged due to a poor pipeline of successful drugs to replace the current blockbuster drugs for which patents will soon expire. However, within the broad industry of pharmaceuticals is a smaller subset of growing "bio-pharmaceutical" companies that have been successful in developing unique and innovative drugs. These companies are using biological advances to change the nature of the pharmaceutical industry.

Furthermore, a unique movement within the bio-pharmaceutical segment of the industry has emerged in the last decade. Companies have begun to vie for smaller and segmented, yet highly

lucrative, markets. These markets are characterized by patients with rare life-altering and life-threatening diseases. Because of high development costs and corporate interests in common conditions for the sake of volume, these patients have, until recently, had little recourse for treatments and drugs. But with the aid of government and insurance subsidies, it has become economically feasible for corporations to provide treatments for those with these rare diseases, and also feasible for people with these rare conditions to purchase the same treatments.

Revolutionary technologies are allowing companies to "grow" enzymes to replace those lacking in individuals and causing health problems. These enzyme replacement drugs are created with processes and materials that are closely kept and safeguarded. Unfortunately, however, because of the unique industry attributes (high cost of a lost sale, small specialty markets etc.) vendors and internal departments have not been held to normal manufacturing and supply chain standards. Rapid company growth has also provided an atmosphere where many companies have had to "scramble" to assemble supply chain capabilities to support the burgeoning demand. This explosive growth necessitates that materials be in place and drugs delivered to the needing patients before structure can be injected into procurement systems.

Specifically, in material procurement from the various vendors, significant opportunities exist for supply chain improvement and collaboration. In general, the importance of the availability of finished products to serve the final consumers dictates most supply chain decisions, which has resulted in large amounts of inventory throughout the system. Consequently, there is ample opportunity to reduce inventories and reduce costs related to holding inventory without sacrificing drug availability.

The "newness" of the industry and the rapid growth of biopharmaceutical companies have resulted in a lack of development of proper supply chain and inventory management practices. Fire fighting is the norm for material management teams as they scramble to keep up with growing demand and

manufacturing requirements. Regulatory restrictions coupled with high quality standards further complicate any improvement initiative.

Also, a unique set of business parameters in the industry mean that traditional supply chain metrics and methods may not be appropriate. Inventory management in the bio-pharmaceutical segment can be especially difficult: long manufacturing lead times, the "life and death" nature of products and variable demand dictate a new approach to an old problem.

1.2 ABC Pharmaceuticals as an Inventory Case Study

NOTE: With the purpose of protecting the proprietary information of the pharmaceutical company studied in this thesis, all company and material titles have been removed and replaced with proxy values. The company is referred to as ABC Pharmaceuticals or ABC and specific materials are referred to as Material 1, Material 2, etc. The numbers included have not been modified.

ABC Pharmaceuticals is a bio-pharmaceutical company that manufactures many drugs (biologically based and otherwise) that are used to treat various diseases. An in-depth analysis of the procurement and quality control process for ABC Pharmaceuticals is provided as an example for demonstration of inventory sensitivity to changes in lead time length and variability. An examination of Quality Control processes is also presented. There are many inputs in ABC's supply chain that could have been modeled and incorporated into the scope of this thesis, but for the sake of time and resources, only the first stages from material procurement to manufacturing availability are included in this study.

This thesis describes ABC Pharmaceutical's management of inventory for the production of a single drug substance. Within that single drug substance, an in-depth analysis is provided for six distinct

materials or "ingredients". Two methods are used to make recommendations for their inventory levels and management policies:

1. Other industries with similar problems and constraints will be examined and appropriate methods will be applied to ABC's policies.

2. A simulation model will be developed to determine appropriate inventory levels under different scenarios.

The drug addressed in this thesis is controlled by a single purchasing/materials management group that is accountable to the manufacturing group for material availability and quality. All materials used in the production of the drug and all decisions concerning quality control (QC) and vendor selection are dictated by this single group. A very simplified overview of the procurement and material inspection process is shown in Figure 1-1. This flow includes only a few nodes and arcs to include: Purchase Order issued, vendor lead time, Quality control, and availability for manufacturing.

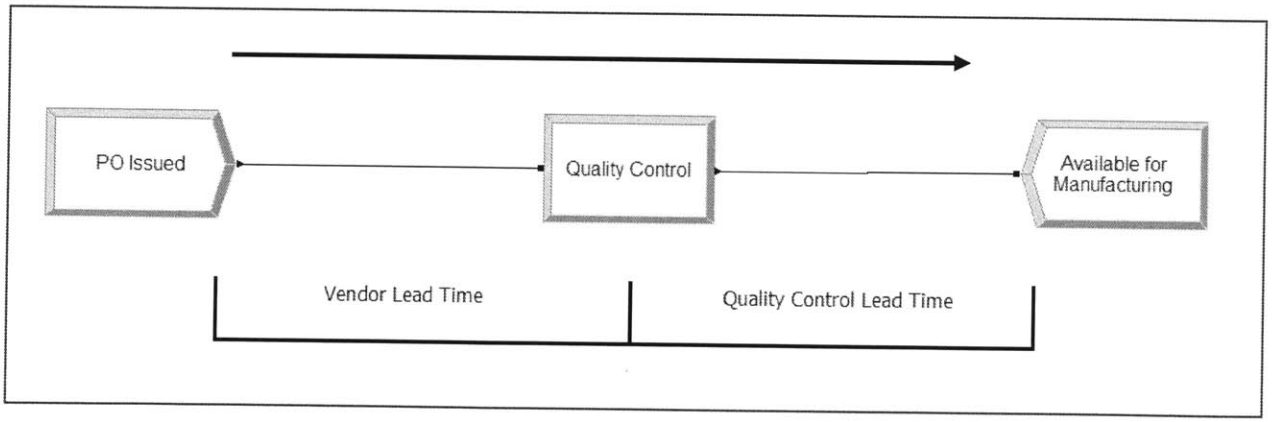

Figure 1-1 - Simplified Process Flow Representation of ABC's Material Procurement Process

The central goal of the material management team is to provide materials for the production of drug-substance without fail to the manufacturing team. This goal requires them to carry enough

inventory to buffer the variation in demand from manufacturing and variation in vendor and QC lead times. Secondary goals for the department include reducing costs related to carrying inventory and managing that inventory.

Another area of focus is the QC department of ABC Pharmaceuticals. Because of the nature of pharmaceuticals, documentation and control of these materials must be of the highest quality. Many of the materials are shipped from vendors with documentation but may have quality problems, while other materials are not sent as per the quality specifications or are adversely affected by the specific QC procedures and how they are treated. Most of the time when a problem is identified with a "lot" of materials, there is a resultant delay associated with that problem in the QC process. Granularity of these problems and their associated delays are incorporated into the study of this system. Because the lead-times within the QC department are so closely tied to the problems associated with material lots, it is appropriate to detail their effects in the model.

Specific insights gained from this analysis will be limited to application within the company under investigation, but general recommendations may be appropriately applied and valid in similar companies under similar assumptions and circumstances.

1.3 Analysis Structure

Because of the complexity of the variations involved with the procurement of the pharmaceutical materials, a mathematical model is not appropriate for estimating inventory impacts and changes in policy based on vendor lead time and QC improvements. After a basic understanding of the problem and situation was conveyed, it was decided that a computer simulation would be the most appropriate tool to assist in the process of understanding and analyzing the dynamics of ABC's

procurement flow. Simulation software has assisted in estimating a model that accurately reflects the system and its reaction to certain changes.

By simulating the variations associated with vendor lead times, QC process times and the demand from manufacturing, the system response to buffer inventory was observed. Changes in these inputs as a basis for hypothetical scenarios resulted in changes in inventory levels and holding costs. A more detailed account of the methods and results associated with this model and its estimations are included in Chapters 3 and 4 respectively.

This thesis presents the data from various scenarios that give ABC pharmaceuticals motivation and direction to concentrate their ongoing improvement efforts in recommended areas. Several recommendations are proposed based on the results of the simulation and the detailed study of the business and procurement process.

To properly convey the subject matter in this thesis, it is organized in the following manner. Chapter 2 presents a thorough examination of the extant literature pertaining to the problem. Chapter 3 outlines, in detail, the methods used to dissect and analyze the data and inputs. Chapter 4 presents the results and data gathered through the simulation and mathematical analysis portion. Chapter 5 offers specific recommendations and possibilities for academic and industry application and Chapter 6 presents conclusions. Appendix and Reference sections are also included to present cited material and additional information not included in the main text.

2 Literature Review

Several factors influence the reliability and availability of materials to manufacturing in the bio-pharmaceutical segment. Because of the complexity of the system and multiple factors that contribute to inventory levels, a comprehensive study of an entire comparable system poses a formidable challenge. In the system that is addressed in this paper, raw materials are bought from vendors and must be available for production on certain dates (Singh, 2005). Long and variable lead times are coupled with internal service variation and frequent changes in manufacturing schedule to meet similarly variable demand patterns. Most of the research in this field leans on mathematical models to deal with distinct aspects of this problem.

There has been limited research on the pharmaceutical industry supply chain as a whole. Many of the unique issues, disadvantages and advantages as they relate to supply-chain functions were compiled and demonstrated by Singh (2005). His research addresses the differences between pharmaceutical companies and typical industries. These differences include the emphasis on development and new drug introduction. These factors and the historically high margins and profitability have fostered an environment in which supply-chain functions have not received the attention or emphasis that they deserve.

Singh touches upon the problem of raw material difficulties, but does not go into depth on the subject. Whereas, Goren and Clapp describe how FDA regulations require large capital investments by suppliers to comply with the law (Goren & Clapp, 2005). Because of this barrier to entry, it is often difficult to dual-source materials or for buyers to have leverage with suppliers based on threat of alternatives in the market.

Beyond the relevant literature related to the biopharmaceutical industry, we will review sources and practices outside of the pharmaceutical industry that can be applied to this specific situation.

There is extensive literature that relates directly to specific attributes of the system under investigation. These areas of research can be categorized as dealing with either the supply side or the demand side influences. The applicable research can be divided into the following areas on the supply side:

1. Varying and long supplier lead times in procurement (2.1.1)
2. Long and varying internal lead times (2.1.2)

And on the demand side:

1. Highly variable short term demand coupled with predictable long term demand (2.2.1)
2. High service levels for material availability to manufacturing (2.2.2)

2.1 Supply

2.1.1 Varying Supplier Lead Times

The problem of varying lead time in procurement can be perplexing and several methods for managing this variation have been proposed in the literature. Louly and Dolgui (2009) propose a method in which several components, all with varying lead times and lead time factors, are brought in for assembly of a single product. Their method for planning the orders of the products involves a simple process of determining individual component safety stocks.

Just as safety stocks in finished goods inventory buffer against variation in customer demand, component safety stocks buffer against changes and uncertainty in supplier performance and lead time. This method, of using time as a buffer, applies to bio-pharmaceutical manufacturing as multiple chemicals and ingredients are brought in to contribute to a single final batch of products.

It is important to recognize that coordinating the availability of all components is key since a batch of final product cannot be made unless all components are available. This method, however, applies only when orders from suppliers will be used for multiple production runs. If orders are made on a single-production-run basis, keeping a safety stock of a component may not make sense.

In the case of the bio-pharmaceutical industry, orders from suppliers are often completely used up by a single production run. That makes the use of a "safety stock" system for components applicable only for materials that can be used in multiple batches or for multiple products. In the case where an entire order is consumed in a single production run and, since production batches cannot be initiated until all components or ingredients are available, another method must be used. Kumar (1989) describes a simple method, similar to the "safety stock" method, where lead times are variable and the production batch has a defined start time but can be delayed by the late delivery of any single component. Determining when to order components so that costs (holding costs and production delay costs) are minimized and service levels to the customer are still met is of utmost importance. Instead of using safety stock to buffer uncertainty, Kumar describes a method that uses time to buffer uncertainty. Essentially, materials are ordered well in advance based on historical information so that lead time uncertainty is accounted for in planning.

Bollapragada, Rao and Zhang (2004) talk about combining random supply and random demand in an inventory system. They use mathematical methods to estimate appropriate buffer inventory levels. Much of their research centers on a multi-echelon inventory environment, but many of the insight gained from combining supply and demand uncertainty mathematically are still applicable.

As discussed in section 2.2.1 in this chapter, the σ_L term in equation 2.1 is generally used to calculate safety stock needs per the demand variability. However, Silver, Pike and Peterson (1998) also demonstrate the same variability term can be converted to determine lead time variability in supply for a specific material inventory.

2.1.2 Internal Lead Time Variability

Wilson (2010) describes that anytime there is variation in a system, there must be something to buffer that variation. Buffers can come in any of three forms: inventory, time, or capacity. In the case of the internal system investigated in this thesis, all three of these buffers could apply. Raw material inventory currently buffers the lead times associated with QC processing the lots. Extra time built into the ordering of materials could also buffer the lead time variation. Capacity is also a concern that could alleviate the variation in the Quality Control department.

2.2 Demand

2.2.1 Highly Variable short term demand

Variability in demand and the effects on required inventory levels can be characterized for the most part with mathematical models. Silver Pike and Peterson demonstrate that under the assumption that demand variation can be aggregated and under the assumption of normally distributed demand equation 2.1 can be used (Silver et al., 1998).

$$SS = k\sigma_L \tag{2.1}$$

where:

SS = Safety Stock
k = is a safety factor related to a desired service level
σ_L = the standard deviation of forecast errors over the period of duration L

This model is useful under any demand regime where inventory can be monitored on a continuous or near-continuous basis. The model is also applicable under circumstances of low demand variability.

2.2.2 High service Levels to an Internal Customer

High service levels to internal customer can be related to high service levels respective to any customer or demand. Service level targets can be used to determine inventory levels mathematically as shown in Equation 2.1. The "k" parameter can be inflated to mathematically represent better service level to a final customer (Silver et al., 1998).

Beyond mathematical models and equations lies an application aspect of inventory control. Articles by Ouellet, et al. (1982) and separately Gross, Harris and Robers (1972) demonstrate how to properly implement mathematically derived service levels into real-world inventory situations. These applications are important for validation of the mathematical models. Mathematical models are not useful unless they have been implemented and validated in real world settings. For this reason, the two case studies cited here are important.

2.2.3 Unpredictable events/market uncertainty

To a certain extent, statistical models can account for uncertainty and wild fluctuations in demand or supply. However, most of the time, large events that may affect inventory levels can't be planned or not factored into inventory levels. Wild fluctuations that cannot be predicted by demand forecasts are hard to plan, especially when methods used to analyze costs and profits only are used. Lau (1980) addresses this unpredictability by using the newsboy model to optimize parameter other than profit. His notion of utility may be adapted to integrate a notion of risk aversion in inventory planning.

2.3 Summary

There are many sources in literature that describe mathematically how systems can properly buffer against uncertainty using inventory, time or capacity. There are also pieces of important literature that demonstrate the application of mathematical models in real-world applications. The combination of these sources provides an important backdrop for the work presented here. In this thesis, application of inventory policies is modeled using simulation tools. Also, the mathematical models that underlie inventory policies are used to calculate many of the results from the simulation model.

3 Methods

We have chosen discrete-event simulation technique to map and analyze the procurement process at ABC Pharmaceuticals. The simulation model helps to track the impact of lead times and their variations associated with different raw materials and the attributes of the raw materials.

A base simulation model was created and several variations of the model were also tested. These variations are referred to as scenarios. The methods and assumptions used to create and analyze the base model along with the scenario changes are described in this section. Those methods and assumptions are listed here:

Methods

- Simulation Model
- Scenario testing
- Best practices outside the bio-pharmaceutical industry

Basic Assumptions

- Variations in the system are represented as statistical distributions.
- Structural simplicity is implemented in certain areas of the model to allow easier understanding and quicker modeling of the system.
- Base-model data is assumed to represent the current state and near-future state of the procurement system.

Also, just like any model, there are limitations, and some of those limitations are described in section 3.4 of this chapter.

3.1 Arena Model

The model for this thesis was developed in Arena. Arena is a discrete-event-simulation software product licensed by Rockwell Automation Technologies Inc. The software is used to create interactions between processes and entities. Entities are the objects that move through the flow path of the simulation. Processes and decision points determine the attributes and the delays associated with moving through the system. The entities can be programmed to possess certain attributes which affect how they are treated by different steps and processes.

Each input to the model (arrivals, delays, attributes, etc.) can be set to statistically resemble real-world conditions. Probabilistic and stochastic variables can be simulated through computer generated random variables. The type of probability distribution can range anywhere from something simple like a discrete uniform distribution to a much more complex user-defined schedules and sub-models. We are using a combination of mostly uniform, discrete and normal distributions to characterize the data and input it into the model. A list of model input and the associated distributions are included in Table A-1 of the Appendix.

3.1.1 Modeling Approach

The model used for this thesis treats individual raw material lots as entities. A single lot in the model is defined as the quantity that would be ordered for a minimum production run. The reason lies in the way that the QC data was presented. The Quality Control department measures its own performance and deals with materials in the form of lots instead of individual units of measure.

The processes used in the model relate to various lead times associated with vendor delivery and QC inspection. Each lot that enters the system has probability of possessing certain attributes.

These attributes signify errors and problems with the raw materials. QC lead times are directly linked to the types of problems incoming raw materials possess. A list of the QC problem codes and the associated delays is included in Table A-4 in the Appendix.

The model was created using historical data from ABC Pharmaceuticals. After the model was run using historical data and validated (see Section 3.1.2), inputs were changed through a source spreadsheet file that feeds back into the model. This allows the user to easily "test" scenarios that may occur in the future, or scenarios that may improve the performance of the model. For example, the user can reduce vendor lead time on a single material by changing the value in the spreadsheet and by doing so can quickly see how raw-material inventory levels are affected. These scenarios are detailed in section 3.2.

A snapshot of the model is shown in Figure 3-1 and Figure 3-2. The model has six main modules and the sub-models dictate the behavior at the "vendor lead time" module and the "QC" module. Demand for raw material inventory by manufacturing is also modeled as a random process.

Manufacturing demand is modeled as an independent process in the model. The two processes work hand-in-hand to represent the real world processes. The models simulate the process in which manufacturing signals the beginning of a production campaign in a specified amount of time. This specified time is equal to the combined stated lead times for the material from the Vendor and through QC (Table A-2 Appendix). When the procurement process receives the signal from manufacturing, it "orders the materials". When the combined lead time has elapsed, manufacturing sends a signal to the raw material inventory to release the prescribed number of material lots. The manufacturing process is diagramed in Figure 3-2.

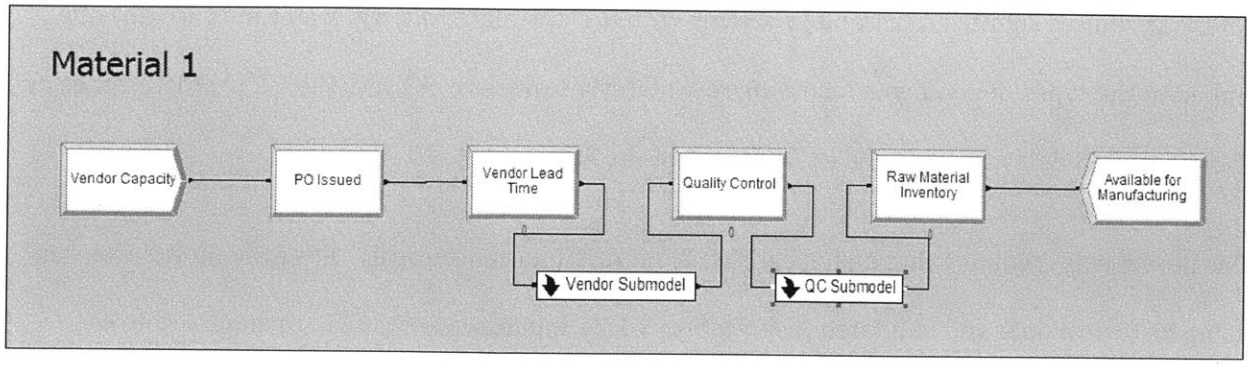

Figure 3-1 – Procurement process as modeled in Arena for Material 1

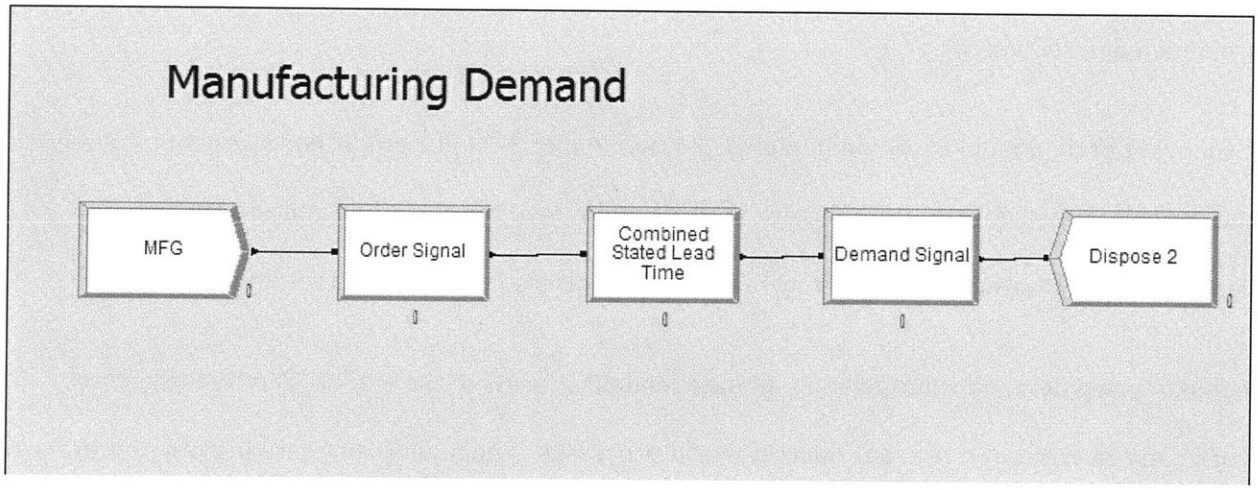

Figure 3-2 – Manufacturing demand process as modeled in Arena

Figure 3-3 – Snapshot of the entire model, including the procurement processes for all six materials on the left and the associated manufacturing demand processes on the right.

3.1.2 Verification and Validation

Any model must be verified and debugged to ensure that any unexpected results are due to probability and stochasticity and not model or human error. This step can be performed by

removing all initial probability and variation built into the model and running the model. The model should perform predictably under the set of ideal circumstances. Adding probabilities and variation factors individually and independently in the model should also produce a predictable set of results. The model was verified following this method. All outputs performed predictably with variation removed.

After the initial model was built, validation step was performed. Since the model is meant to mimic reality in its current state, it must demonstrate behavior similar to what has been observed by the bio-pharmaceutical team. To properly validate the base model, output data was shared with the materials management team at ABC Pharmaceuticals to ensure that it reflected reality.

In this validation phase, the model was run and the output (overall lead times and raw material inventory requirements) was compared with the data that is being collected empirically. Although the model will not exactly mirror reality, it should give a reasonable representation of what is being observed, in other words, the output ranges and averages should be comparable. Without the validation that the model represents current state system behavior, it is useless to model scenarios or to even infer possible strategies from the model. The management team at ABC Pharmaceuticals reviewed early model outputs and determined that they correlated with their knowledge of the system and the data with which they were familiar.

3.2 Scenario Modeling

Most of the scenarios have been developed in conjunction with the team from ABC Pharmaceuticals. These scenarios are suggested based on what is thought to be ideal realities and possible improvements to the current system. Other scenarios are based on "best practices" from outside of

the bio-pharmaceutical industry, or insights gained from testing the model. As mentioned before, the scenarios are tested by changing model input on the source spreadsheet and running additional replications of the model. Structural scenarios have not been modeled, although some suggestions for structural changes are made in the findings of this thesis (Chapter 5).

3.2.1 Vendor Lead Time Scenarios

Vendor lead times comprise two parts: the average lead time and the variation around that average. Both of these inputs can be important relative to the required inventory levels. That said, all vendor lead time scenarios were either based on reducing the lead time for a material (by working with a vendor or changing vendors) or reducing the variability of the lead time. In general, vendors quote maximum lead times and often deliver early or later than the quoted lead times. The assumption is that by reducing this uncertainty, inventory levels can be reduced. The model helps us to predict how the levels could change based on the different lead time parameters.

3.2.2 QC Improvement Strategies

It is much more difficult to predict how certain changes will affect QC lead times. The QC department at ABC Pharmaceuticals is fairly complex and a simple change to error rates or error types may not have a linear effect on lead times. Similar to section 3.2.1, lead times can be altered by changing the average or the variation. Additionally, within the QC portion of the model, certain material attributes that cause added delays within the QC department can be eliminated or minimized to view the affect on required inventory levels.

3.3 Sensitivity Analysis

To understand the significance of the model, it is important to test its responsiveness to input changes and to understand the limitations of the model. The sensitivity analysis performed for this model was important as it increased understanding pertaining to significant and non-significant results and shed light on which inputs influenced the dependant variables to the greatest extent. Basic input manipulation very similar to the design of the various scenarios was performed as well as analysis related to margins of error and confidence intervals.

Because the simulation model is an exercise in statistical manipulation and combination, there is an inherent margin of error associate with all outputs. To this end, along with normal outputs, the software has the ability to generate statistically derived margins of error associated with certain confidence levels. The base model and all the scenarios were developed and simulated with a 95% confidence interval. The margin for error is especially relevant as cost savings are reported in Chapter 4.

3.4 Limitations

Simulation models have their own analytical limits. The model is meant to represent reality and to predict what could happen in the future based on a set of defined circumstances. Unfortunately, because the model represents a random system and does not encapsulate the infinite detail of the real-world, the model and its outputs will not and cannot be completely accurate. We can, however, gain a better knowledge of how a system works by building a representation and testing the representation to gain important insights.

Another limitation pertains to the inputs to the model. Some assumptions were made that may not be valid with further collection of data. For example, some inputs were modeled with normal distributions, but more data may show that they should characterized by alternate distributions. Also, in the case of the demand from manufacturing, it was difficult to collect accurate data during the study period. In the instances where data was not readily available, proxy representations were used in the model based on interviews or empirical estimates given by the ABC Pharmaceuticals team. Referencing Table A-1 in the Appendix can give a sense of statistical and data limitations presented here.

4 Results

This chapter summarizes the results from running several versions of the base simulation model. It highlights important findings that will be discussed further in the conclusions section of this thesis. After building the model, a sensitivity analysis was performed to better understand the results and the key drivers to the dependant variable in the model (raw material inventory levels). Some of the results from the sensitivity analysis are incorporated into the scenario results.

The results from the base model will first be described followed by the several scenarios that were also developed. For each case (base and scenarios), several variables will be reported. These include, but are not limited to: appropriate safety stock levels, annual holding costs, vendor lead times and QC lead times. The variation associated with each of these outputs will also be reported. In this way each scenario can be compared with the base case and other scenarios with consistent criteria. The numbers are reported for each of the six included materials.

Additionally, with the exception of the combination scenarios described in Section 4.2.6 of this chapter, all scenarios were developed to isolate a specific input change so that the change was not confounded with the presence of other variable changes. For example, in Scenario 1, the vendor lead time is reduced by 20%. This reduction is made with lead time variation and all QC lead times remaining consistent. In this way, the policy of reducing vendor lead time can be examined independent of any other process changes.

NOTE: All simulation results, holding cost and safety stock calculations were made with the assumptions of a 12% holding cost rate and a z = 3.02 (99.9% Fill Rate).

4.1 Baseline Model Data

The baseline model in this thesis simulated the current materials management process at ABC Pharmaceuticals. The resultant metric measurements are approximations of real world metrics. This being said, the insights gained from the data can be used in a relative sense to predict what could happen at a high level if certain improvements or changes are made to the system.

The base model was developed to represent as closely as possible in the available time, the system that currently exists at ABC Pharmaceuticals. Running the base case resulted in the model outputs summarized in Table 4-1.

Table 4-1– Base Scenario Inventory Results

		Base Scenario
Total	Holding Costs	$5,342,518
	Total Inventory Value	$44,520,980
Material 1	Safety Stock (Lots)	25
	Holding Cost/year	$464
	QC WIP (Lots)	55
Material 2	Safety Stock (Lots)	31
	Holding Cost/year	$3,079,512
	QC WIP (Lots)	11
Material 3	Safety Stock (Lots)	18
	Holding Cost/year	$224,198
	QC WIP (Lots)	29
Material 4	Safety Stock (Lots)	20
	Holding Cost/year	$285,694
	QC WIP (Lots)	27
Material 5	Safety Stock (Lots)	22
	Holding Cost/year	$16,094
	QC WIP (Lots)	24
Material 6	Safety Stock (Lots)	17
	Holding Cost/year	$11,219
	QC WIP (Lots)	27

As Table 4-1 shows, safety stock quantities vary from 17 to 31 lots and annual holding costs total more than $5.3 million. Also, the table demonstrates that a large portion of the costs are being accumulated for a single material, Material 2.

4.2 Scenario Data

Several scenarios were developed and run for comparison against the baseline model. Raw-materials inventory was the main dependent variable that was measured. Closely related to inventory levels are the calculated holding costs. Most of the scenarios are presented in the form of the following question: How is inventory affected and how much money is saved in holding costs if a certain improvement or change can be made to the system? Improvements in lead times and reduction in variability were also analyzed for each scenario.

Further scenarios detail situations in which certain Problem Codes can be eliminated within the QC process. The final two scenarios describe combinations of the other basic scenarios. One of these combines the three error-elimination scenarios into one and the final scenario combines an *increase* in vendor lead time coupled with decreased lead time variability for a single material. The scenarios and the resultant data associated with those scenarios are presented in Sections 4.2.1 through 4.2.7.

4.2.1 Scenario 1 – Decreased Vendor Lead Times

In this scenario, and its sub-scenarios, lead times were decreased proportionally across the board for all suppliers. For example, if a supplier has an average delivery lead time of 50 days and the scenario calls for a 20% improvement, this simulation was run with an average lead time of 40 days. In this scenario, the variability in lead times for each supplier remained constant. The inventory improvements and holding cost savings are shown below in Table 4-2.

Table 4-2 – Summary of Vendor Lead Time Reduction Simulation Results

		10% Vendor Lead Time Reduction	25% Vendor Lead Time Reduction	50% Vendor Lead Time Reduction
Total	Holding Cost Savings over base	$26,352	$143,231	$352,047
	Available Inventory Reduction	$132,970	$1,136,674	$2,952,571
	Total Inventory Savings (Year 1)	$245,955	$1,336,826	$3,285,775
	Safety Stock (lots)	25	25	24
Material 1	Holding Cost/year	$470	$464	$456
	Safety Stock (lots)	31	29	27
Material 2	Holding Cost/year	$3,071,297	$2,964,473	$2,767,362
	Safety Stock (lots)	18	17	16
Material 3	Holding Cost/year	$221,798	$215,952	$207,321
	Safety Stock (lots)	20	19	18
Material 4	Holding Cost/year	$280,483	$273,659	$262,480
	Safety Stock (lots)	22	21	20
Material 5	Holding Cost/year	$16,140	$15,411	$14,888
	Safety Stock (lots)	17	17	16
Material 6	Holding Cost/year	$11,038	$10,822	$10,367

Table 4-2 and Figure 4-1 show that as vendor lead times are decreased, cost savings increase. A lead time reduction of 10% results in a $246,000 savings while decreasing lead times by 50% results in a much more significant savings of $3,286,000. Larger decreases in vendor lead times result in greater cost savings.

Safety stock values are also lower as the lead times are shortened. As an example, at a 10% reduction in lead time the safety stock for Material 2 is 31 lots. When the lead times are decreased by 50% the safety stock only needs to be 27 lots.

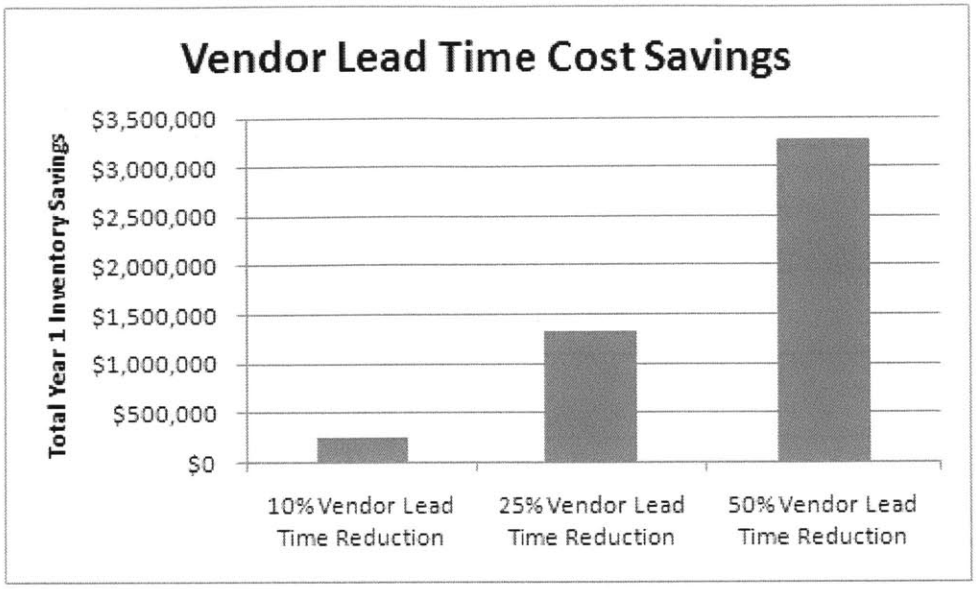

Figure 4-1 - Vendor Lead Time Reduction Cost Savings

4.2.2 Scenario 2 – Decrease Vendor Lead Time Variability

This scenario models the case where vendor-lead-time variability is decreased by proportional amounts. An example of a scenario detailing a 20% improvement in lead-time-variability across all vendors would be the following: Currently, a vendor has an average lead time of 50 days with a standard deviation of 20 days. The scenario would model that same vendor having a lead time of 50 days (same) with a standard deviation of 16 days. The proportional improvement is applied to all vendors for this scenario.

The changes to raw-material inventory and subsequent holding cost are displayed in the Table 4-3.

Table 4-3 - Summary of Vendor Lead Time Variability Reduction Simulation Results

		25% Vendor Lead Time Variability Reduction	50% Vendor Lead Time Variability Reduction	75% Vendor Lead Time Variability Reduction
Total	Savings over base	$415,934	$852,406	$1,141,465
	Available Inventory Reduction	$3,431,712	$7,089,284	$9,558,539
	Total Inventory Savings (Year 1)	$3,882,049	$7,955,788	$10,653,673
Material 1	Safety Stock	24	22	21
	Holding Cost/year	$448	$421	$412
Material 2	Safety Stock	27	23	20
	Holding Cost/year	$2,719,962	$2,323,216	$2,056,002
Material 3	Safety Stock	16	15	14
	Holding Cost/year	$207,559	$192,645	$183,682
Material 4	Safety Stock	17	15	14
	Holding Cost/year	$252,982	$227,769	$209,115
Material 5	Safety Stock	19	17	16
	Holding Cost/year	$14,341	$13,193	$12,337
Material 6	Safety Stock	15	14	13
	Holding Cost/year	$10,085	$9,224	$8,609

Figure 4-2 and Table 4-3 demonstrate the significant savings that can be realized by reducing the variability of vendor lead times. When vendor lead time variation is reduced by 25%, holding costs are reduced by over $400,000. When that same lead time variability is reduced by 75%, the holding cost savings increase to over $1.1 million. Total inventory savings are much higher, but increase comparable with the changes in variability.

Safety stocks are decreased significantly as well. Twenty-four lots are needed for the safety stock of Material 1 when the vendor lead time variability is reduced by 10%. Only 21 lots are needed when that variability is reduced by 75%.

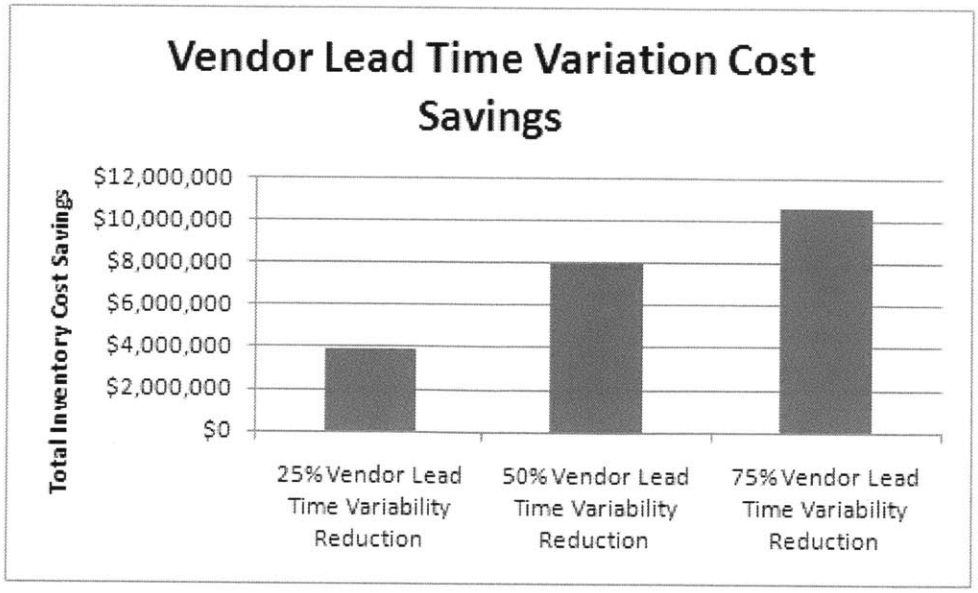

Figure 4-2 - Vendor Lead Time Variation Reduction Cost Savings

4.2.3 Scenario 3 – Decreased Quality Control Lead Times

Similar to Scenario 1, Quality Control lead times can be decreased proportionally to gain improvements in inventory and holding costs. Those associated improvements are shown in Table 4-4.

Table 4-4 - Summary of QC Lead Time Reduction Simulation Results

		10% QC Lead Time Reduction	25% QC Lead Time Reduction	50% QC Lead Time Reduction
Total	Holding Costs	$5,232,467	$5,206,901	$4,883,246
	Savings over base	$110,051	$135,616	$459,272
	Available Inventory Reduction	$227,264	-$427,439	$843,358
	QC Inventory Reduction	$689,828	$1,557,573	$2,983,906
	Total Inventory Savings (Year 1)	$1,027,143	$1,265,750	$4,286,536
Material 1	Safety Stock (lots)	24	24	24
	Holding Cost/year	$463	$461	$452
	QC WIP	53	50	45
Material 2	Safety Stock (lots)	30	31	30
	Holding Cost/year	$3,056,842	$3,130,305	$2,987,051
	QC WIP	10	10	9
Material 3	Safety Stock (lots)	18	18	17
	Holding Cost/year	$222,210	$224,482	$221,352
	QC WIP	28	26	24
Material 4	Safety Stock (lots)	20	20	20
	Holding Cost/year	$283,045	$286,124	$280,063
	QC WIP	26	24	21
Material 5	Safety Stock (lots)	22	21	22
	Holding Cost/year	$16,260	$16,002	$16,049
	QC WIP	23	21	19
Material 6	Safety Stock (lots)	17	17	17
	Holding Cost/year	$11,090	$11,101	$11,012
	QC WIP	26	24	21

As can be seen in Table 4-4 and Figure 4-3, the savings resulting from decreases in QC lead times are not as clear as they are for vendor lead times. In fact, only the savings related to a 50% reduction in QC lead times is significantly lower than for the same decrease in vendor lead time. The QC savings at that level are over $4.3 million. This result is evident in the lot quantities required for the safety stocks. The lots composing the safety stocks are only reduced by one lot overall for all the materials. Material 3 is the only material for which less safety stock is needed at the 50% reduction level. These savings therefore, can be attributed to the reduction in QC WIP (Work in Process Inventory).

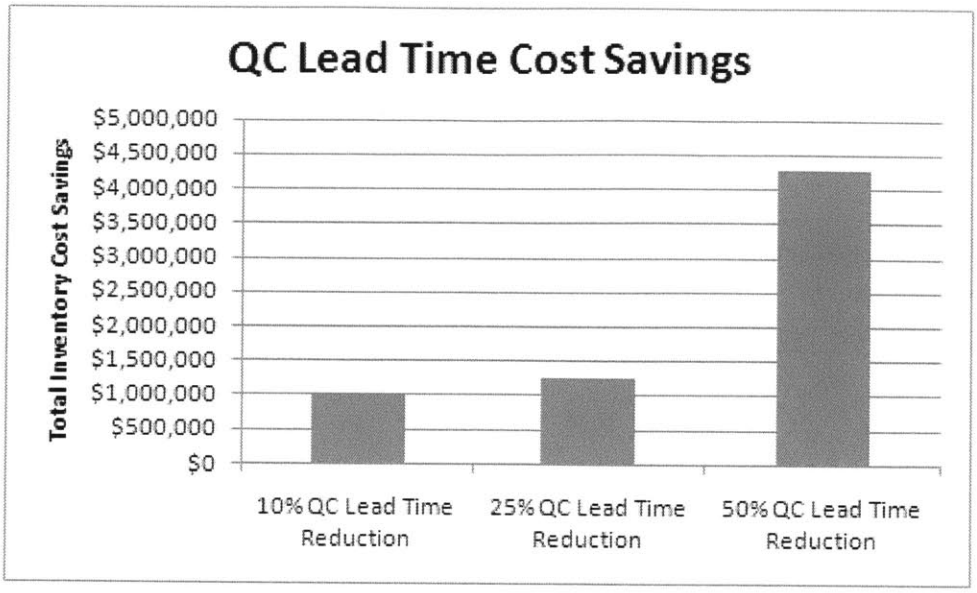

Figure 4-3 – QC Lead Time Reduction Cost Savings

4.2.4 Scenario 4 – Decreased Quality Control Lead Time Variability

Following the pattern that Scenario 2 laid out, QC lead time variability can be decreased proportionally and modeled to simulated projected changed in inventory and holding cost levels. Table 4-5 shows those changes.

Table 4-5 - Summary of QC Lead Time Variability Reduction Simulation Results

		25% QC Lead Time Variabiltity Reduction	50% QCLT VAR REDUX	75% QCLT VAR REDUX
Total	Holding Costs	$5,362,170	$5,347,658	$5,290,900
	Savings over base	-$19,652	-$5,140	$51,618
	Available Inventory Reduction ($)	-$288,067	-$93,766	$357,696
	QC Inventory Reduction	$124,298	$50,933	$72,453
	Total Inventory Savings (Year 1)	-$183,422	-$47,973	$481,766
Material 1	Safety Stock	24	23	22
	Holding Cost/year	$446	$434	$424
	QC WIP	55	55	56
Material 4	Safety Stock	20	20	20
	Holding Cost/year	$283,336	$284,174	$287,290
	QC WIP	27	27	27
Material 3	Safety Stock	18	18	18
	Holding Cost/year	$222,523	$222,645	$224,055
	QC WIP	28	29	29
Material 5	Safety Stock	21	21	21
	Holding Cost/year	$15,850	$15,937	$15,858
	QC WIP	23	23	23
Material 2	Safety Stock	31	31	30
	Holding Cost/year	$3,118,489	$3,094,381	$3,035,858
	QC WIP	11	11	11
Material 6	Safety Stock	17	17	17
	Holding Cost/year	$11,106	$10,862	$10,772
	QC WIP	27	27	27

Figure 4-4 and Table 4-5 demonstrate a lack of clear evidence to show that reducing QC lead time variability leads to holding cost savings. All cost savings values are not very significant and therefore not considered relevant.

The same trend is manifest in the safety stocks. Safety stocks are only reduced by one lot overall for the 75% lead time variability reduction. The other two levels of variability reduction result in insignificant cost savings. QC WIP levels are almost unchanged as well.

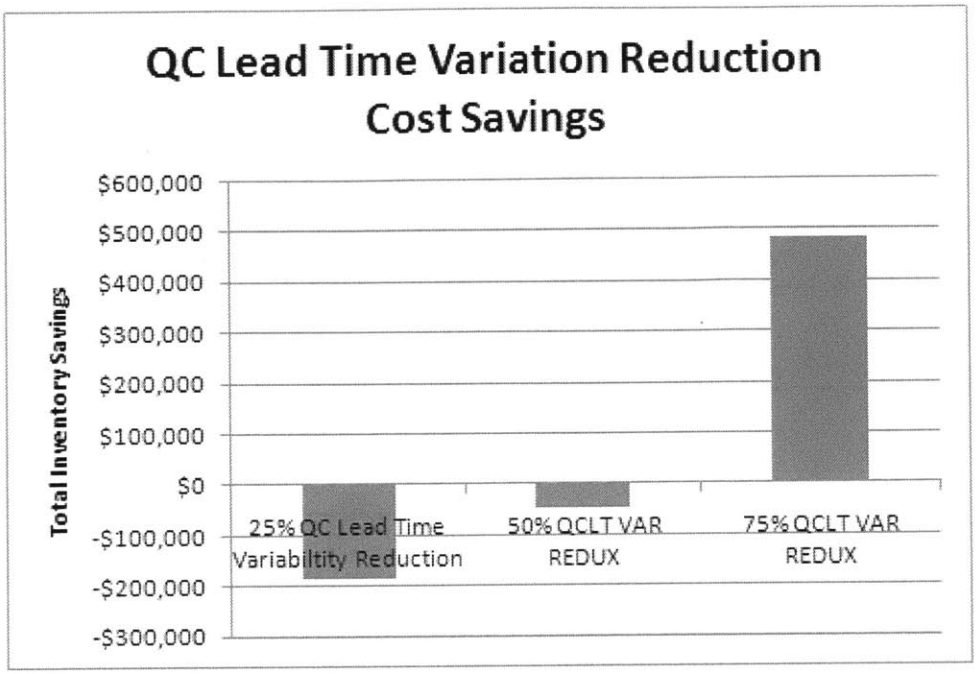

Figure 4-4 – QC Lead Time Variation Reduction Cost Savings

4.2.5 Scenario 5 – QC Problem Code Elimination

The QC process in the model includes 23 error codes where each error code is associated with a delay for each material in the QC process. By eliminating certain QC errors, QC lead times may decrease and result in inventory savings. This is done in the model by allowing material entities to still gain the error code attribute, but setting the delay associated with that attribute to zero. Essentially, the error code has no resultant delay and the entity is treated as though it went through QC "right first time".

Not all codes were modeled individually for this model, but the few that were are detailed in Table 4-6. All error code eliminations were modeled individually and independently to gain the most insight on which error codes are causing the greatest delays and costing the most per the system.

In this way, error code elimination can be associated with inventory improvements and QC lead time improvements.

Table 4-6 - Summary of QC Problem Code Elimination Scenarios

		Elimination of Problem Code 12	Elimination of Problem Code 13	Elimination of Problem Code 15
Total	Holding Cost Savings over base	$117,889.21	-$1,048.13	$4,328.79
	Available Inventory Reduction	$397,697.08	-$102,685.71	-$286,207.42
	QC Inventory Reduction	$584,713.01	$93,951.32	$322,280.71
	Total Inventory Savings (Year 1)	$1,100,299.30	-$9,782.52	$40,402.08
Material 1	Safety Stock	25	25	25
	Holding Cost/year	$468.02	$463.88	$467.93
	QC WIP	55	52	56
Material 2	Safety Stock	30	31	31
	Holding Cost/year	$3,032,163.80	$3,088,873.03	$3,109,703.62
	QC WIP	11	11	11
Material 3	Safety Stock	18	18	18
	Holding Cost/year	$223,252.26	$227,322.80	$225,744.91
	QC WIP	23	29	25
Material 4	Safety Stock	20	20	20
	Holding Cost/year	$286,260.04	$286,536.99	$288,531.63
	QC WIP	27	27	27
Material 5	Safety Stock	22	21	21
	Holding Cost/year	$16,108.37	$15,784.92	$15,965.57
	QC WIP	19	19	21
Material 6	Safety Stock	17	16	17
	Holding Cost/year	$11,205.69	$10,522.49	$11,113.06
	QC WIP	27	18	27

Only the elimination of Problem Code 12 proved to be significant in the simulation. Regardless of the negative or positive results associated with the removal of the other two problem codes, the monetary results are small enough and not considered statistically valid.

One reason for the insignificant results can be derived from Figures Figure 4-5 and Figure 4-6. It is easy to see that "on time" lots and lots associated with Problem Code 14 compose the largest majority of Problem Codes. It wasn't considered appropriate to model the removal of Problem

Code 14 because of its general nature - essentially represents a general "late" comment coming from QC and is most likely comprises multiple smaller problems.

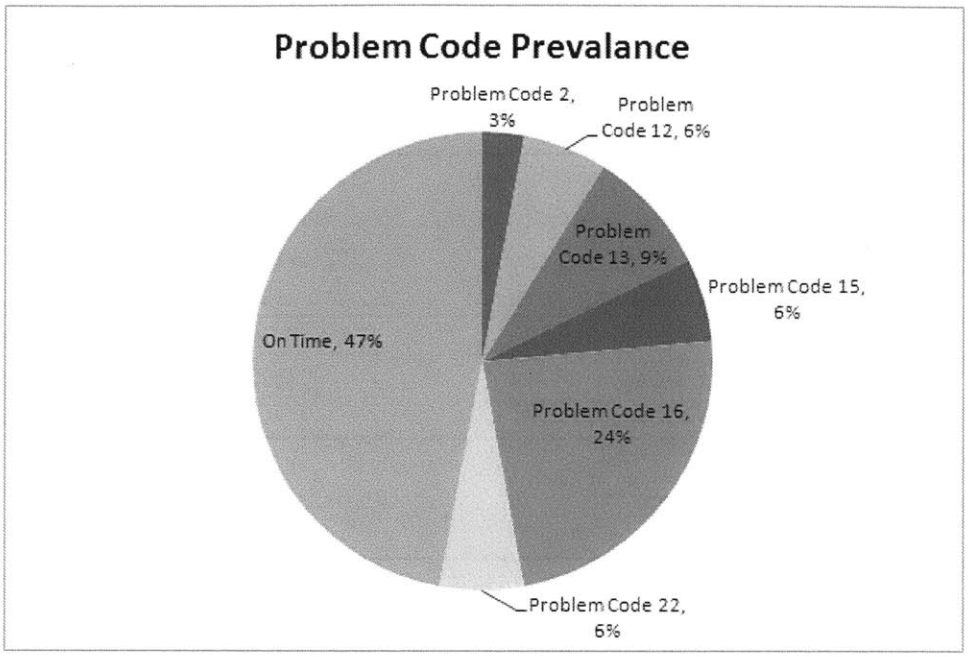

Figure 4-5 – Breakdown of problem codes by percentage of total lots

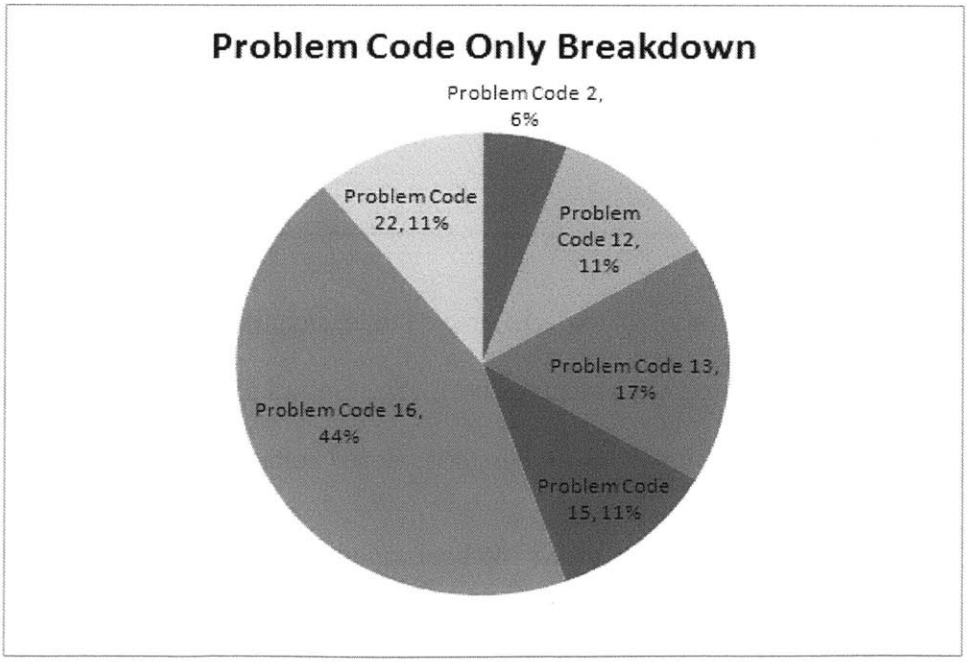

Figure 4-6 – Breakdown of problem codes without the "on-time" category

4.2.6 Combination Scenarios

Two combination scenarios were tested. Each one of the combined sets of changes to input was previously incorporated individually in other scenarios. Both scenarios also attempt to simulate real world situations. The first scenario presents a situation in which all three problem codes listed in Section 4.2.5 are "eliminated". Theoretically, the elimination of all three problem codes should result in an aggregate savings equal to the sum of all the savings from Section 4.2.5.

The other scenario attempts to model a scenario in which the management team is able to negotiate reduced vendor lead time variability, but only at the cost of an extended lead time. Essentially the scenario models a vendor who has increased their lead time (by 25%), but is now delivering much more consistently (75% reduction in variability). Another important note about this scenario is that the changes are implemented with the supplier that supplies Material 2. Material 2 being the most costly material in the simulation and its holding costs are generally the largest contributors to total holding costs.

The summary for the two scenarios is included in Table 4-7.

Table 4-7– Summary of Cost and Safety Stock Reductions for two combined scenarios

		Problem Code Elimination - All 3 codes combined	Material 2 Vendor Lead Time 25% Increase Lead Time variability 75% Reduction
Total	Holding Costs	$5,224,628	$4,490,461
	Savings over base	$117,889	$852,056
	Available Inventory Reduction	$397,697	$7,154,813
	QC Inventory Reduction	$584,713	-$54,345
	Total Inventory Savings (Year 1)	$1,100,299	$7,952,524
Material 1	Safety Stock	25	25
	Holding Cost/year	$468	$468
	QC WIP	55	55
Material 2	Safety Stock	30	21
	Holding Cost/year	$3,032,164	$2,220,616
	QC WIP	11	11
Material 3	Safety Stock	18	18
	Holding Cost/year	$223,252	$225,926
	QC WIP	23	29
Material 4	Safety Stock	20	20
	Holding Cost/year	$286,260	$284,391
	QC WIP	27	27
Material 5	Safety Stock	22	21
	Holding Cost/year	$16,108	$15,987
	QC WIP	19	23
Material 6	Safety Stock	17	17
	Holding Cost/year	$11,206	$11,215
	QC WIP	27	27

Even by eliminating three of the most prominent errors that QC encounters, Table 4-7 shows that the result is on the same level of significance as the elimination of Problem Code 12 only, as shown in Table 4-6. In comparison to the base scenario, minimal cost savings are realized with this combination scenario.

The second combination scenario, however, is extremely revealing. For Materials 2, the vendor lead time was *increased* by 25% and the variability of that lead time was reduced by 75%. The cost

savings for this scenario nearly reached the cost savings for the 75% variability reduction scenario in Section 4.2.2. Even increasing the lead time could not largely offset the savings from decreasing the variability for this high-cost material. Nearly $8 million in cost savings were predicted by this scenario.

4.2.7 Scenario Comparison

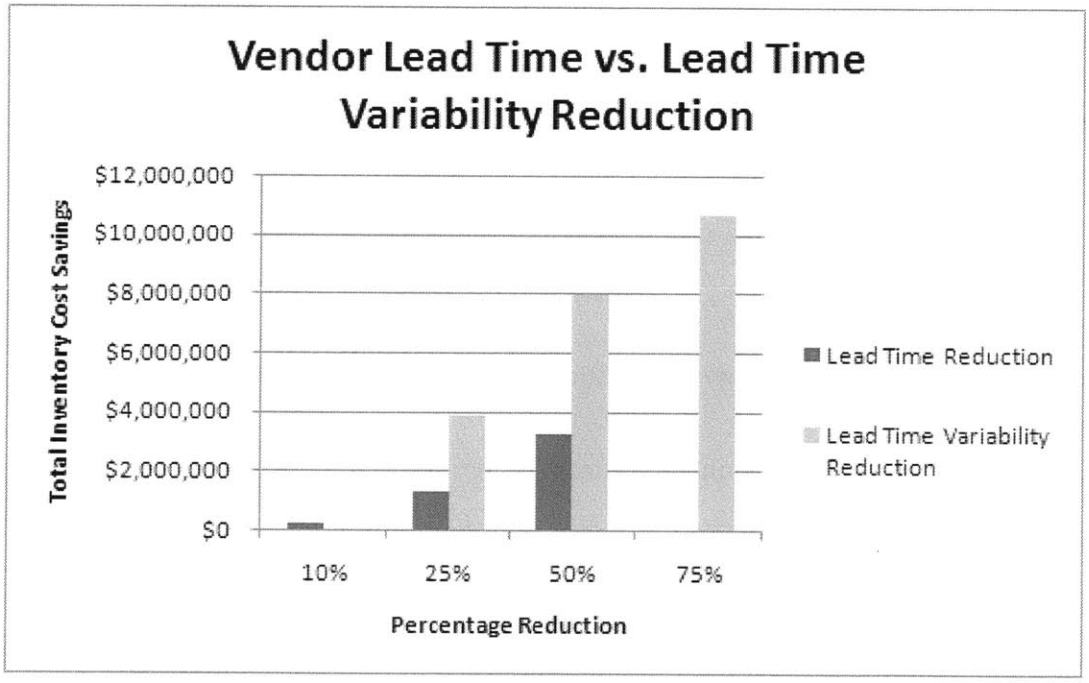

Figure 4-7 – Comparison for vendor lead time reduction and lead time variability reduction

Figure 4-7 shows the comparative savings for decreasing vendor lead time for all Materials (Section 4.2.1) and decreasing the variability while maintaining the same original lead times (Section 4.2.2). While the reductions are made on slightly different scales (Lead time reduction ranges from 10%-50% and variability reduction ranges from 25%-75%), it is still easy to see the comparative disparity between lead time reduction and variability reduction.

While the difference is quite obvious for vendor lead times, the trends are not so discernible for QC lead time changes. Figure 4-8 attempts to demonstrate the differences.

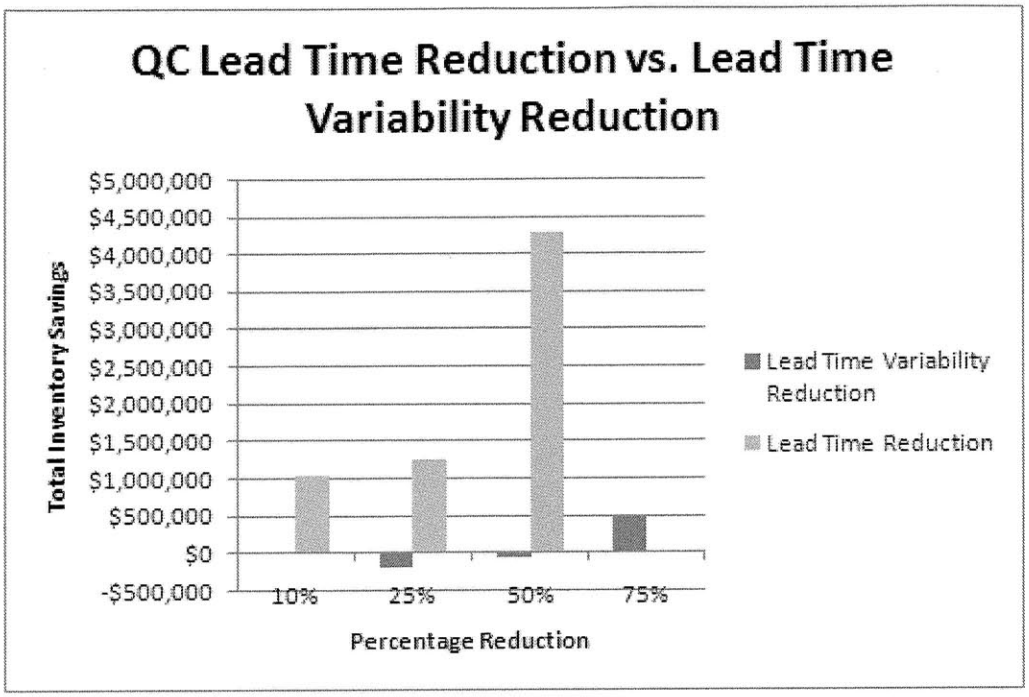

Figure 4-8 – Comparison for QC lead time reduction and lead time variability reduction

According to the simulated scenarios, the only significant reduction came from a 50% reduction in QC lead times. This finding seems somewhat counterintuitive, especially when compared to the similar scenarios for vendor lead times. The odd data point cannot be automatically dismissed, but is most likely an outlier that can be considered insignificant. Overall, the QC lead times are significantly shorter with less variability than the vendor lead times. For this reason, they have much less marginal influence on the response variables in the model.

Greater insight can be gained as all the scenarios are compared in Figure 4-8. In this table, it is easy to see and compare all of the scenarios. Also, percentage savings not given in the other tables in this chapter are given here.

Table 4-8 – Scenario comparison for all scenarios including cost savings and percentage

	Total Holding Costs	Total Inventory Value	Total QC Inventory Value	Costs (Holding + Value)
Base Scenario	$5,342,517.60	$30,143,181.87	$14,377,798.15	$49,863,497.62

	Holding Cost Savings over base	Available Inventory Reduction	QC Inventory Reduction	Total Inventory Savings (Year 1)	% Total Savings over base
10% Vendor Lead Time Reduction	$26,352.27	$132,969.92	$86,632.32	$245,954.51	not significant*
25% Vendor Lead Time Reduction	$143,231.33	$1,136,674.08	$56,920.34	$1,336,825.74	2.7%
50% Vendor Lead Time Reduction	$352,047.34	$2,952,570.61	-$18,842.76	$3,285,775.20	6.6%
25% Vendor Lead Time Variation Reduction	$415,933.84	$3,431,711.55	$34,403.80	$3,882,049.19	7.8%
50% Vendor Lead Time Variation Reduction	$852,405.86	$7,089,284.09	$14,098.05	$7,955,788.00	16.0%
75% Vendor Lead Time Variation Reduction	$1,141,464.99	$9,558,539.46	-$46,331.20	$10,653,673.24	21.4%
10% QC Lead Time Reduction	$110,051.02	$227,264.27	$689,827.57	$1,027,142.87	2.1%
25% QC Lead Time Reduction	$135,616.11	-$427,439.16	$1,557,573.40	$1,265,750.35	2.5%
50% QC Lead Time Reduction	$459,271.67	$843,357.58	$2,983,906.32	$4,286,535.57	8.6%
25% QC Lead Time Variation Reduction	-$19,652.39	-$288,067.48	$124,297.54	-$183,422.33	not significant*
50% QC Lead Time Variation Reduction	-$5,140.01	-$93,766.40	$50,932.98	-$47,973.43	not significant*
75% QC Lead Time Variation Reduction	$51,617.81	$357,695.65	$72,452.74	$481,766.19	not significant*
Elimination of Problem Code 22	$117,889.21	$397,697.08	$584,713.01	$1,100,299.30	2.2%
Elimination of Problem Code 13	-$1,048.13	-$102,685.71	$93,951.32	-$9,782.52	not significant*
Elimination of Problem Code 16	$4,328.79	-$286,207.42	$322,280.71	$40,402.08	not significant*
Error Elim 4 - All 3 combo	$117,889.21	$397,697.08	$584,713.01	$1,100,299.30	2.2%
Single Vendor LT 25% up VAR 75% down	$852,056.12	$7,154,813.10	-$54,345.47	$7,952,523.74	15.9%

**If the difference was less than 1.2% or $600,000 it is not statistically significant*

As Table 4-8 demonstrates, many of the scenarios modeling QC lead time changes and QC problem code elimination yield insignificant cost savings. The most significant cost savings are realized as the parameters representing vendor performance are altered. Reductions in vendor lead times yield up to 6.6% savings in total inventory costs. These savings come only with great change, however, as lead times must be reduced by 50% to obtain those results.

The most significant cost savings are predicted with the model by reducing vendor lead time variability. Reducing vendor lead time variability by only 25% results in 7.8% cost savings. When variability is reduced by 75%, the savings are significantly more at 21.4%.

The last part to note in this comparison summary is the 16% savings that are predicted by focusing on a single material and trading variability reduction for increased lead times. The savings predicted for this situation can be seen in the last row of Table 4-8.

5 Synthesis and Insights

Based on the results obtained and described in the previous section of this thesis, we synthesize the findings in this chapter and share some of the key insights gained from the research. The immediate application of this synthesis is specifically relevant to ABC Pharmaceuticals. However, the insights shared here can have extended application throughout the pharmaceutical industry as well as throughout academia and industry.

5.1 Insights

Insights come from more than just the results. As the model was in development, there was a need to gather data and to better understand ABC's business. This exploration and data mining exercise was invaluable both for the research team including ABC's management team. Data that they had not collected previously and data that were not initially considered valuable ended up being critical in generating insights and understanding. Learning more about ABC's business from the materials management department as well as from ABC planners and buyers also provided valuable information that helped explore the problem in a more holistic manner.

5.1.1 Model Development

Any exercise in which a manager attempts to analyze a business case or situation in depth requires use of data and deep knowledge of the process. Building and using the model that was developed for this case provided opportunities for the research team to mine and test their data against the tacit knowledge of the business and the results of the simulations. The ability to control inventory in this case is based on how well lead time and demand from downstream manufacturing are

controlled and understood. It is also vital to know where to look for data and what to do in response to certain occurrences.

The simulation exercise also provided insight into the limitations of the methodology. More qualitative metrics, such as responsiveness and flexibility, were difficult to model. For example, the model showed that reducing vendor lead times did not have as large an impact as reducing the variability of those lead times. However, reducing lead times would allow ABC to become much more responsive to possible product and demand changes. Unfortunately, the simulation model is not all-inclusive or encompassing.

5.1.2 System Knowledge and Inventory Management

Proper collection and mining of data can yield tremendous benefits. In order to effectively manage inventory, first and foremost, we need good information. At ABC Pharmaceuticals, the data exists in many forms and in many places. The difficulty in analysis also arises because we often don't know what to look for and where to look for it. Several inputs should be well understood to properly manage raw-material inventory. These inputs may seem obvious but worth reiterating for clarity.

The first important data input is demand from manufacturing. It is not only vital to know the manufacturing plan, but it is also necessary to know how much the actual manufacturing quantities may vary from that plan. For example, a campaign may be scheduled for a date several months in advance. What are the chances that that campaign is pushed back, or moved up? Also, when that campaign is executed, how closely are the original planned quantities followed? Manufacturing can change dates of production and production quantities. What is the variability associated with these changes?

The second input that should be well understood is the lead times from vendors. This data is readily available at ABC Pharmaceuticals. The data, however, needs to be reviewed often. One way to monitor vendor performance is with a vendor scorecard. Currently, ABC Pharmaceuticals orders materials in advance based on stated vendor lead times. A more effective approach could be to order based on actual lead times, or based on an average lead time with maximum variability factored in.

The third process/input that is critical to provide raw materials to manufacturing is Quality Control. This process can be viewed in several ways. From a purely lead-time perspective, QC is very similar to the vendors. Average lead times can be tracked and materials can be ordered according to actual lead times. The entire procurement process could also be treated as a separate business unit and positioning QC an independent corporate service to the business. With this viewpoint, QC would be more actively managed and viewed as the critical point in the flow of materials. Either way, a better understanding of what is happening within the department and how disturbances to the process affect inventory levels is crucial to the continual improvement of the system performance.

Once a firm knowledge of these inputs is obtained, effective inventory policies can be implemented confidently. Because of the intricacies of the pharmaceutical industry, recommended inventory policies may or may not follow traditional methods and mathematical models. But without sufficient knowledge of the key parameters, an inventory policy is either going to result in too much inventory (and unnecessary holding costs) or a lack of service to the customer (manufacturing).

Lastly, ABC Pharmaceuticals currently orders materials only when they receive a campaign plan from manufacturing, and the order is placed for the quantities needed for the specific campaign. This method, while very transparent, should be further investigated. It is not to assert that the existing method for obtaining materials is the wrong method; however, with good information

about demand and supply variation, it may be possible and more effective to order materials to maintain inventory levels instead of ordering per campaign. This is something that can be investigated further by ABC Pharmaceuticals.

5.1.3 Vendor Management

The data presented in Chapter 4 made two things very clear. First, that it is much more important to address the variability coming from vendor lead times than it is to reduce those lead times. It is also clear that one or two of the materials provide the greatest opportunity for cost savings. Also, as the final scenario results indicate, savings can be achieved even if lead times are increased, as long as those increases are coupled with a reduction in lead time variability. This conclusion excludes the consideration of the flexibility and responsiveness that may be sacrificed if lead times are increased. If only inventory costs are a consideration then reducing variability is much more important.

Materials arriving late are clearly more harmful, especially in the current system of ordering materials based on stated lead times. When a material lot arrives late, the lot must either be expedited through the QC department, or manufacturing must dip into buffer stock to satisfy demand requirements. Materials arriving early are also detrimental. Assuming that transfer of ownership occurs when the materials are received by ABC Pharmaceuticals, any material that arrives early will sit in inventory accruing unnecessary holding costs.

With the understanding that both early and late lots cost money, specific delivery windows should be set for vendors. These windows should set an expectation for a delivery date as well as giving the vendors some slack on delivering a little early or late. Material 2 has a stated lead time from the vendor of 70 days. Data from ABC Pharmaceuticals shows that on average, Material 2 is delivered

13 days early (See Table A-3 in the Appendix) but as a range, it can be delivered anywhere from 160 days early to over 300 days late. The variability associated with these delivery inconsistencies requires large amounts of inventory to ensure that manufacturing demand is satisfied.

Because the cost of holding inventory is most often associated with the value of the inventory, it is easy to know which materials are contributing the largest amounts to holding costs. Variability must be combined with material cost to determine holding cost contribution. If a material is purchased for $1 million for a specific campaign, but there is no variability in the vendor lead time, no inventory needs to be held for that material (assuming no demand variability). Inversely, a material can have low value, with high variability and inventory costs can be significant.

The scenarios included in Chapter 4 repeatedly showed that Material 2 was the largest contributor to inventory holding costs. Not only does Material 2 have the highest per-lot value, but vendor lead times and lead time variability are both high for the material as well. If the materials were to be ranked by impact on holding costs, Material 2 would be a strong number one, with Material 3 being placed in distant second.

5.1.4 Vendor Negotiation

Proper negotiation of delivery terms will not be effective unless the impact of all factors is well understood. We recommend that lead time variability reduction is much more effective than actual lead time reduction. However, reducing variability from vendors is the most powerful lever only up to a certain point after which shorter lead times become more important. Additionally, supply chain responsiveness should also be considered when negotiating delivery terms.

Figure 5-1 shows the interplay between vendor lead time and vendor lead time variability and the effects on inventory reduction.

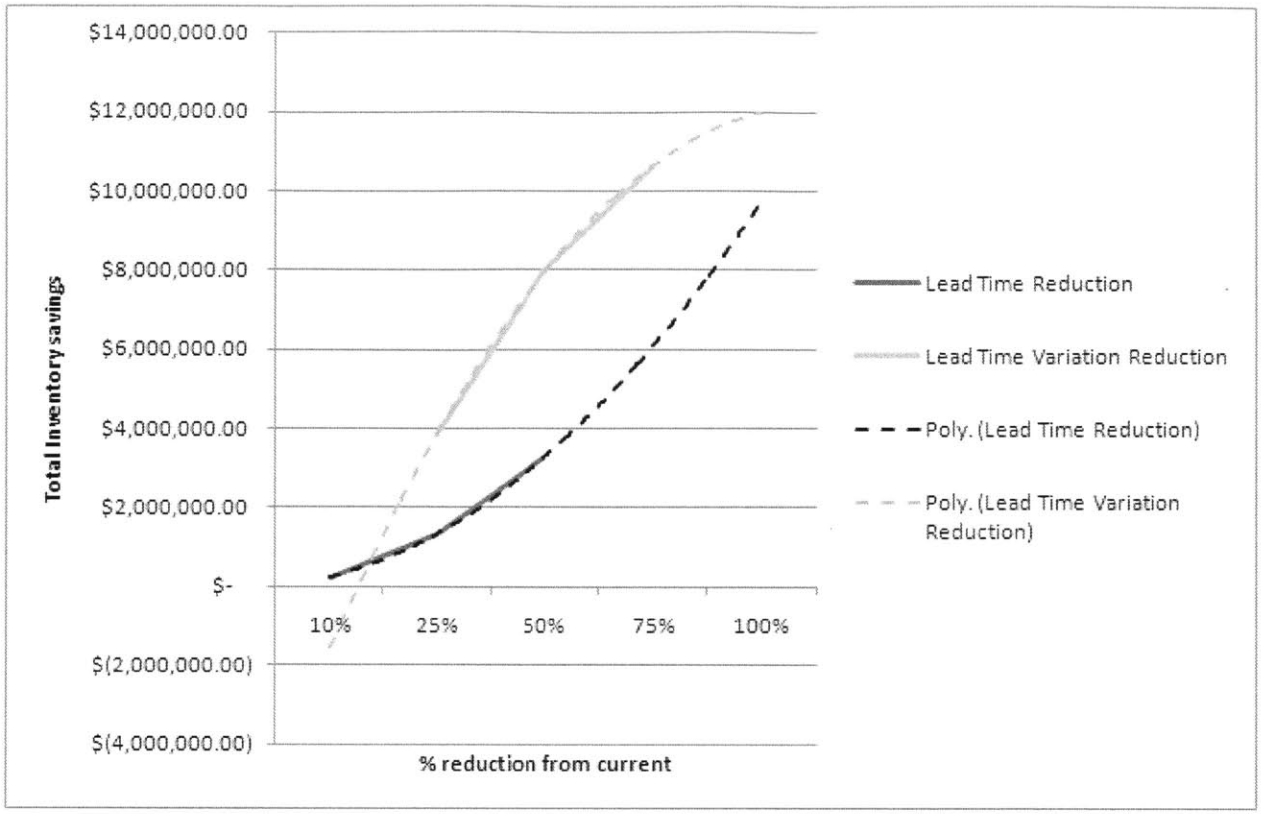

Figure 5-1 - Interpolated curves showing inventory savings for lead time improvements

As can be seen in Figure 5-1, for the parameters explored in this study, vendor lead time variability is a much more impactful lever. However, once variability is improved to a certain level, overall lead time becomes the more important factor.

This interplay is highly reliant on the variation in demand from manufacturing. When the variation in demand is doubled (original standard deviation of 2 lots), lead time become a more significant influence on inventory reduction. This change can be seen in Figure 5-2.

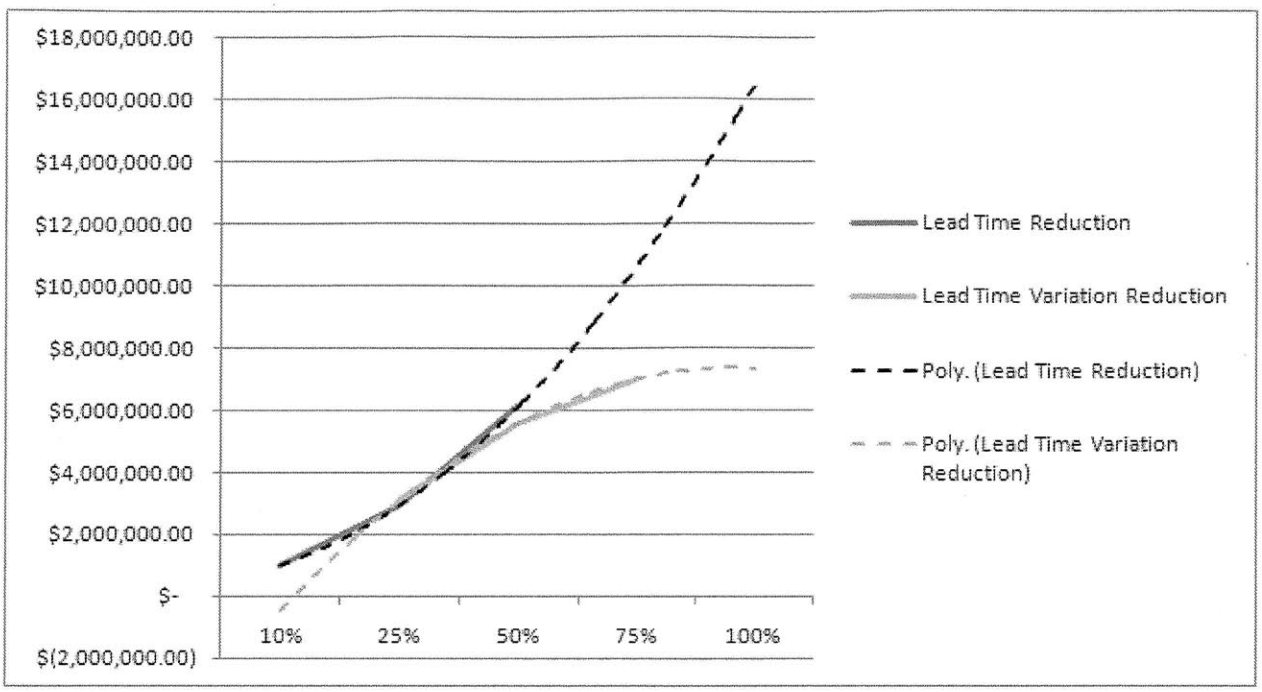

Figure 5-2- Interpolated curves showing inventory savings for lead time improvements with demand variability doubled

With demand variation doubled, lead time reduction is more important for every percentage reduction scenario.

This interplay is derived from mathematical models. Using Equation 2.1 from Chapter 2, we can determine how demand variability affects inventory levels. To incorporate lead time variability into the model we can use the Equation 5.1 to determine a new sigma term to substitute the original σ_L term in Equation 2.1 (Silver et al., 1998).

$$\sigma(D_{LT}) = \sqrt{\sigma^2 E[L] + \mu^2 Var[L]} \quad 5.1$$

where:

$\sigma(D_{LT})$ is the Demand Variation over the lead time
σ^2 is the standard deviation of the demand for the lead time, squared
E[L] is the expected lead time (lead time average)
μ^2 is the average demand over the lead time, squared
Var[L] is the variation (standard deviation) of the lead time

General assumptions govern this mathematical model, however. Demand and lead time must be normally distributed. Also, the assumption of continuous inventory monitoring is used for this model.

Knowing which factors contribute most to the need to hold inventory is essential in negotiating delivery terms as effectively as possible with vendors.

5.1.5 Quality Control Management

While many of the scenarios dealing with changes in the Quality Control department did not predict overly significant savings, it should not be assumed that real-world changes would not yield positive results. Most of the savings coming from QC change scenarios resulted from the decreased inventory held up in the QC department. QC changes did not have much effect on buffer inventories.

Echoing the comments set forth in Section 5.1.3, efforts should be made to improve QC performance for specific materials to start and eventually focus on overall performance. It costs the most to hold inventory for Material 2, whether that inventory in available for manufacturing or being process by QC. Material 2 should be a high priority for the QC department.

Anecdotal accounts of QC identified possible causes for the department's inconsistent performance. These include problems with incoming materials, lack of staffing and disruptive expedites which caused late delivery of lots. The legitimacy of each of these complaints needs to be explored.

The problems associated with incoming materials can be separated into two categories: problems internal to QC, and problems originating with the vendors. When materials come from vendors with a lack of documentation or even a lack of quality, QC has trouble making the lots available for manufacturing. The number of these problems could most likely be reduced by working with individual vendors. The internal QC problems are probably related to the second complaint that QC is understaffed.

An understaffed QC department will perform similar to a manufacturing process that does not have sufficient capacity. Many materials will be released to manufacturing on time, while others will be forgotten or mishandled and QC lead times will become erratic. It can be argued that in a constrained environment, quality will become a concern and the throughput of the system will also suffer. Re-work and more quality testing will in turn cause a constant need to resort to fire fighting.

As demand outpaces capacity, expedited orders will cause even more of a disruption in the QC system. The expedited orders should not be a large problem for QC unless they are understaffed. A QC department with excess capacity would be able to handle the low number of expedited lots.

5.1.6 Demand Management

Demand variation contributes largely to the need for excessive inventories especially under a high product availability regime. This thesis did not deal with the management of demand variation. However, reducing this variation can yield similar benefits as a reduction in the variation in lead times from vendors and QC.

The underlying demand for many of ABC's finished drugs is fairly predictable and stable. The small number of consumers makes it easy to predict future demand for a drug. Further investigation may show that variations in demand are only due to a lack of communication or a misalignment of supply-chain metrics. Indeed, erratic ordering or scheduling patterns, regardless of the underlying reason, can reverberate upstream through the supply chain to the point where demand appears to be extremely variable. This amplification of demand variation can occur even in situations where the underlying demand is very stable.

5.2 Pharmaceutical Industry Applications

5.2.1 Vendor Power and Regulation Compliance

Many of the suppliers to the pharmaceutical industry are not held to the same lead time standards as those outside the pharmaceutical industry. This is not to say the suppliers in the industry are incompetent or do not perform to the standards that are set forth by their customers. Generally, buyers in the pharmaceutical industry are more concerned with regulation compliance, quality and availability rather than inventory or raw material delivery performance.

Based on data from ABC Pharmaceuticals, suppliers are generally very good at providing materials that are of very high quality and arrive with proper documentation. Compared with outside industries, the quality of the materials they deliver may be much higher but delivery consistency falls well below other industries standards.

Influencing change in this area may be difficult for ABC Pharmaceuticals, as the company is not a major player in the broad Pharmaceutical industry. Because of the smaller quantities that ABC orders for some of its drugs, it may not have the leverage to influence the delivery patterns for many vendors. However, as described in Chapter 4, ABC Pharmaceuticals may be able to negotiate

tighter delivery windows by allowing longer lead times. Influencing vendors that provide materials for the very specific biopharmaceutical segment may be more realistic.

ABC Pharmaceuticals can try to establish standards related to on-time delivery and can attempt to enforce these standards with all vendors. However, because much of the power may reside with the suppliers, it may be difficult to ensure compliance to these standards. It may be more effective to work with suppliers one-on-one to reduce lead time variability and overall performance. Specific collaboration may be required in the areas of demand planning as well. Or possibly, information systems may need to be integrated to provide more consistent results

Another difficulty inherent to the biopharmaceutical industry is the issue of dual sourcing raw materials. Because of the complex nature of the materials and the extra effort surrounding federal regulations and certification, it is often difficult to find and qualify new vendors. The problem of proving equivalence when changing a material adds to the challenge.

5.3 Academic Applications and Extensions

5.3.1 Lead Time Reduction vs. Lead Time Variability Reduction

This thesis has shown ample evidence to support the assertion that to reduce inventory it is better to reduce lead time variability than to reduce the actual lead times for our study. This, however, is not an assumption that is applicable to any situation. The definition of a couple of key parameters drove the outcome in the model.

The inventory required to buffer lead time is dependent on the variation triggered by the demand signal. In the presence of a highly variable demand, the influence of changes in lead times is even greater in the calculation of safety stock inventory. As demand variation diminishes, lead times become less impactful. Section 4.2.6 gives a perfect example of this. An already long lead time is

increased by 25% and the impact fails to offset the savings gained by reducing the variability of the same lead time.

The demand variation used in the simulation is small compared to the wildly inconsistent delivery times coming from the suppliers. If these two variation sources were closer in magnitude, reductions in lead times would have even more influence on the dependent inventory levels.

6 Conclusions

The goal of this thesis was to help ABC Pharmaceuticals better understand the variations that were driving the decisions in the raw material procurement process. The proposed model is expected to enhance the operational understanding of the raw material procurement process at ABC Pharmaceuticals. By modeling and performing sensitivity and scenario analysis using a simulation model, we were able to predict responses in the system based on several levers or parameters. The analysis and synthesis yielded insights that were supplemented by information gained by talking with employees of ABC Pharmaceuticals and applying concepts borrowed from other industries

Analysis made it clear that improving vendor reliability was by far the most important lever for the modeled system. Vendor lead time reduction is also a tool that can help reduce inventory levels. Working with vendor to improve both lead times and the consistency of those lead times can result in a more responsive lead time and more flexibility in ensuring that materials are available for the manufacturing department.

Another insight gained from the research process, although obvious in hindsight, was that a single yet very costly material drove most of the cost improvements in the simulations. Not only was the material very costly, but the variation associated with delivery of the material was high, and the lead time was long. Focusing efforts on this single product should yield immediate results. This insight falls in line with the 80/20 rule.

At present the Quality Control department acts as a source of additional variation, albeit to a lesser degree than the suppliers. This is being caused by a lack of understanding of how the department can perform more effectively as well as inadequate knowledge of proper staffing requirements. If the department can be organized and staffed effectively, it can be used as a tool to buffer the variability originating from vendors instead.

Also related to the QC department, it may not be useful to spend time and energy on eliminating specific problem codes. As vendor relations improve and more collaboration stems from the relationships, the problem codes originating from external sources should decrease. Also, as QC performance improves, the problem codes should also disappear over time. Problem codes are most likely symptoms of deeper systemic problems. Further improvement opportunities exist if manufacturing demand can be understood better and collaboration can be extended between the planning, buying and manufacturing departments. Beyond the specific model, ABC Pharmaceuticals would benefit by gaining a deeper understanding of various sources of variation in their environment and learn how these variations affect what they do on a daily basis to order and manage materials.

6.1.1 Future Research

There are several aspects of ABC's system that lend themselves to a more detailed inspection and could provide for valuable research. For instance, it would be important to understand why seemingly predictable demand coming from patients would translate into variable demand upstream through ABC's supply chain.

The market for the drug being studied has experienced disruptions in the past year. These disruptions were caused by an inability by a competitor to reliably supply patients with a similar drug. It would be beneficial for ABC Pharmaceuticals to understand how these disruptions affect the demand for their products and also how the changes in demand reverberate up the supply chain. Once the impact of disruptions on the supply chain is understood, ABC Pharmaceuticals can prepare itself better for similar possibilities in t he future.

A deeper dive into the QC department could merit quite a bit of further research. Process effectiveness and value stream mapping techniques could be applied in the context to better

understand where the root of the QC problems lay. If the QC department is better understood, ABC should be able to further reduce variability and subsequently inventory levels.

Appendix A

Table A-1 - Inputs to the procurement model and how they have been represented statistically

Input	Data Source	Distribution	Application Level
Stated QC Lead Times	ABC Pharmaceutical MRP system	Discrete	Per Material
Percentage QC delays	Data gathered by ABC Pharm.	Normal Distribution	Per Problem Code
Problem Code Assignment	Data gathered by ABC Pharm.	Probabilistic	Per Entity (single material lot)
Stated Vendor Lead Times	ABC Pharmaceutical MRP system	Discrete	Per Material
Actual Vendor Lead Times	Data gathered by ABC Pharm.	Normal Distribution	Per Material
Time between Manufacturing Campaigns	Anecdotal - ABC planner	Discrete	Campaign
Manufacturing Demand Quantity (Lots)	Anecdotal - ABC planner	Normal Distribution	Campaign
Manufacturing Time Deviation from stated plan	Anecdotal - ABC planner	Triangular Distribution	Campaign
Lot Value	ABC Pharmaceutical MRP system	Constant	Per Entity (single material lot)

Table A-2 - Stated lead times from the vendors and the QC department for each material

Material	*Stated Vendor Lead Time (Days)*	*Stated QC Lead Time (Days)*
Material 1	70.00	84.00
Material 2	180.00	28.00
Material 3	70.00	28.00
Material 4	70.00	42.00
Material 5	90.00	28.00
Material 6	45.00	28.00

Table A-3 – Actual vendor lead times with the variability for each material

Material	*Actual Vendor Lead Times*	*Observed Vendor Lead Time Standard Deviation*
Material 1	56	94.5
Material 2	167.4	180.18
Material 3	65.1	79.8
Material 4	70.7	70.7
Material 5	93.6	107.1
Material 6	49.5	84.15

Table A-4 - Percentage Delays associated with the several Problem Codes assigned to material lots that passed through the QC process. NOTE: 0% in the average delay column signifies lack of any data points for that problem code.

	QC LT % average delay	*QC LT% delay Std dev*
On time	-31%	25%
Problem Code 1	52%	30%
Problem Code 2	85%	77%
Problem Code 3	0%*	0%*
Problem Code 4	131%	7%
Problem Code 5	267%	0%
Problem Code 6	117%	93%
Problem Code 7	29%	16%
Problem Code 8	325%	0%
Problem Code 9	164%	56%
Problem Code 10	27%	33%
Problem Code 11	0%*	0%*
Problem Code 12	71%	36%
Problem Code 13	79%	95%
Problem Code 14	28%	15%
Problem Code 15	30%	29%
Problem Code 16	64%	103%
Problem Code 17	9%	10%
Problem Code 18	321%	102%
Problem Code 19	18%	26%
Problem Code 20	75%	0%*
Problem Code 21	127%	119%
Problem Code 22	21%	22%
Problem Code 23	164%	135%
Problem Code 24	7%	4%
Problem Code 25	48%	13%

***0% callouts signify a lack of any data points for this problem code, or a single data point only if the 0% falls in the standard deviation column**

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